

Published monthly

On the web continuously

www.pharmachinaonline.com



In This Issue

SinoPharm confirms IPO for CNBG

SinoPharm Group plans an independent IPO for China National Biotechnology Group and its six subsidiary institutes. P11 SMEI releases Chinese pharma

Sanofi-Aventis to acquire BMP Sunstone

Sanofi-Aventis and BMP Sunstone entered into an agreement whereby Sanofi would acquire 100% of BMP Sunstone for US\$520.6 million. P13

Nycomed acquires Guangdong **Techpool Biopharma**

Nycomed seeks to expand its China presence through the acquisition of a 51.34% stake in Guangdong Techpool Bio-Pharma for US\$210 million. P14

Novartis to relocate China HQ to Shanghai

Novartis is going to move its China headquarters to Shanghai after a strategic move to invest US\$1 billion into developing R&D in Shanghai. P14

Alliance Boots eyes more deals in China

Alliance Boots joins race for reorganization of Nanjing Pharmaca, the fourth largest Chinese pharma distributor and eyes more deals in the country P15

BMS, Simcere to co-develop cancer drug candidate

Bristol-Myers Squibb and Simcere announced a strategic partnership to co-develop BMS-817378. P16

ONTENTS

Editorial

MNCs escalates China deals and investments in the face of increased short term risks 2

News in Focus

- Health Minister Chen Zhu delivers speech on public hospital reform 6
- Essential drug policy under pressure for revision 6
- Essential drug price cut likely to be postponed to next year 6
- China to expedite pharma industry restructure under new policy document 7

The Market

- McKinsey: Chinese healthcare market to reach US\$600 billion in ten years 7
- industry and market forecasts 8
- IMS: China to overtake Japan as the 2nd largest drug market in 2015 8
- China offers great prospects for outsourcing of preclinical and toxicology studies 8

Industry News

- NSB announces leading 100 Chinese pharma manufacturers by revenues 10
- Chinese media bashes high prices of foreign drugs 10
- More pharma companies head for the bigger Chinese cosmeceutical market 10
- Pharma distribution giants battle for reorganization of Nanjing Pharma 11
- Local company news 11
- Foreign company news 13
- Service Provider News 18

Regulatory News

- SFDA issues Guidelines for Ethical Review of Drug Clinical Trials 19
- SFDA issues lists of export-licensed drug and medical device manufacturers 19
- SFDA seeks comments on regulation for drug quality in medical institutions 19
- SFDA withdraws Sibutramine from the Chinese market 20
- MOH to introduce rules for antibiotic use 20

The 4th Joint ChP-USP International Symposium held in Hangzhou 20

API/Bulk Drugs News

- Esteve Pharma forms API joint venture with Hangzhou Huadong Pharma 20
- Pharma industry cooperation under discussion between leading Chinese and Indian trade groups 20

Product and R&D News

- New report: pharma becomes more active in R&D in Asia-Pacific 21
- Monitor Group: China to Become Life Science Powerhouse by 2020 21

General Health

- Vice Premier Li Keqiang pushes for steady healthcare reform progress 22
- China will integrate different basic medical insurance programs 22
- CHA: China's surveillance network for rational drug use in preliminary shape 22
- MOH launch new measures to fight rebound of commercial briberies in hospitals 22
- Shanxi adds 209 drugs to its EDL 23
- Chongqing Drug Exchange begins member registration and operation 23
- MOH issues guidelines for colorectal cancer 23
- CMA launches standard reference for clinical use of glucocorticoids 23
- AIAP survey reveals high incidence of nasal allergies in Asia Pacific 24
- China's diabetes prevalence and medical expenditures soar 24
- CDS release survey of type II diabetes selfmanagement by patients 24

People in the News

- Executive moves 25
- Former SFDA official tried for corruption 25

Other News

Upcoming events 25

Feature Articles

- Latest Updates on the Upcoming New Regulation for Drug Pricing 26
- Leading drugs by hospital consumption in six major Chinese cities in 2009 27
- 2009 China Pharma Rich List Landscape Reshaped by IPOs & Aggressive Valuations 28

PUBLISHER'S INFORMATION

Publisher: James J. Shen Chief Editor: James J. Shen Associate Editors: Joanne Xiao-Hua Zhou, Jenny Wang Correspondents: Chaojuan Jia, Yumei Li Editorial Assistant: Jessica Shen Editorial Consultant: David Xue, Luke Treloar Advisory Board: 12 distinguished industry leaders

US Head Office:

449 Sayre Drive, Princeton, NJ 08540, USA Tel: +1 609-919-0898 Fax: +1 702-995-3905 E-mail: info@pharmachinaonline.com Internet: www.pharmachinaonline.com

China Editorial Office:

B-17D, Oriental Kenzo Plaza, 48 Dongzhimenwai Dajie, Dongcheng District, Beijing 100027, China. Tel: +86 10 8447-6010 Fax: +86 10 84476110

China Sales Representative:

David Xue, PharmaGuys Info Tel: +86 10 8530-0937 Fax: +86 10 8530-0938 Cell: 13911325130 e-mail: dxue@pharmaguys.com

Subscriptions (2010):

Subscription Rate for Journal Edition: US\$1,650 for Print or PDF inclusive of S&H (additional print copy in the same envelop is US\$1,000).

Gold Package: US\$2,750 (includes single subscriptions to both Pharma China *Journal Edition and Web Edition*, Weekly Alert, Breaking News Alert, Pharma China Archive and Online Databases).

Request order forms from:

WiCON International Group LLC 449 Sayre Drive, Princeton, NJ 08540, USA. Tel: +1 609-919-0898 Fax:+1 702-995-3905 E-mail: info@pharmachinaonline.com

Conditions of Sale:

© All rights reserved by WiCON International. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any other means, electronic, mechanical, photocopying, recording or otherwise without the written consent of the Publisher. Any abstraction of data for republication and sale requires prior written permission from the Publisher and provided due acknowledgement is made to the source. Without prior written permission of the Publisher, Pharma China may not be circulated outside the staff employed at the mailing address to which it is sent by the publisher. Please contact info@pharmachinaonline.com for details of multiple sites or global licenses. While due care has been used in compiling this information, the publisher makes no claim that it is free of error or fit for any particular purpose, and does not accept liability to anyone for the consequence of any decision or action taken in reliance on any information contained herein.

MNCs escalates China deals and investments in the face of increased short term risks

.

James J. Shen

Just a day before President Obama returned to the U.S. from the G20 Summit in Seoul, he praised Japan as "a model citizen internationally" which "works in support of international rules and norms ..."

While many interpret his comments as targeting China, it seems absurd to hope China, or any other emerging countries for this matter, to become the next submissive "*Hello-Kitty*" like Japan. No wonder Obama had to go home almost empty-handed, the expectations were simply too high.

But China is by no means a winner either. Despite its tough stance against the U.S. pressure, China has been forced to promise gradual appreciation of its currency which surged faster than usual during the G20 Summit.

This may be one of China's toughest times, both politically and economically, during its four decades of economic reform. On the one hand, China's stability is currently under threat with most of its population, who have benefited inadequately from the country's existing prosperity, demanding a re-engineering of wealth distribution through better pay, more welfare entitlements, increased political liberalizations and the wish list goes on. On the other hand, the Chinese government is facing broad economic challenges ranging from insufficient domestic consumption, structural issues with housing, healthcare and education sectors, blazing inflation, unmanageable foreign exchange reserve, global economic downturn & trade imbalance, and international currency issues.

China's gigantic economic stimulus in the past few years, incoming speculative investment funds and quantitative easing policy of the U.S. are rocking the country's economy with almost infinite and unbounded money which is beyond the control of even China's authoritarian government.

Efforts by the country's central planners so far to contain inflation in a few essential sectors such as housing and healthcare have led to nothing but to create more troubles to the flimsy economy. Without any lucrative outlets, opportunistic funds have flooded the country in search of profits, thus causing widespread and soaring inflation in recent months.

Despite its commonly perceived fat margins, the pharmaceutical industry in China is actually quite volatile to inflation and rising costs as the sector is under rigid government price control and manufacturer/distributor drug sales margins are generally at a low level after repeated government price cuts. With inflation reaching a historical high at present, it is inconceivable to me why the government is still planning renewed price cuts on drug products (under irrational public pressure). Instead, the government should expedite the creation of a competent drug price review mechanism that ensures sustainability of the pharmaceutical industry in a time of financial turbulences.

Increased short term risks

On top of the macro-economic challenges, there are signs recently showing increased short term risks which are specific to the pharmaceutical industry in China, especially to multinational pharmaceutical companies (MNCs).

New measures of the SFDA, which aim to raise sharply the quality and manufacturing standards of drug products, such as the new 2010 edition of China Pharmacopoeia and the upcoming new cGMP regulation, will lead to fast growth of costs and significant upfront investments in a time of prevailing inflation. The current drug pricing regime is unfortunately not well-established to cope with such economic conditions, thus creating short term turbulences, falling profits, working capital shortage and various other sustainability issues for the pharmaceutical industry.

Nonetheless, higher drug quality and manufacturing requirements in China will generally have minimal impacts on MNCs as they have much higher standards than most local players to begin with. In fact, the situation is even positive to MNCs in many ways.

RDPAC, the industry association of research-based MNCs in China, has been promoting the importance of higher drug quality and the idea of better pricing for better quality products.

The real threat to MNCs comes from attacks by local pharma industry and Chinese media which seek to force the Chinese government to minimize the price gap between local products and those of MNCs. So far, the National Reform and Development Commission (NDRC) has counted on cutting mostly prices of local products for cost containment but sought to minimize policy impacts on most MNC products.

For MNCs, it must be realized that continued reliance on its offpatent originator products for commercial success in China is no longer viable and growth has to come from patented innovative products and other business areas or models.

NDRC said this month it hopes to release its new drug pricing regulation before the end of this year and we heard from sources that the agency has already completed the second draft of this important document. It is almost certain that the NDRC will remove the drug pricing bracket of and provisions for off-patent "originator drugs" (or "innovative category drugs"). Although there may be provisions for quality-based price differentiations, the NDRC is expected to gradually reduce the existing large price gaps between off-patent originator drugs and their local generics over a four-year transition period.

If the price differentiation on quality basis is not as generous as MNCs hope, as seen in the ongoing trials in Guangdong province (as little as 5%), foreign companies will also be exposed to serious challenges with inflation and rising costs, especially if foreign companies want to target the essential drug market.

There is also discouraging news for foreign companies eyeing the potential of essential drug business. An important domestic industrial policy recently-released by the Ministry of Industry and Information Technology (MIIT), the Ministry of Health (MOH) and the SFDA, Guidelines for Accelerating Restructure of the Pharmaceutical Industry, seeks to expedite domestic pharma industry consolidation and to foster large local groups with significant market dominance. It openly sets the goal of having the top 20 domestic manufacturers of essential drugs control at least 80% of the Chinese market for such drugs. It is apparent that the government wants only the largest Chinese conglomerates, especially state-owned or state-controlled companies (although this is not spelled out), to be the main players for the game of essential drugs and I suspect the objective will be gradually facilitated through different implementation level policies and rules which will favor preferred players. It is a harsh wake-up call to those foreign companies which are pinning great hope on building growth through the huge volume of essential drugs.

On a brighter note, the NDRC is likely to postpone the comprehensive price cut on essential drugs to sometime next year, in part due to pressures from the pharma industry and complexities in determining true costs of drug products. Hopefully, inflation and rising costs are also taken into consideration.

In a separate development, the Chinese government approval for Novartis's proposed acquisition of 85% stake in the privatelyheld Zhejiang Tianyuan Biopharma has not been forthcoming despite expiration of the normal one-year regulatory approval period. The deal was reached last November and it is the largest M&A in the Chinese vaccine sector.

Sources suggest that the Chinese government is disappointed with MNCs like Novartis for their lack of enthusiasm in providing technological help to potential Chinese partners during the period of raging H1N1 flu outbreak, thus dampening the government's willingness to let go of domestic assets and provide improved market access to a strategic sector like vaccines. In addition, China is also becoming increasingly defensive about M&As involving foreign acquisition of strategic assets with many foreign M&A plans of Chinese companies being rejected by Western governments.

At a time when MNCs seek to accelerate growth in China healthcare through M&As, the tendency is definitely troubling. To deal with the situation, MNCs will have to lobby for support from their own governments, improve communications with the Chinese government and increase transparency of their China strategies to demonstrate commitments.

Hospital reform experiment accelerates as other fronts stumble

The MOH escalated the hospital reform in November and designated 31 provincial level trial sites in addition to the existing 16 national sites. In a recent policy speech, Health Minister Chen Zhu outlined a plan for hospital reform in 2011 and the next five years.

It seems the MOH has carefully steered around and avoided tackling directly the toughest parts of the reform - reshaping the hospital financing model and separating medical institutions from drug sales. Instead, the reform of the medical payment/ reimbursement system is now given higher priority with the hope of breaking through the above two critical reform components.

Other hospital reform priority areas in the next five years are generally peripheral in nature and less disputed. They include separation of government ownership from hospital management as well as non-profit from for-profit medical institutions, integration of urban basic medical insurance (BMI) programs and new rural cooperative medical scheme (NRCMS), reorganization and integration of services provided by medical institutions at different levels, improving hospital services and processes, boosting infrastructural investments for primary and county level medical institutions, and enhancing hospital IT infrastructure building.

In the interim, reform stalled on a number of other fronts. The essential drug system implementation is now behind schedule due to lack of local government funding support for the zero drug sales markup policy in many areas. Besides, the MOH was supposed to issue the hospital volume of the *National Essential Drug List* (NEDL) before the end of last year. Nearly a year has passed and there is not even an official comment about it anymore.

There are also many unresolved issues with government-led tender purchase and distribution of essential drugs. Some promised guidelines were not issued in time despite repeated comment-seeking. It is believed that the government is now increasingly inclined to centralize the tender purchase and distribution of essential drugs with strengthened government leadership, but I have yet to hear about any prevailing model being picked or preferred. A few local government models were previously reviewed and investigated by the MOH, but they were all abandoned due to oppositions from stakeholders.

Despite introduction of two regulations for hospital drug purchase tenders by the MOH in July this year, progress in this area has been muted. It is interesting, however, to note Chongqing's innovative experiment of trading drugs like stocks with opening of China's first drug exchange in the city recently. The exchange is a "government-led third party online drug purchase transaction platform" and it replaces the traditional hospital drug purchase tender platform in Chongqing. Drug products of approved manufacturers are listed at, and all public hospital drug demands are required to purchase through the exchange. It remains to be seen how this experimental platform will deal with many existing issues of the drug purchase tender system such as the balance between price and quality, but at the least it can improve transparency of the drug purchase process and settle payments within 60 days after delivery.

MOH/SFDA step up regulations for drug prescriptions and clinical use

The MOH announced lately the preliminary establishment of a national network for surveillance of rational drug use in 960 medical institutions nationwide and it hopes to cover all grade II or above medical institutions before the end of 2012. Success of the agency's plan will not only help rationalize the country's drug consumption and improve adverse drug reaction reporting in urban hospitals, but also make the government's cost containment efforts much more effective.

In a related development, the MOH is developing rules to control use of anti-infective drugs through imposing compulsory ceiling limits on the share of such drugs in total hospital drug consumption.

On the other hand, the agency recently vowed to crackdown on the resurgence of commercial briberies in hospital drug sales process. Well, it seems the MOH is getting better at this - apart from its conventional weapons of punishing physicians and suppliers, the ministry is now focusing on banning any hospital drug sales data collection/analysis for commercial purposes. Aha, the sidekick is smart enough to disrupt any systematic kickback schemes of unethical drug companies.

The MOH also lined up with the SFDA and four other central government agencies for a new round of campaign against counterfeit drugs and illegal sales of pharmaceutical products in early November.

On the part of the SFDA, it recently issued a new rule for ethical review of drug clinical trials and solicited public comments on its proposed regulation on drug guality in medical institutions. The latter move represents SFDA's first attempt ever to cross into the boundary of the MOH. It is encouraging on the surface but enforcement will be the real test.

As a highlight of the month, the SFDA ordered the withdrawal of Sibutramine from the Chinese market following the lead of EMEA and USFDA. The move devastated Chinese manufacturers of the drug including Taiji Group whose early success was entirely built on its branded Sibutramine (Qu Mei). Roche's Xenical, the archrival of Qu Mei in China, is expected to grab most of the market vacuum left by Sibutramine, making the company the biggest winner from the SFDA tough stance.

MNCs open floodgate of M&As as cross-border licensing deals rise

During my recent meetings with senior executives from various MNCs and at our Pharma China Seminar in Princeton in November, I sensed growing impulse for buying healthcare business assets in China to facilitate fast growth although few at HQ have in-depth understanding of their Chinese M&A targets.

MNC pharma giants had not been active at the M&A scene of Chinese pharma until recently when we saw a flurry of deals. With a price tag of US\$135 million, Bayer's acquisition of the cough & cold business of Topsun in 2006 had been hailed as the biggest acquisition deal by a MNC big pharma in China until late October this year when a deal almost four times as big took place. Sanofi Aventis agreed to acquire BMP Sunstone, a leading pediatric OTC player, for US\$520.6 million. I already heard rumors of a possible deal months ago although BMP Sunstone's chairman declined to comment on it when I had lunch with him in August. But the news shocked me nevertheless with its price tag.

Just a few days later, Nycomed bought 51% of Guangdong Techpool for US\$210 million which was again much larger than the Bayer-Topsun deal with a very impressive price tag too.

We all know that many MNCs have been shopping around for deals in China but little has come out of it until now. The hesitation is believed to be related to various business issues but price plays a big part. A senior GSK executive complained about the high valuations of Indian and Chinese companies not long ago.

The new deals with higher-than-expected valuations might be a wake-up call for CEOs of those big pharma companies which are still holding out for bargains. Alas, thrifty deals are hard to come by in a market with blazing growth and few desirable companies.

Alliance Boots is not waiting. Its Executive Chairman Stefano Pessina visited China lately with British Prime Minister David Cameron and was busy talking to potential acquisition candidates on the sideline. It was later learnt that the company joined in the competition for reorganization of Nanjing Pharmaceutical Group (NPG), the fourth largest pharmaceutical distributor in China. Three other contenders are dominant Chinese players including SinoPharm Holdings, Shanghai Pharmaceutical Group and China Resources Group. While some analysts rank Alliance Boots high for this deal, I am much less optimistic as NPG is a major stateowned enterprise and the three Chinese contenders possess formidable political influence.

Eli Lilly also seems ready to jumpstart its acquisition drive in China by putting together a dedicated team this month for Chinese M&A opportunities in ethical drugs. The company also announced a new diabetes research center in Shanghai and pledged US\$2.5 million to support a new partnership with the Chinese Diabetes Society and European Foundation for the Study of Diabetes.

Later Novo Nordisk also released a plan to inject an additional US\$100 million into expansion of its R&D center in Beijing to facilitate the company's growth in China.

Aside from M&As and new investments, there are plenty other notable developments involving MNCs in the past month.

It is reported that Novartis plans to move its China headquarters from Beijing to Shanghai after reaching a US\$1 billion strategic alliance pact with Shanghai Municipal Government for R&D and others. The company's proposed acquisition of Zhejiang Tianyuan, however, is now shaky with delayed government approval.

Many MNCs and Chinese pharma companies are stepping up their Chinese OTC and consumer healthcare business. GSK and J&J are the two established players which are working hard to expand beyond their traditional OTC drug business into the much more dynamic and lucrative market of consumer healthcare. Pfizer, backed by its recent acquisition of Wyeth, is trying to catch up in this area and Merck, which just took over Schering Plough, is planning a major expansion of its OTC business in China next year. Even smaller foreign companies like Boehringer Ingelheim are eyeing OTC expansion in the Chinese market, as local players such as Yunnan Baiyao Group setting up this month a consumer healthcare division as a part of the company's diversification drive.

In the area of licensing, there have been many cross-border deals noteworthy in the past month. Bristol-Myers Squibb entered a strategic partnership with Simcere Pharmaceutical Group to codevelop early-stage cancer drug BMS-817378 in China, while Sanofi Pasteur licensed its manufacturing human diploid-cell rabies vaccine technologies to Beijing Minhai Biotech.

Germany's Evotec AG agreed to license China rights of its potential insomnia drug EVT 201 to Zhejiang Jingxin Pharma, as U.S.-based Fibrocell Science formed a joint venture with Hefei Meifu Biotech for developing and marketing autologous fibroblast therapies in Asia. Conversely, Dongbao Group granted Swedish Orphan Biovitrum the distribution rights to market Iron Sucrose Rechon in Europe with a regulatory approval milestone of EUR1. 2 million.

On the developments of leading Chinese pharmaceutical players, SinoPharm Group confirmed in late October that it plans to spin off China National Biotechnology Group soon for an independent IPO, which is expected to be at least an equal success as the recent SinoPharm Holdings IPO in Hong Kong which raised over US\$1.1 billion.

China Resources Group, a close competitor of SinoPharm, made a number of high profile moves in recent weeks. Following acquiring 100% of Beijing Pharmaceutical Group in August, CRG became a leading player in pharmaceutical distribution with both Anhui Worldbest Pharmaceutical and Beijing Pharmaceutical Co. Ltd. (BPCL) in its pocket. Combining these two assets, CRG's pharmaceutical distribution business is already the third largest in China overtaking Jointown Group. In order to consolidate its presence in North China, BPCL reorganized the largest distributor in Shandong and laid foundation of a CNY500M-pharma logistics center in the province recently. At the same time, CRG entered into a strategic alliance framework agreement with Suzhou Municipal Government under which BPCL will also reorganize a leading local distributor and build a new CNY300M-pharma logistics center there.

Meanwhile, Kelun Pharma, the largest Chinese manufacturer of IV solutions, further consolidated its IV market dominance by acquiring Zhejiang-based IV transfusion company Guojing Pharma for CNY 246.5 million.

Future outlook remains rosv ...

Many favorable predictions about China's healthcare market were released by the world's elite data sources and consulting firms. Some cheers are surely welcome after reviewing many challenges above.

McKinsey & Co. recently predicted the size of China's market to exceed US\$600 billion within 10 years as the nation moves forward with its universal basic healthcare coverage plan, up from US\$240 billion or about 5% of the nation's GDP at present. The firm believes China's healthcare spending will rise faster than GDP growth, driven by better insurance coverage, improved access to high-quality care and rising demand from aging, urbanization and lifestyle shifts.

IMS Health, on the other hand, foresees China to overtake Japan as the world's second-biggest pharmaceuticals market in 2015. The company admitted having to continually revise up its numbers for China due to stronger than expected growth in the country.

But China may already be the second largest pharmaceutical market in the world if we turn to a different source, Southern Medicine Economic Institute (SMEI) under the SFDA. The Chinese drug market size in 2010 is estimated by SMEI to reach CNY 755.6 billion (US\$114.5 billion), up 22% year on year.

On a different segment of the market, Frost & Sullivan suggests

that the Chinese drug discovery outsourcing market reached US\$315.0 million in 2009 and is expected to grow at a CAGR of 23.0% from 2009 to 2016. Expired patents and rise in diseases are expected to fuel the growth of the Chinese drug discovery market. But the firm also sees challenges from the inflation and growing labor and raw material costs in China.

Similarly, Monitor Group expects China to become the global leader in life science discovery and innovation within the next decade. "In just a decade's time, China will not only be a significant engine of innovation, but has the potential to create a new model for advanced drug discovery," said George Baeder, who runs Monitor's China life science practice.

All of the predictions confirm the broadly optimistic picture jalthough challenges are abound in the real world, it is always good to be reminded of the rosy future prospects.

Hall of Fame for this month

Time flies and it is time for Hurun Report's China Pharmaceutical Rich List again. Mr. and Mrs. Li Li, founders of IPO champion Shenzhen Hepalink, topped the 2009 list with a personal fortune of CNY 40 billion (approx US\$6 billion). They are trailed by Li Jinyuan of Tiens Group, who was No.1 in 2007 and 2008, with a personal fortune of CNY 20.0 billion (up from CNY 17.5 billion last vear).

Fast pharmaceutical business growth and aggressive IPO valuations produced five more pharmaceutical tycoons with personal fortune over CNY 10 billion last year and propelled fortunes of the top 30 entrepreneurs on the 2009 list by 76% and 157% respectively against the 2008 and 2007 lists.

IPOs and M&As are expected to place more new faces on the list next year. Most likely we will see the boss of BMP Sunstone making it. You could have probably seen me there too if I had held on to my stake in BMP (Beijing MedPharm) in its early days. Nevertheless, my stake in Pharma China already earned me a place on the best-wish lists of many readers which, believe it or not, gives me much greater pleasure ...

Enough with my day-dream, let's turn to another figure who rose to fame this month. Wei Liang, a former division head level inspector with the SFDA, sought to make his fortune through corruption. Compared with Chen Haifeng, a former CDE official who was sentenced last month for taking in CNY 1.3 million from one drug company for inside help with a couple of drug registration applications, Wei priced his services "cheap" and "earned" his CNY 1.5 million bribes from a total of 25 companies for various inside helps.

In close ...

The Christmas tree of Novo Nordisk campus in Princeton, which neighbors my community, is now up again with the blue lights beautiful as ever. It reminds me that Thanksgiving is only a few days away!

Though I have long forsaken the protocol of sending holiday greeting cards, I'd like to take this opportunity to wish you all a Happy Thanksgiving!

I will be in China in December again and look forward to meeting many of you there.



News in Focus

Health Minister Chen Zhu delivers important speech on public hospital reform

Chinese health minister Chen Zhu delivered a keynote speech on November 11 at a national forum on public hospital reform sponsored by the Ministry of Health (MOH).

In his speech, Chen expressed satisfaction for the progress of public hospital reform experiment thus far. Besides the existing 16 national trial sites for public hospital reform, he announced the designation of 31 additional cities (including Beijing) as the provincial level public hospital reform trial sites with experiments to be launched soon.

Chen introduced the overall plan and priorities for public hospital reform in 2011 and in the 12th five-year plan period (2011-2015). He stressed that while public hospital reform is key to the success of the entire healthcare reform, other aspects of healthcare reform must lay a solid foundation for implementation of the hospital reform.

Regional healthcare planning and localized regulation of medical institutions should become the breakthrough point for the public hospital reform objective of "separating government and stateowned institutions, dividing state ownership from hospital management, and splitting for-profit from non-profit medical institutions," according to Chen. At the same time, reform of the medical payment/reimbursement system and the hospital financing mechanism should help facilitate the reform objective of "separating medical institutions from drug sales", he added.

In the near term, Chen pledged to push forward the following reform aspects as priorities for the ongoing public hospital reform experiment.

- Optimizing the structure and distribution of medical institutions and strengthen infrastructural building in rural, suburban and new urban residential areas and for various healthcare service specialties including pediatrics, OB/GYN, mental health, senior nursing and rehabilitation;
- Establishing long term interconnectivities between public hospitals and primary healthcare institutions in order to build a classified medical service model with primary institutions delivering frontline services and referring patients with more serious conditions to bigger and specialized hospitals;
- Reforming the medical service payment/reimbursement systems of public hospitals to enable direct settlements at hospitals for local and non-local patients who are covered under the urban basic medical insurance (BMI) programs and the new rural cooperative medical scheme (NRCMS). The reform is also an opportunity to develop internal cost-containment mechanisms of public hospitals;
- Prioritizing the infrastructural development of county level hospitals which serve as the leading force for the three-level rural medical service network;
- Improving the quality of medical and nursing services of medical institutions including the medical service process in hospitals, the medical appointment system, the electronic clinical pathway management system, specialized medical research and qualification of medical professionals;
- Developing the standardized resident physician training scheme in order to build up a high-standard talent pool for all levels of medical institutions; and

 Pushing forward the infrastructural building for hospital IT systems (with emphasis on electronic medical records and hospital management) and the remote real-time medical consultation system.

Essential drug policy under pressure for revision

Various research reports on essential drug policy implementation, which were undertaken by organizations including the China Society for Economic Review (CSER) and the Chinese Peasant's and Worker's Democratic Party (CPWDP), have recently been submitted to the State Council.

While each of these research projects has its own angle, they all report mounting difficulties and problems for implementation of the existing essential drug policies.

The CSER report points out that zero drug margin policy implementation is faced with many serious challenges in almost all regions, while the CPWDP's report focuses on the problems related to widespread overemphasis of drug prices in essential drug purchase. To deal with these problems, CPWDP is calling for centralized uniform purchase and distribution of essential drugs at the national level.

A number of leading pharmaceutical groups are believed to have reached consensus recently over their common positions on essential drug policies and will submit their petition to the central government soon.

Meanwhile, sources suggest that many local governments have been very slow in pushing forward the policy of zero essential drug sales margins in primary medical institutions and it seems unlikely they can achieve the national healthcare reform objective of introducing the policy in at least 60% of all primary medical institutions nationwide by the end of this year.

Experts say that the policy of zero essential drug sales margins face three major challenges including 1) medical institutions are resentful to this policy; 2) local government funding is often not in place to support the implementation; and 3) affordability of local governments was not properly considered in the development of the essential drug list.

The State Council's Leaders Group for Deepening Pharmaceutical and Medical System Reform is working on revising the existing policies for the essential drug system and is believed to be conducting various trials in Anhui province, according to Prof. Ll Xianfa, Deputy Director of People University's Pharmaceutical Logistics Research Center. Earlier, the central government showed strong interest in promoting the reform model adopted in Minhang District of Shanghai which emphasizes uniform purchase and distribution under government leadership, but the initiative has been met with strong resistance from the pharmaceutical industry.

Affected by the potential policy swings, a number of complementary policies of the essential drug system as well as the planned price cut on essential drugs are believed to be put on hold.

Essential drug price cut likely to be postponed to next year

The proposed government price cut on essential drugs, which is being closely watched by the pharmaceutical industry and the investment community, is likely to be postponed to sometime

next year, according to the Shanghai Securities News quoting source in the NDRC. It is believed that the delay is related to various disagreements from the pharmaceutical industry and changing market environments.

The essential drug price reduction speculations have depressed the performance of Chinese healthcare stocks since early October and led to numerous wild stock price swings. It is estimated that net CNY 9.1 billion stock investment funds flowed out of the sector last month alone.

Earlier, Luo Yan, Deputy Director of Drug Price Division under the Price Department of the NDRC, said that her agency hopes to release its new regulation for drug prices before the end of this year and it is working hard on a scheme to adjust prices of essential drugs.

The NDRC stresses that the price adjustments will emphasize cutting the prices of essential drugs which are higher than prevailing tender prices, but the agency will not cut prices of drugs which are already at a low level and may even raise prices of some exclusive drug products which are under-priced.

Meanwhile, other factors may have also played a part in the delay of the NDRC's plan to cut essential drug prices.

Firstly, inflation has been hitting China hard in recent months and has led to sharp growth of raw materials and production costs; and

Secondly, the Chinese Pharmacopoeia Commission announced that it will complete revision of the drug standards for all 307 essential drugs before the end of this year. While the revision will raise the quality requirements for essential drugs sharply, it will also boost costs significantly.

Recent cost growth will surely narrow the room for additional price cuts on essential drugs and undermine the abilities of the NDRC to maneuver on this front.

China to expedite pharma industry restructure under new policy document

The Ministry of Industry and Information Technology, the Ministry of Health and the State Food and Drug Administration recently issued a major new policy document, Guidelines for Accelerating Restructure of the Pharmaceutical Industry, as a part of the healthcare reform package.

The guiding principles of the policy document aim to strengthen domestic drug innovation, promote research of new products and technologies, push forward industry consolidation and M&As, foster the formation of big pharma groups, expedite technical upgrading, boost company cultures and improve global competitiveness through the pharmaceutical industry restructure in the next five years.

In order to accelerate the restructure, the role of market force will be combined with policy guidance and enterprise management will be strengthened to facilitate structural optimization of the pharmaceutical industry through competition, according to the document.

Pharmaceutical enterprises are encouraged to upgrade to meet the requirements of the upcoming new GMP (2010 edition) with elimination of high-energy-consuming and highly-polluting processes and equipment. The policy calls for control of new production capacity in the pharma industry and coordinated development of essential and non-essential drugs. It also reinforces the perception of manufacturers being the No.1

responsible party for drug quality and demands them to improve drug standards and relevant testing systems.

The document contains some specific goals for the next five years including: 1) the top 20 manufacturers of essential drugs should control at least 80% of Chinese market share; 2) a minimum of ten domestically-originated innovative chemical drugs and 15 domestically-originated biopharmaceuticals should be industrialized; 3) 50 modern TCMs with solid therapeutic efficacy, clear composition, specific claims, good safety profile, advanced dosage forms and reliable quality control should be developed, while TCM IP protection as well as R&D of ethic medicines should be strengthened; and 4) a minimum of 200 domestically-originated and globally advanced medical device products with over CNY 10 million in annual sales should be developed.

Additionally, the policy plans to develop three regional centers for pharmaceutical manufacturing along the vicinity of the Yangtze River Delta, Pearle River Delta and Bohai economic rim.

The expansion and upgrading projects of large pharma companies under inter-provincial M&As will be given priorities for relevant approvals. Such companies will also receive government support in various other areas including stock listing, bond issuance and bank loans. Additionally, individual pricing policies will be developed for new drugs with independent intellectual properties.



McKinsey: Chinese healthcare market to reach US\$600 billion in ten years

As the nation moves forward with its universal healthcare coverage plan, the size of China's market could exceed US\$600 billion within 10 years, according to a report from management consulting firm, McKinsey & Co. The healthcare market, currently estimated at US\$240 billion, is about 5% of the nation's GDP.

McKinsev states in the report that the healthcare market in China offers great potentials for foreign companies, yet challenges such as market pricing and consumer preferences pose challenges.

But McKinsey asserts that healthcare spending will rise faster than GDP growth, driven by better insurance coverage, improved access to high-quality care and rising demand from aging, urbanization and lifestyle shifts.

A few MNC providers, such as Singapore-based ParkwayHealth, have already established a presence in China and have plans to expand gradually, the report said, adding that several others are looking to tap into opportunities within the next few years.

Currently, rumors are apparently circulating that the government will open the market to 100 percent foreign ownership in privatehealthcare facilities, but no official word has been given, the McKinsey report said. Foreign ventures are currently allowed to hold a 70% stake in such facilities.

Sector reforms, therefore, will affect many facets of healthcare delivery including insurance, primary care, hospital management, medications and public health.

But the government will continue to dominate the market, because the country's healthcare reforms' primary objective is to ensure broad access to basic health services.

McKinsey pointed out that opportunities do exist for private sector

healthcare-service providers, such as insurance companies, private hospitals, and healthcare information technology providers.

With the market in China still in its infancy, national reforms targeting healthcare improvements in rural areas offer great opportunities for medical-device makers, said a senior official with the European Union Chamber of Commerce in China's Healthcare Equipment Working Group.

Since Chinese healthcare reforms favor the use of low-priced medical devices - and most foreign firms produce more highend products - these companies may have to change strategy to adapt, the European Chamber official said. Some firms have done so, including medical-device producers GE, Philips and Siemens, which seek to lower prices by producing locally.

SMEI releases Chinese pharma industry and market forecasts

The Southern Medicine Economic Institute (SMEI) recently released its forecast for the Chinese pharmaceutical industry and market performance in 2010 and 2011.

The total output value of the Chinese pharmaceutical industry in the first eight months of this year was CNY 770,838 million, up 25.23% year on year, according to official statistics.

SMEI anticipates the overall output value of the Chinese pharmaceutical industry to reach CNY 1,256 billion, up 25% year on year and accounting for no less than 7% of the Chinese GDP in 2010.

The Chinese drug market size in 2010, on the other hand, is expected to reach CNY 755.6 billion, up 22% year on year. Among the total, the hospital, retail pharmacy and third terminal (community + rural) market segments are estimated to reach CNY 452.0 billion (+22.5%), CNY 173.9 billion (+17.0%) and CNY 129.7 billion (+27.9%) with market shares of 59.8%, 23.0% and 17.2% respectively.

Assuming the Chinese government fulfilling, as planned, its commitment for an additional CNY 850 billion investment into the healthcare sector and the world economy does not dip into the bottom again, SMEI believes that total output value of the Chinese pharmaceutical sector will see 23% further growth in 2011, reaching CNY 1,545 billion.

SMEI also predicts the cumulative annual growth rate (CAGR) of the Chinese pharmaceutical sector in the next decade to be 20% with its output value reaching CNY 4,018.8 billion in 2019.

Based on drug purchase audits of representative hospitals in 16 Chinese cities, SMEI said the growth rate of the Chinese hospital market was 30.4% in the first half of this year, while the average prices of drug products sold in hospitals rose 6%.

Among the top 20 pharmaceutical companies by hospital drug sales in the first half, 14 were multinational pharma companies and six were local firms. The leading five companies were AstraZeneca, Pfizer, Roche, Bayer and Shandong Qilu Pharma.

SMEI estimates the Chinese hospital drug market to grow around 22.5% for the full year in 2010 reaching CNY 452 billion. The continued hospital market growth this year is attributed to expansion of the basic medical insurance (BMI) programs, improved BMI outpatient coverage and elevated BMI reimbursement levels.

Meanwhile, the third terminal drug market (urban community and rural healthcare facilities) this year is anticipated to be CNY 129.7 billion with growth of only 27.9%, which is much lower than the 42.0% forecasted previously.

However, a number of concerns will impact the growth trend next year, according to Lin Jianning, President of SMEI. They include: 1) excessive consumer price index (CPI) growth may lead to changes in the government's macroeconomic policies which will affect the pharma industry; 2) the expected new pricing policy for drug products, under which the NDRC may seek to control drug retail prices, drug sales margins and ex-manufacturer prices, will lead to more turbulences in the marketplace and may result in significant changes of the existing pharmaceutical business models; and 3) the ongoing medical reimbursement reform is likely to take shape soon and create structural changes in the contemporary therapeutic and drug prescription landscape.

IMS: China to overtake Japan as the 2nd largest drug market in 2015

China is set to overtake Japan as the world's second-biggest pharmaceuticals market after the United States in 2015. Murray Aitken, senior vice president with IMS Health, told the Reuters Health Summit.

China's ascent to the No. 2 spot in just five years time may surprise some, but Aitken said his company had been forced to continually revise up its numbers for the country in the face of soaring demand for Western medicines.

"China continues to grow a little faster than we expected and we don't see any sign that momentum is slowing down. Each year we tend to underestimate how fast China will grow," he told the meeting at Reuters office in New York.

China, which is predicted by IMS to see drug sales increase 25% to 27% to more than US\$50 billion next year, is currently the world's third-largest pharmaceutical market.

As sales growth in Europe, the United States and Japan stalls and many blockbusters lose patent protection, new markets -particularly in Asia and Latin America -- are being targeted by makers of both prescription and over-the-counter drugs. With its rising middle class, China is the biggest prize.

Overall, IMS forecasts that 17 emerging markets will account for around 50% of global growth in pharmaceutical sales worldwide over the next five years, making them an irresistible target for Western manufacturers.

The current leaders in the space include smaller players with a long history of access to a wide range of countries, such as Bayer.

Aitken said other European drugmakers had also been growing well and investing hard in emerging markets in recent years, including Sanofi-Aventis SA, AstraZeneca Plc and GlaxoSmithKline.

"These are all European companies and it seems, in general, that those companies are more likely to have had a position in emerging markets longer and be more familiar with them," he said.

"They have also had to pursue growth beyond the developed markets perhaps more than U.S.-based companies that have been disproportionately strong in the U.S."

China offers great prospects for outsourcing of preclinical & toxicity studies

As all drug companies are vigorously controlling the R&D cost, the high failure rate has become a controlling factor for them to improve the efficiency and productivity of drug discovery and WiCON | Pharma China

development. To reduce the overall cost of drug development, eliminating un-developable drug candidates and avoiding them being unnecessarily advanced to any late development stage have become critical to all drug companies. As such, all drug companies are now conducting extensive toxicology and safety pharmacology research for any drug candidates.

Although relatively young, the service capability of Chinese CROs in preclinical and toxicology research has been significantly improved in recent years, according to a new report from Research and Markets, "Future Outlook of China Preclinical and Toxicology Outsourcing". As China possesses a number of advantages in preclinical and toxicology research, many drug companies are attracted by the significant benefits of conducting this type of research in the country.

Key Findings of the report

- The Chinese pharmaceutical outsourcing industry has been growing in an exponential rate in the past decade. Most early established Chinese CROs almost all started with chemistry service only. However, after having practiced for a few years, a number of them have now also gained sufficient experience and skills in preclinical and toxicology research.
- The rapid development and growth of the Chinese preclinical and toxicology outsourcing industry is, to a large extent, contributed by the entrance of a number of multinational CROs that are attracted by the fast growth history and still huge future growth potential of the Chinese industry. Their presence has greatly enhanced the overall service capability of the Chinese industry.
- Currently, there have been about 65 CROs in total, including the China divisions/branches of those multinational CROs, in the Chinese preclinical and toxicology outsourcing service industry. Combined together, they provide a wide spectrum of services covering almost all areas of the preclinical and toxicology research. One of the key features of the Chinese service industry is that most Chinese CROs have non-human primates for in vivo efficacy testing and other pharmacological property studies, which have become more and more important in the modern preclinical and toxicology research.
- Most China-based CROs have brand new, state-of-the-art preclinical research facilities including animal vivaria. Currently, Chin has a capacity of more than one million square-foot animal space. About another one million square-foot animal facility is under construction.
- China started implementing the GLP standard for preclinical and toxicology research in 2007, including the regulations on the use of animals in medical research. As the FDA gradually recognizes the Chinese GLP standard, more and more data generated in the laboratories of Chinese CROs are now accepted by the agency.
- Responding to the improvements, a large number of drug companies, both major pharma and small biotech, have outsourced their preclinical and toxicology research to China. Having conducted drug discovery research in China for several years, the China R&D centers of many major pharma companies have generated a number of lead compounds in their pipelines which are ready to enter the next development stage. They are currently expanding their R&D focus in China along the value chain, from originally only discovery-focused research to now also early development.
- Although the current outsourcing demands for preclinical and toxicology research service are still relatively soft in China (and in the globe as well) compared with those years before the

financial crisis, in the long term, these demands will be still strong. A number of positive drivers, both globally and regionally and both internally and externally, all determine the anticipated fast future growth of the Chinese industry.

- Globally, as more major pharma companies will be implementing the strategy of networked partnership and as a key stage of drug development, outsourcing demands for preclinical and toxicology research will only become stronger and stronger. Similarly, outsourcing demands by small biotech companies will also become stronger as more and more of them now pursue virtual operation model, which determines that they will mostly rely on CROs to fulfill their R&D work.
- Regionally, as China will still possess a number of advantages even five to seven years from now in preclinical and toxicology research over many of its competitors in the world, drug companies from around the world will be attracted to conduct this type of research in the country.
- Internally, continually working with experienced multinational companies is steadily improving the skills and experience of Chinese CROs, which will in turn attract more drug companies to outsource to the country. The outsourcing service demand by the local domestic Chinese drug companies is also expected to grow rapidly in the near future as more and more Chinese drug companies are now embarked on innovative drug research.
- Externally, as many pharma companies have now recognized the power and usefulness of the large talent pool in China, conducting drug R&D directly in China can enhance their productivity. The fast development of the Chinese industry will also attract more multinational CROs to enter the Chinese market in the near future, which will further accelerate the development and growth of the Chinese industry.
- In the past several years China has been recognized as one of the best places in the world for small molecule drug discovery research. The country is currently also emerging as one of the most favored places for preclinical and toxicology research as well. It is therefore expected that the outsourcing service of preclinical and toxicology research will be the next wave in China. Major pharma companies will be looking for outsourcing or collaboration opportunities in China. They will also be implementing the networked partnership strategy in China through partnering with preferred local companies or research organizations.
- The report thus forecasted that the Chinese preclinical and toxicology outsourcing industry will likely grow in a CAGR of 27% for five years after 2010 and its market value will likely reach more than US\$760 M by 2015.
- As the fast growth of the Chinese industry attracts more multinational CROs to enter the Chinese market, the current industry landscape of the Chinese preclinical and toxicology service sector will soon be changed as the competition will rise rapidly. For Chinese CROs to survive the anticipated competition, it is expected that more consolidations within the Chinese industry will take place in the very near future.



Industry News

NSB announces leading 100 Chinese pharma manufacturers by revenues

The National Statistics Bureau of China (NSB) published its ranking of leading Chinese pharmaceutical manufacturing companies in 2009 by their core business revenues.

The following table shows the top ten such companies.

Top ten Chinese pharma manufacturers in 2009 (by core business revenues)

Rank	Company Names
1	Yangtze River Pharmaceutical Group
2	Harbin Pharmaceutical Group
3	Xiuzheng Pharmaceutical Group
4	China Shijiazhuang Pharmaceutical Group Corporation
5	Hangzhou Huadong Pharmaceutical Group
6	Weigao Group
7	Northeast Pharmaceutical Group Corporation
8	North China Pharmaceutical Group Corporation
9	Taiji Pharmaceutical Group
10	Tianjin Kingyork Pharmaceutical Group
Courses	NCD

Source: NSB

All of the top 14 Chinese pharmaceutical manufacturing companies are local firms, but there are eight multinational subsidiaries or joint ventures in leading 100 as follows:

MNC subsidiaries or JVs in top 100 Chinese pharma manufacturers in 2009*

Rank	Company Names				
15	XiAn Janssen Pharmaceutical Co. Ltd.				
24	Pfizer Pharmaceutical Co. Ltd.				
31	Shanghai Roche Pharmaceutical Co. Ltd.				
36	Sanofi-Aventis (Hangzhou) Pharmaceutical Co. Ltd.				
37	AstraZeneca Pharmaceutical Co. Ltd.				
41 Beijing Novartis Pharmaceutical Co. Ltd.					
70	Baxter China				
100	00 Beijing Fresenius Pharmaceutical Co. Ltd.				
Source:	NSB * by core business revenues				

by core business revenues

Chinese media bashes high prices of foreign drugs

A recent report on the 21st Century Business Herald, a leading Chinese business newspaper, claimed the prices of originator drugs made by foreign-invested enterprises (foreign drugs) to be 1311% higher on average than those generic drugs made by local Chinese enterprises (local generic drugs).

The paper claims that it recently obtained a pricing comparison chart between foreign originator essential drugs (which are individually-priced) and local drugs (which are uniformly-priced) from "relevant authorities".

Using this chart, prices of nine foreign originator drugs and those of their local generic drugs are compared and it is concluded that the average price gap between the two groups of products to is 1311% with the highest gap (Capoten/Captopril) being 2319% and lowest gap being 643%.

The report further alleges that the prices of foreign drugs are often exempt from government price cuts and the reasons behind are "complex", Song Ruilin, Executive Director of China Association for Promotion of Pharmaceutical Industry R&D, was quoted as saying. Song agrees that foreign drugs have higher quality standards and better brand images, but he is unsure if the huge price gaps between foreign originator drugs and local generics are warranted in view of their minor quality differences.

The paper singles out BMS's Capoten (Captopril) as its price gap with local generics is ranked the highest. The price of Capoten (12.5 mg/100 tablets) is CNY 160 while that of local generic (25 mg/100 tablets) is only CNY 13.8.

Other products that are spotlighted by the report including Bayer's Cipro, Nebo a/s's DexFerrum, Bayer's Nimotop, Roche's Rocephin, Abbott's Rytmonorm, Takeda's Nicholin, Novartis' Tegretol and Pfizer's Diflucan whose prices are reported to be 1880%, 1534%, 1461%, 1340%, 1017%, 962%, 647% and 643% higher respectively than those of their local generic drugs.

Meanwhile, the report on the 21st Century Business Herald guotes a number of local pharma executives who claim their product quality to be equivalent to those of originator drugs and challenged the designation of "originator (or innovative category) drugs" under China's drug price regime. Local executives also complain about the "super-national treatments" offered to foreign drug companies which they say do not conform to requirements of the WTO.

Responding to public pressures, the category of "originator drugs" was no longer present in the draft of NDRC's recently proposed drug price regulation.

This has poked the weakest spot of foreign drug companies which grouped around their industry association RDPAC in the submission of a joint petition to the government against removal of the individual-pricing policy for "originator drugs", the report concludes sarcastically.

More pharma companies head for the bigger Chinese cosmeceutical market

Some leading Chinese and foreign pharmaceutical producers are tapping into the potentially big cosmeceutical market.

Yunnan Baiyao Group Co., Ltd. has set up a specialist health products division as part of strategy to build an entire industry chain in addition to the pharmaceutical business. It just launched a traditional Chinese medicine anti-dandruff shampoo in Yunan and Hubei provinces in addition to current healthcare products of Yunan Baiyao toothpaste, herbal medical body lotion and shower cream, effervescent shower tablet, effervescent foot bath tablet, shoe sterilization product and Yunnan Baiyao first aid kits. The company hopes to build a full presence in cosmeceutical personal care products sector in the future.

China's cosmeceutical sales grew at 10% to 20% pace between 2004 and 2007, which is expected to continue between 2008 and 2012. China's cosmetics sales are estimated to reach CNY 120 billion in 2010, including CNY 48 billion in cosmeceutical sales with a 40% market share.

Incomplete statistics show that over 170 pharmaceutical companies in China including Beijing Tongrentang Group, Kunming Dihon Pharmaceutical Co. and Shenghuo Pharmaceutical Holdings have tapped into cosmeceuticals sector.

GlaxoSmithKline plc (GSK), a global leading research-based pharmaceutical and healthcare company, recently introduced Stiefel brand into China. After completing the acquisition of Stiefel Laboratories, Inc. last July, GSK's prescription dermatology business expanded nearly two times last year with its share in the global cosmeceutical market rising to 8%.

Pharma distribution giants battle for reorganization of Nanjing Pharma

Four leading players in pharmaceutical distribution, including China Resources Group (CRG), SinoPharm Holdings, Shanghai Pharmaceutical Group (SPG) and Alliance Boots, are competing for the opportunity to reorganize Nanjing Pharmaceutical Group (NPG), the fourth largest Chinese pharmaceutical distributor.

NPG is 100%-owned by Nanjing Pharmaceutical Industries Group Co. Ltd., a state-owned corporation under the Nanjing Municipal State Asset Supervision and Administration Commission (Nanjing SASAC). NPG is the controlling shareholder of the publicly-traded Nanjing Pharmaceutical Co. Ltd. (NPCL) with a 21% stake.

In April, SinoPharm Holdings signed a framework agreement with Nanjing Municipal Government, leading to speculations for reorganization of NPG. But the agreement was merely for closer collaborations between SinoPharm and Nanjing instead of reorganization, said a source from SPG.

As a dominant player in East China, SPG will be seriously threatened if SinoPharm gets to acquire NPG or its subsidiary NPCL. So it is critical for SPG to win an upper hand against SinoPharm in the battle to reorganize NPG.

Meanwhile, CRG is highly motivated to acquire NPG in order to consolidate its foothold in pharmaceutical distribution after acquiring 100% of Beijing Pharmaceutical Group, a dominant pharma distribution player in North China, in July this year.

Alliance Boots is reported to be the latest contender for NPG or its stake in NPCL. Alliance Boots already owns 50% of Guangzhou Pharmaceutical Co. Ltd., the fifth largest pharmaceutical distributor in China. There were reports earlier that the company is eyeing more acquisitions in China and its chairman Stefano Pessina was in China recently with visiting British Prime Minister David Cameron to gather political support for his company and meet with potential acquisition candidates.

Some Chinese analysts predict Alliance Boots to be the most likely winner in this battle backed by its financial muscle, desire to step up its China presence and the positive Sino-British political environment at the moment. However, such a deal involving substantial state-owned assets will trigger various government approval procedures. Also, a deal of such magnitude between a state-owned company and a foreign company may require considerable political support from the central government.

CRG, which needs the deal badly to boost its presence in pharma distribution, is believed to be the next likely winner, followed by SinoPharm Holdings and SPG.

So far, representatives of NPCL and Nanjing SASAC declined to acknowledge or comment on the speculations for potential reorganization of NPG or NPCL.

NPCL's annual sales in 2009 was CNY 14 billion, which was about 75% of Jointown Pharmaceutical Group Co. Ltd.'s sales in the same year. However, its market capitalization was only CNY 5 billion which was about 20% of Jointown's market cap when it became publicly-traded on November 2.

Depressed market capitalization of NPCL makes the potential deal very attractive for contenders and provides Nanjing SASAC the strong incentive to reorganize NPG and NPCL.



Local company news

SinoPharm confirm IPO plan for CNBG

Song Zhiping, chairman of China National Pharmaceutical Group Corporation (SinoPharm Group), confirmed on October 24 the company's plan to launch an independent IPO for China National Biotechnology Group (CNBG) and six institutes of biological products under it. SinoPharm acquired CNBG in 2009.

The IPO of SinoPharm Holdings, another subsidiary of SinoPharm Group, in Hong Kong last year was a huge success and it raised over US\$1.1 billion. The IPO facilitated fast growth of SinoPharm Holdings and revenues the company is expected to exceed CNY 100 billion this year compared with CNY 60 billion in 2009. Song is confident that the planned IPO for CNBG will be even more "influential" and receive popular investor support.

CNBG is the largest Chinese company for blood products and vaccines. It has the largest market shares for state-funded class I vaccines (80%) and controlled drug substances in China.

Last week, SinoPharm Group acquired central governmentowned China National Service Corporation for Chinese Personnel Working Abroad (CNSC) which surprised many industry observers. The biggest core business of the acquired company is actually a retail network of duty-free goods, but Song explained that SinoPharm took over CNSC for its international business resources and foreign office network. CNSC is expected to be renamed SinoPharm International Co. Ltd. soon.

Meanwhile, Shanghai Institute of Pharmaceutical Industry, another central government-owned enterprise acquired by SinoPharm Group this year, is undergoing a name change to SinoPharm General Research Institute.

"SinoPharm was a leading pharmaceutical distributor in the minds of many before," Song said, "but the company has become the most vertically-integrated Chinese pharmaceutical group with diversified businesses in R&D, production, sales & marketing and distribution (of drug and biological products) after this round of mergers and acquisitions".

CRG enters strategic alliance with Suzhou Municipal Government

China Resources Pharmaceutical Group (CRPG), a subsidiary of China Resources Group (CRG), announced a strategic alliance framework agreement with Suzhou Municipal Government of Jiangsu province on November 18.

As part of the agreement, Beijing Pharmaceutical Co. Ltd. (BPCL) will reorganize Suzhou Li'An Pharmaceutical Co. Ltd. and invest CNY 300 million to build a major pharmaceutical logistics center in Suzhou.

Following acquiring 100% of Beijing Pharmaceutical Group in August, CRG became a top player in pharmaceutical distribution. Two core assets of CRG in this sector are Anhui Worldbest Pharmaceutical and BPCL whose 2009 annual turnover was CNY 13 billion and CNY 10 billion respectively. Combining these two assets, CRG's pharmaceutical distribution business is already bigger than Jointown Group, the third largest pharmaceutical group in China with CNY 22 billion in 2009 sales.

However, CRG's pharmaceutical distribution business presence in East China is relatively weak, as the market strength of BPCL and Anhui Worldbest lie with North China and Mideast China at present. The latest deal reveals CRG's continued ambition in the East China pharmaceutical distribution market despite its recent failure to acquire the majority stake in Shanghai Pharmaceutical Group, the second largest pharmaceutical distributor in China and the dominant player in East China.

CRG expands business in Shandong province with new JV and logistics center

The largest pharmaceutical logistics center in Shandong province. which is invested by Shandong Beiyao Zhongxin Pharma (SBZP), laid foundation recently. Total investment of the logistics center is CNY 500 million. SBZP is a joint venture 95%-owned by Beijing Pharmaceutical Co. Ltd. (BPCL) and 5%-owned by Jinan Zhongxin Pharmaceutical Co. Ltd. (JZPCL).

BPCL is a subsidiary of China Resources Group (CRG) and the seventh largest pharmaceutical distributor in China with anticipated annual sales of CNY 15 billion in 2010. JZPCL is the largest pharmaceutical distributor in Shandong province with CNY 4 billion projected sales in 2010.

The annual sales of SBZP is expected to reach CNY 10 billion by 2013 and its logistics center has an annual turnover capacity of 3 million cases of drug products, making it one of the ten largest pharmaceutical logistics centers nationwide.

The sales of BPCL subsidiaries and joint ventures in Shandong province are projected to reach CNY 6 billion this year and over CNY 100 million in three years.

CRG and its subsidiaries already own a number of major pharmaceutical operations in Shandong province including Shandong Dong-e E-jiao Group and Shandong Beiyao Lukang Pharma (a joint venture of BPCL and Shandong Antibiotics).

Sanjiu to build new antibiotic facility and spin off Canadian assets

Sanjiu Medical & Pharmaceutical Co Ltd., a publicly-traded subsidiary of China Resources Group, announced on Oct. 18 its plans to spend CNY 48.67 million to build an antibiotic manufacturing facility in Shenyang, capital of Liaoning Province.

Separately, Sanjiu plans to sell its 54.04% stake in Canada-based subsidiary 999E-Tech Inc for symbolic C\$1 to a natural person Li Jinrong, who is also one of the target firm's shareholders. Upon the completion of the deal, Li's shareholdings in 999E-Tech will increase from 14.96% to 69%.

In 2000, Sanjiu Medical injected C\$2.94 million into 999E-Tech that had C\$910,503 in registered capital at that time. As of Mar. 31, 2010, 999E-Tech had C\$100,853 in total assets and C\$102, 248 in total debts.

Kelun acquires IV transfusion manufacturer Zhejiang Guojin Pharma

Kelun Pharma, the largest Chinese manufacturer of intravenous solutions (IV solutions), announced on November 10 that it had reached agreement with major shareholders of Zhejiang Guojing Pharma to acquire an 85% stake in the latter company for CNY 246.5 million.

Zhejiang Guojing Pharma is an established producer of IV solutions in China with four manufacturing plants for such products as well as two oral solid dosage plants. It owns 74 approvals for various drug products.

Kelun Pharma expects Zhejiang Guojin's sales volume to reach 240 million bottles/bags in 2011 with annual revenues and net profits reaching CNY 400 million and CNY 40 million respectively.

Livzon reaches framework agreement with Zhuhai government for more investments

Livzon Pharmaceutical Group announced on October 18 a framework agreement with Zhuhai municipal government for stepping up its investments in the city.

Under the terms of the agreement, Livzon will make Zhuhai city its priority for strategic investment in the next decade, build a large scale industrial park in the city and bring in new technology projects. Livzon is also committed to keeping its headquarters in Zhuhai city.

In return, the Zhuhai municipal government promises to give the company preferences in land acquisition, taxation and talent recruitment.

As part of the deal, the company will invest a total of CNY 2 billion within the next five to eight years to build and develop Livzon Biotech Park in Jinwan District.

Separately, Anxing Securities reported that Livzon's three vaccine products for encephalitis, hepatitis B and rabies are expected to be launched in the first half of 2011 (encephalitis vaccine) and 2012 respectively. The company's novel monoclonal antibody drug for rheumatoid arthritis currently under research is also expected to go into clinical studies in two to three years.

Revenues and profits of Shanghai Pharma up sharply in first three quarters

Shanghai Pharmaceutical Holding (601607) said in a company filing that its revenue and net profit in the first three guarters of this year surged 19.19% and 66.16% year-on-year to CNY 27.89 billion and CNY 1.11 billion.

Sales of its pharmaceutical business increased 13.56% yearon-year to CNY 6.11 billion in the first nine months, including CNY 918 million, CNY 2.34 billion, CNY 2.53 billion and CNY 318 million respectively from its biopharmaceutical business, chemical pharmaceutical business, Chinese medicine business and medical devices business.

Its pharmaceutical distribution and retail business contributed revenue of CNY 21.7 billion in the first nine months, up 21.38% year-on-year.

Through the end of September, the company had the second largest market share in the pharmaceutical distribution and retail business in China, having an 18% market share in east China and 54% in the Shanghai area.

Founder Group consolidates pharma businesses into Southwest Synthetic Pharma

Southwest Synthetic Pharmaceutical Co. Ltd., a publicly-traded subsidiary of Founder Group, announced recently that it would issue an additional 9.36 million shares to purchase 100% of Beijing Beiyi Pharmaceutical Co. Ltd. from PKU International Hospital Group Co. Ltd., another subsidiary of Founder Group.

The move represents an effort by Founder Group to consolidate all of its pharmaceutical assets into Southwest Synthetic. In 2009,

Southwest Synthetic also acquired 90.63% of Chongqing Daxi Pharma from PKU International Hospital Group.

Following this transaction, PKU International Hospital Group's stake in Southwest Synthetic will be boosted to 51.94%.

Harbin Pharma completes facility for genetically-engineered drugs

Harbin Pharmaceutical Group announced on October 21 the completion of its state-of-the-art facility for manufacturing and R&D of genetically-engineered pharmaceuticals.

The facility is built on a site of 150,000 square meters and includes manufacturing plants, a R&D center, an analytical testing center and an animal experiment center.

Total investment of the project was CNY 160 million and its output value in 2010 is expected to reach CNY 250 million with over CNY 100 million in profits. It is expected the facility's annual output value will reach CNY 1 billion by 2015.

Lerentang Pharma completes logistics center in Shijiazhuang

Lerentang Pharmaceutical Group announced completion of the phase I of its modern pharmaceutical distribution & logistics center in Shijiazhuang city, capital of Hebei province.

As one of the largest pharmaceutical logistical facilities in China, the center seeks to improve operating efficiency and reduce drug delivery costs through scale of economy.

Total investment of the phase I of Lerentang's pharmaceutical logistical center in Shijiazhuang is CNY 200 million. Phase I of the facility has a total building area of 30,000 square meters on a 150-mu site with an expected annual turnover of CNY 20 billion worth of drug products.

Largest R&D operation for anti-depression TCMs established in Henan

Zhengzhou Yumi Pharmaceutical Co. Ltd. recently laid foundation of its expanded R&D center for anti-depression traditional Chinese medicines (TCMs) in Xinmi City, Henan province. The facility is reported to be the largest of its kind in China.

Total investment of the project is expected to be CNY 300 million and the project is planned for completion in August 2012.

Henan is well-known for its rich herbal material resources and can therefore support the company's R&D for anti-depression TCMs, according to Henan Yumi Pharma.

Seven retail pharmacy chains in Beijing enter into alliance

Beijing's retail pharmacy chain operators, including Cachet, Golden Elephant, Yishou Baixing, Haodekuai, and Jewim Pharmaceutical have jointly initiated a pharmacy alliance, which is the seventh provincial-level pharmacy alliance in the country.

The Beijing pharmacy alliance includes 23 drugstore chain retailers with over 800 outlets, and their total annual sales are more than CNY 3 billion. Members of the alliance plan to implement joint procurement from pharmaceutical manufacturers.

The alliance will also seek to standardize operations of the pharmacy retail chain stores of its members. In addition, it will offer long-term health tracking, medical consulting, and health lectures to residents in Beijing.

Zhou Li, first chairman of the alliance and general manager for Cachet, told local media that the alliance aims to create scale of economy and gain more policy influence and competitive strength amid the ongoing healthcare reform.

Foreign company news

RDPAC goes public to promote importance of drug quality

RDPAC recently launched three media events in Shanghai (Oct 19), Guangzhou (Oct 21) and Beijing (Oct 25) introducing its latest drug guality study which was undertaken by Ernst & Young Consulting China and covered 13 large pharmaceutical companies. They included eight international players, such as AstraZeneca, Eli Lilly and Novartis, in addition to the larger Chinese companies, including Zhejiang-based Hisun Pharmaceutical Company, Kunming Pharmaceutical Corporation and Beijing No.2 Pharmaceutical Company.

James Liu, Acting Executive Director of RDPAC, kicked off the events with a macro view of the pharmaceutical industry in China and RDPAC's focus on industry issues, while Vivian Chen. RDPAC's Director of Healthcare Economic Policy, elaborated the background of the study and RDPAC position on drug quality issue. Cherrie Che. executive director of Ernst & Young Consulting China, offered valuable insights of this study report.

These media events were aimed at introducing the outcomes of its drug quality study and advocating the idea of improving drug quality to the media and public, therefore, nurturing a positive public opinion environment, according to the industry group.

RDPAC also called for the establishment of a drug-pricing mechanism which is quality-oriented and at the same time spurs drug innovation. The mechanism should follow international principles and promote the sustainable development of the Chinese pharmaceutical industry, it stated.

RDPAC hopes that a differential pricing mechanism, combined with a new quality control and product approval system, will transform the pharmaceutical industry in China.

"The new pricing mechanism has been proposed to set higher prices for drugs developed domestically and to differentiate between prices for generic medicines produced by different companies at different levels of quality," said James Liu, managing director of RDPAC.

Che said the companies believe a new pricing system will encourage the manufacturing of high-quality, domestically developed products, maintain profit levels and facilitate higher investment in R&D.

"This will reduce problems with quality, and lead to the elimination of some smaller drugmakers who lack quality awareness and professional ability," she added.

Sanofi-Aventis to acquire BMP Sunstone for US\$520.6 million

Sanofi-Aventis and BMP Sunstone Corporation (Nasdaq: BJGP) announced on October 28 that they had entered into an agreement whereby Sanofi would acquire all outstanding shares of BMP Sunstone for a consideration of US\$10 per share, or US\$520.6

million total. Sales of BMP Sunstone was US\$146.87 million in FY09, a 28% increase over FY08.

Sanofi Chief Executive Officer Christopher Viehbacher commented. "The acquisition of BMP Sunstone will not only leverage our consumer healthcare business in China, but will also bring us unique access to new expanding distribution channels which are expected to account for a third of the pharmaceutical market in China in the coming years."

The acquisition is expected to make Sanofi one of the leading OTC players in China following their recent establishment of the Hangzhou Sanofi Minsheng Consumer Healthcare joint venture.

Sanofi Pasteur licenses HDVC technology to Beijing Minhai Biotech

Beijing Minhai Biotech announced recently a license deal with Sanofi Pasteur for latter's manufacturing technologies of human diploid-cell rabies vaccine (HDCV).

Sanofi Pasteur is reported to be the only manufacturer in the world for HDCV, which is said to be the gold standard globally for rabies vaccine. It is the first time Sanofi Pasteur out-licenses the technology for HDCV.

The licensing deal includes the complete HDCV manufacturing technology package, plant design, equipment purchase and production/quality control management systems, according to Chinese press reports. No information is available on the price tag of the deal.

Beijing Minhai Biotech expects to invest a total of CNY 200 million into this project and it hopes to achieve an annual output value of CNY 1.2 billion (for HDCV vaccine) by 2012.

Nycomed acquires Guangdong Techpool Biopharma to accelerate China business

Nycomed announced on November 1 that it is significantly expanding its presence in China through the acquisition of a majority stake in Guangdong Techpool Bio-Pharma Co., Ltd. (Techpool), a fast-growing Chinese bio-pharmaceutical company based in Guangdong.

Nycomed, which is privately owned but is considering a public offering, paid around US\$210 million for the 51.34% stake in Guangdong Techpool Bio-Pharma, according to Chief Executive Hakan Bjorklund.

Techpool, founded in 1993, specializes in the research, development, manufacturing and marketing of biologic drugs derived from natural sources. The company has developed and launched a number of innovative protein drugs, including Ulinastatin, a broad-acting trypsin inhibitor, which is a leading compound in the treatment of sepsis and multiple organ dysfunctions. Kallikrein, a serine protease, is used as a neuroprotective agent in the treatment of stroke.

Nycomed believes there is significant potential for the continued strong growth of Techpool's key products through expanded hospital and reimbursement coverage in China. While Nycomed China and Techpool will be run as separate companies, value will be created through various forms of alliances between the two entities. The two companies will continue to expand their footprint in China and will focus their efforts around five core brands: Ulinastatin, Kallikrein, Pantoloc, Ebrantil and Actovegin.

"The acquisition of the majority stake in Techpool provides us with a unique opportunity to strengthen our business in China. Techpool's specialty franchise is highly complementary to Nycomed's development strategy and will become a cornerstone of our expansion in emerging markets," Bjorklund said. Further details of the agreement were not disclosed.

Novartis to relocate China HQ to Shanahai

Novartis is going to move its China headquarters from Beijing to Shanghai, according to First Financial Daily quoting a source with Novartis China.

Currently most of the leading 20 multinational pharmaceutical companies have established their China or Asian headquarters in Shanghai and only Pfizer, Novartis, Bayer and Novo Nordisk still maintain their China headquarters in Beijing.

Novartis announced late last year a strategic move to invest US\$1 billion into developing R&D in Shanghai and the planned China headquarter relocation reflects an effort by the company to integrate R&D and business management under one roof.

The new R&D center of Novartis in Zhangjiang Hi-Tech Park of Shandhai is reported to be ready for construction now.

A substantial proportion of the company's US\$1B R&D investment will be used to hire high-level research talents, according to Herve Hoppenot, President of Oncology Business with Novartis.

The planned investment will expand the company's Institute for BioMedical Research in Shanghai (CNIBR), which specializes in basic research and developing new drugs, and boost the number of employees at the institute to 1,000 from 160 now. That will put it on a par with Novartis's research headquarters in Cambridge, Mass., which is second in size to the center in the company's headquarters in Basel.

China's needs will drive research at Novartis's Shanghai R&D center

Novartis oncology president Herve Hoppenot visited the company's US\$1 billion R&D center in Shanghai, the company's third largest R&D center globally. The center is expected to hire 1,000 researchers.

The center will focus on prevalent diseases, including lung, liver, breast and colon cancers, which have been growing in China, according to Hoppenot.

"The main tasks of the Shanghai R&D center include basic research and new medicine development, and we are going to complete the whole R&D process in China," Hoppenot said.

China's medical needs will drive research at the Shanghai R&D center to target prevalent diseases, concluded Alessandro Riva, head of global oncology development at the company.

Hoppenot said in-depth cooperation with domestic research institutions will be further encouraged. The Novartis Shanghai R&D Center has already co-founded a laboratory with Fudan University to provide strengthen research.

"We are ready to share the Novartis's platform of R&D and decades-long experience in medicine development," he added.

Novartis's China vaccine acquisition shaky with delayed government approval

Novartis AG reached an agreement to acquire an 85% stake in Chinese vaccine maker Zhejiang Tianyuan Bio-Pharmaceutical Co. Ltd. for US\$125 million in early November last year. The deal is pending approval by the Ministry of Commerce (MOC).

Normal MOC approval timeframe is one year which is already expired for the deal. So far, the MOC has neither take any actions nor made any comments on the deal. MOC did not respond to requests of the Chinese press for information.

Last year, DSM had to terminate its joint venture plan with North China Pharmaceutical Corporation after waiting years without approval or denial from the Chinese government.

Meanwhile, a spokesman of Novartis Pharma China said that he does not know anything about the progress of this deal.

The term of the acquisition agreement is one year but the contract lock-in time is 18 months, said Ding Xiaohang, chairman of Zhejiang Tianyuan Biopharma.

The acquisition agreement was agreed on and won government support at a time when China was in fear of a major H1N1 flu outbreak and the Ministry of Industry and Information Technology wished to secure more H1N1 flu vaccines from Zhejiang Tianyuan.

The Chinese government was expecting relevant technology support from Novartis to Zhejiang Tianyuan for the manufacturing of such vaccines but the company failed to deliver any material help, according to a senior executive of another leading Chinese vaccine company who is familiar with the situation. The Chinese government is disappointed and therefore becomes more prudent with its approval now.

The original plan of the government was to offer access to the vast Chinese market in exchange for foreign advanced vaccine technologies, said the executive. The idea seems rather naive now because what really interests foreign companies is "making huge profits from conventional vaccines" which most local manufacturers can produce, he added.

For Zhejiang Tianyuan, losing the deal with Novartis is also bad news. The executive admits that the domestic policy environment and competitive landscape is inadequate for private Chinese vaccine makers to sustain. He revealed that Zhejiang Tianyuan also sought to sell itself to China National Biotechnology Group which was not responded positively.

Privately-held Tianyuan sells vaccines against diseases such as hemorrhagic fever with renal syndrome caused by hantaviruses, and conducts research into various preventable viral and bacterial diseases. It had net sales of US\$25 million in 2008.

Novo Nordisk to add US\$100 million investment into Chinese R&D center

Novo Nordisk A/S announced on November 12 that it would inject as much as US\$100 million to expand its R&D center in Beijing in order to facilitate the company's growth in China.

Of all the increased capital, between US\$30 million and US\$40 million will be used to build new R&D facilities expected to complete at the end of next year, according to the Denmark-based company. The company is also scheduled to move its existing R&D facilities to the new center in the second half of 2012.

Novo Nordisk plans to lift the number of its researchers in the Beijing R&D center to 200 by 2015, making the center its biggest R&D facility outside Denmark.

Eli Lilly eyes deals and R&D boost in China

Following recent announcements of major China acquisitions by peers like Sanofi Aventis and Nycomed, Eli Lilly stated its

keenness to look for acquisition targets in China on Nov. 2.

The company does not exclude the acquisitions of local pharma companies in strategic areas, said Jacques Tapiero, Lilly's President for Emerging Markets, in Shanghai. He confirmed that the company has already put together a team especially for China acquisition opportunities. Lilly is only interested in local candidates in ethical drugs at present and will not consider OTC acquisitions for the time being, Tapiero added.

The company will boost Chinese R&D to develop drugs for diseases with high morbidities in the country. In the next five years, it plans to launch 15 new drugs in China, according to Tapiero.

He also said that Lilly is the only multinational pharma company with a venture capital operation in Asia. So far, Lilly Ventures has completed six deals with a total of over US\$40 million investments.

Dedicated diabetes research center established in Shanghai

Eli Lilly is establishing a dedicated diabetes research center in Shanghai and has pledged about US\$2.5 million to support a new partnership with the Chinese Diabetes Society (CDS) and European Foundation for the Study of Diabetes (EFSD). The new Shanghai facility, due to open in the second half of 2011, will focus on the discovery and development of antidiabetics with novel mechanisms of action, along with treatments that target co-morbid conditions such as cardiovascular disease and obesity.

The aim is to discover therapies that target the molecular basis of diabetes in Chinese and other Asian populations. In parallel, Lilly aims to work in partnership with the CDS and EFSD to promote collaborative diabetes research by Chinese and European academic organizations.

The Shanghai diabetes center will employ about 100 scientists, headed by international diabetes expert Bei Betty Zhang, Ph.D., who acts as VP of research for Lilly Research Laboratories in China.

"Given key differences in the molecular basis of diabetes in Chinese and other Asian populations, a major focus at this center will be on discovering therapies that target critical aspects of the disease," remarked David Moller, M.D., VP of endocrine and cardiovascular research and clinical investigation at Lilly.

"By establishing a diabetes research center in China, Lilly will be better able to discover medicines that are well suited to the particular needs of patients with diabetes in China," added Tapiero.

Alliance Boots eyes more deals in China as Britain lures Chinese investments

British Prime Minister David Cameron visited China this month seeking to expand business ties with the country. He was accompanied by the largest ever British official delegation comprising four Cabinet ministers and about 50 business leaders from sectors including pharmaceuticals.

Stefano Pessina, Executive Chairman of Alliance Boots, was among the 50 business leaders in the visiting British delegation to explore more potential opportunities in China. It is reported that Alliance Boots is currently evaluating several leading Chinese retail pharmacy chains for potential acquisition opportunities. Pessina was expected to hold meetings with potential acquisition candidates in Beijing and Shanghai.

Later it was reported by the Chinese media that Alliance Boots became the latest contender for reorganization of Nanjing Pharmaceutical Group, the fourth largest pharmaceutical

distributor in the country.

In 2007, Alliance BMP Ltd., a joint venture of Alliance Boots and BMP Sunstone, acquired a 50% stake in Guangzhou Pharmaceuticals Corporation (GPC), the fifth largest pharmaceutical distributor in China. BMP Sunstone sold its 20% ownership stake in Alliance BMP to Alliance Boots in 2009, thus making Alliance Boots the sole owner of the 50% stake in GPC. -

Last year, China was Britain's third-largest source of imports and ninth-largest export market. Cameron said he hopes to see annual bilateral trade double by 2015 to more than US\$100 billion, including US\$30 billion per year in British exports.

Meanwhile, three ongoing inward investments from China in the pharmaceutical sector were highlighted during Cameron's visit:

- NewSummit Biopharma will establish a China Biopharma Investment Center in the UK with UK partners. They have set aside GBP 5 million as a first step in a larger UK investment program to enable them as a gateway for Chinese bio R&D projects to and from Europe.
- Xiangxue Pharmaceutical has announced that they are expanding their UK activities and will establish their own R&D center in Cambridge by the end of 2010.
- Fosun Pharma has started recruiting for its UK office and is now going through the registration process to set up its UK company. It also plans to use its London base to look for opportunities in the UK's capital markets.

Merck aims to boost emerging market sales to 25% by 2013

Merck & Co. aims to generate a guarter of annual revenue from emerging markets by 2013 as surging economic growth spurs disease diagnosis and demand for treatments, according to Ramesh Subrahmanian, the company's president of Asia- Pacific. Merck gets 18% of its sales from emerging markets at present.

Merck is currently ranked fifth in emerging markets but it hopes to become No.1 or 2 in seven key countries including China, India, South Korea, Russia, Brazil, Mexico and Turkey within the next five to seven years, Subrahmanian said in an interview in Singapore on November 9.

"The reality is that we are playing catch-up," Subrahmanian said. "We really have guite a lot of work to do to be able to not only keep up with the very fast growth that's happening in these markets in general, but to be able to grow our market share."

Merck expects to outpace market growth in Asia-Pacific with sales of new drugs including Januvia, which has become the topselling diabetes pill in the region since it was introduced in 2007, Subrahmanian said. Older treatments such as the cholesterol drug Zocor, which lost patent protection in the U.S. in 2006, are seeing sales grow in Asia, he said.

The U.S. drugmaker also expects to benefit from sales of contraception and fertility treatments it gained through its US\$49. 6 billion acquisition of Schering-Plough Corp. last November, Subrahmanian said.

BMS, Simcere enter strategic partnership to co-develop cancer drug candidate

Bristol-Myers Squibb and Simcere Pharmaceutical Group announced on November 3 a strategic partnership to co-develop BMS-817378, a preclinical small molecule MET/VEGFR-2 inhibitor.

The two companies said the arrangement represents a creative approach to accelerate a preclinical oncology compound to clinical proof-of-concept by leveraging the complementary strengths of a premier Chinese pharmaceutical company and a global pharmaceutical company. This partnership establishes a novel development stage relationship for Bristol-Myers Squibb with a Chinese company, and a novel partnership approach for Bristol-Myers Squibb to leverage its early stage pipeline in support of its BioPharma strategy.

Under the terms of the agreement, Simcere receives exclusive rights to develop and commercialize BMS-817378 in China while Bristol-Myers Squibb retains exclusive rights in all other markets. The parties will together determine the strategic development plan, which will initially be performed by Simcere. Financial terms were not disclosed.

GSK, J&J led discussions on growth opportunities in China's OTC market

CHINATRIALS 2010, the largest clinical development-focused event in China and North Asia, took place in Beijing between November 7 and 9.

Aside from the event's traditional focus on all aspects of clinical development for new drugs, a panel discussion, "What are the opportunities for growth in the China's OTC market", stood out with an extraordinary theme. The panel was of particular interest to those who are keen on finding the right formula for success in the intensively competitive Chinese OTC market, which just took over Japan last year as the second largest in the world.

The final panel discussion was chaired by Stan Lech, VP of Venture Group and Strategic Relationships at GSK Consumer Healthcare, and he was joined by other MNC executives including Qing Li, Director of Global Medical Affairs with J&J; Sandy Furey, VP of Pfizer Consumer Healthcare; Ding Ming, Senior Director of CHC Medicine with Boehringer Ingelheim; and Yan-Yan Starkey, Medical Director-Global Medical Affairs at GSK Consumer Healthcare.

Earlier, Sandy Furey presented on "Rx-to-OTC Switch Strategies" while Yan-Yan Starkey talked about "Creating a World-Class Innovative Culture to Drive Consumer Healthcare Business Growth" at the event.

The panel sought to explore contemporary trends and growth opportunities in the Chinese OTC market and provide insights to relevant regulatory processes, consumer patterns, branding strategies and key challenges.

A number of mega-trends and critical issues were spotlighted at the discussion as follows.

GSK executives Stan Lech and Yan-Yan Starkey believe that the changing Chinese population trend and structure will lead to elevated role of OTC drugs and consumer healthcare products. Currently the Chinese consumers are more oriented towards OTC products for acute conditions and symptomatic treatment, which may change over a period of three to five years with a shift to those for chronic diseases, asymmetric treatment such as prevention, nutritional and quality life improvement etc. The change can be facilitated and expedited through pharma industrysponsored education of Chinese consumers in association with the Chinese government.

It is interesting to observe that panelists showed strong interest in the role and potential prospects of traditional Chinese medicines (TCMs) in China's self-medication sector. The international interests in TCMs were further underlined by Pfizer executive Sandy Furey who stressed the conceptual similarities between the TCM and the rising field of personalized medicine in Western medicine.

J&J medical director Qing Li suggested that TCMs currently represent about 45% of the Chinese OTC sales and the figure can reach as high as 60% when TCM health supplements are taken into account.

Despite the potential of TCMs, executives commonly called for improved regulation and safety of such products in China. Meanwhile, the international prospects and regulation of TCMs also aroused substantial enthusiasm at the panel.

On a different front, there were complaints and discussions about the slow approval process for OTC drugs in China despite various past attempts by the SFDA to improve the situation. One other challenging issue is about the Chinese process of Rx-to-OTC switches which has stalled again recently due to various legal and regulatory implications.

The panel also spent considerable time discussing about the realities and challenges faced by multinational pharmaceutical companies in China for OTC branding in the context of consumer perception of TCMs vs. Western medicines, generics vs. branded products, direct-to-consumer (DTC) advertising and excessive brand name and package regulation (SFDA Order #24 which requires highlight of generic drug names and restricts brand exposure).

Stan Lech and Yan-Yan Starkey concluded the session by highlighting key challenges and hurdles faced by multinational pharma companies in the Chinese OTC marketplace which include: 1) slow and complicated regulatory process for OTC products; 2) regulatory hurdles and issues over OTC branding; and 3) the challenge to balance competitive generic product pricing and high quality and high technology innovation products and standards development by multinational pharma companies.

Allergan eyes opportunities for cosmetics and glaucoma drugs in China and Asia

Allergan, a global leader for ophthalmological products, expects Asia's contribution to its global sales to grow sharply over the next decade.

Cosmetic products provide an especially good opportunity, Ian Bell, corporate vice president and president for Allergan in the Asia Pacific, said in an interview on November 10.

"Our (Asia's) contribution of the global sales will virtually triple over the next eight to 10 years. That tells you that it is the fastest growing part of the world for us," Bell said.

Bell would not give Asia's present share of the company's global sales, but said the U.S. market made up 63% of total sales volume.

Best known for its Botox wrinkle smoother, Allergan also makes breast implants and glaucoma drugs as well as the stomachsqueezing Lap-Band.

Allergan successfully negotiated with GlaxoSmithKline for the return of rights to market wrinkle treatment Botox in China and Japan for aesthetic purposes, Bell said. Glaxo retains the right to develop and market Botox for therapeutic purposes in both countries.

"We signed the deal at the end of 2009 and we have just started promoting the products for cosmetic use in China and Japan," he stated. "What we are looking to do is bring in more innovative products," he added. "We want to bring them to market in the next few years and there are trials in China to do that."

A clinical trial is under way in China to test the efficacy of Juvederm, an injectable gel to fill in lines in the lower half of the face. It competes with Medicis Pharmaceutical Corp's Restylane. "In Asia, we see cosmetics as being the bigger opportunity," Bell commented.

Bell said Allergan is conducting clinical trials in China to get some of its glaucoma products approved for distribution. Allergan makes three glaucoma drug products, Alphagan, Combigan and Lumigan.

"The majority of our trials in Asia we are playing catch up (with) products that have been approved around the world for treating glaucoma. We have trials going on in China to get those products approved," Bell said.

CMA and Merck Serono co-launch infertility website

Close to 40 million people in China are currently suffering from infertility and the number is growing at a very fast pace as a result of heavy workload, stress, environmental pollution or unhealthy lifestyles faced by many in the country, according to Huang Hefeng, director of the Zhejiang Reproductive Medical Center, at the launch of the website www.fertility.com.cn.

The website was launched by the Chinese Medical Association and sponsored by Swiss pharmaceutical company Merck Serono.

Biocon eyes alternatives for Insugen after its China deal with Bayer terminates

With the 2006 licensing deal between Biocon and Bayer HealthCare for the exclusive marketing and trademark rights for recombinant human insulin (Insugen) in China no longer operational, the Indian drug major is believed to be working on alternative strategies for the Chinese market.

The deal with Biocon covered three formulations of insulin: Fastacting (R), intermediate-acting (N), and mixed-acting, in both vials and cartridges. Such exclusive deals usually have a life-span of 10 years. Biocon itself had anticipated Insugen's launch in China by 2008.

However, Indian industry experts recently suggested that the deal may have been terminated by mutual consent sometime ago. While Biocon could not be reached for comments on the development, Annette Wiedenbach, Head of Global Media Relations & Issues Management, Bayer Schering Pharma AG said, "the deal with Biocon is not operational anymore. We can't give any further details."

An analyst with a foreign brokerage, on condition of anonymity, said: "Market approvals in China could take 3-4 years. We cannot say whether the drug has been approved in China or Bayer opted out because of the delay in getting product registration. It could be that Biocon is partnering with some other local company in China because they can't afford to lose that market."

Earlier in September, Bayer Healthcare launched SciLin, a human recombinant insulin product exclusively licensed from Poland's Biotin, in China.

Biocon and Pfizer have recently entered into a strategic global agreement for the worldwide commercialization of Biocon's biosimilar versions of Insulin and Insulin analog products.

Evotec licenses China rights of insomnia drug to Zhejiang Jingxin Pharma

Evotec AG, a drug discovery and development company, has entered into a license and collaboration agreement with Zhejiang Jingxin Pharmaceutical Co., Ltd, or Jingxin Pharma, for EVT 201, a potential treatment for insomnia.

The agreement grants Jingxin Pharma exclusive rights to develop and market the drug candidate in China. In return, Evotec will receive a small upfront payment, together with commercial milestones and rovalties, the company said.

Jingxin Pharma will initiate clinical trials with EVT 201 in China in 2011. All development costs will be borne by Jingxin Pharma. Evotec will have the right to reference clinical data produced by Jingxin Pharma to support potential further development of EVT 201 in other territories.

EVT 201 is a GABAA receptor partial positive allosteric modulator. Evotec has previously carried out two Phase II trials with the drug. It says the results show that treatment with EVT 201 significantly improves sleep onset and maintenance measures.

Despite the positive Phase II data, Evotec had put further development of EVT 201 on hold until it could find a partner to share the financial commitment.

Fibrocell forms JV with Hefei Meifu Biotech for personalized cancer therapy

Fibrocell Science, a US-based biotech company is establishing a joint venture with China's Hefei Meifu Bio-Tech for developing and marketing autologous fibroblast therapies in Asia, excluding Japan. The JV will be named Fibrocell Science Asia Co. Ltd.

Hefei Meifu is a pharmaceutical company specializing in anticancer intermediates, APIs and generic drugs.

Fibroblast Therapy is an investigational autologous cell therapy. In the Fibrocell Science patented process, a patient's own natural fibroblasts are extracted, multiplied and re-injected as personalized therapy.

Under the terms of the agreement, Fibrocell will provide access to its intellectual property, clinical data and manufacturing processes. Meifu will be responsible for all costs associated with construction and operation of a manufacturing facility in Hefei and commercialization, as well as all ongoing operational, research and development expenses.

Mundipharma to market Horizon's Lodotra in China and other AP markets

Horizon Pharma, Inc., a biopharmaceutical company developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases, announced on November 5 that its Swiss subsidiary had entered into exclusive distribution and supply agreements with Mundipharma International for commercialization of LODOTRA, programmed-release formulation of low-dose prednisone, in Asia Pacific markets including China, Hong Kong and Taiwan.

LODOTRA is a proprietary programmed-release formulation of low-dose prednisone and has received regulatory approval in Europe for reduction in morning stiffness associated with rheumatoid arthritis (RA).

The company has completed a Phase III trial for LODOTRA in

the United States for the treatment of the signs and symptoms of RA. The product is also being investigated for the treatment of severe nocturnal asthma and polymyalgia rheumatica.

SOBI to distribute Dongbao's anemia medication in Europe

Swedish Orphan Biovitrum (SOBI) and Dongbao Group announced on November 3 that Dongbao, through its subsidiary Rechon Life Science Group (Rechon), had granted Swedish Orphan Biovitrum the distribution rights to Iron Sucrose Rechon in geographical Europe.

Under the agreement, SOBI will pay to Rechon a regulatory approval milestone of EUR1.2 million. In addition, SOBI will pay a transfer price and a royalty on net sales to Rechon Life Science.

Iron Sucrose Rechon is an intravenous formulation of iron, used for anemia treatment. It is in registrational phase with Sweden as rapporteur country. Approval is expected by year end or early 2011, and a mutual recognition process in Europe would be initiated immediately after an approval.

This agreement is the first manifestation of the strategic Commercial Alliance that the parties announced in July, 2010. In the alliance, Sobi will be the marketing and sales partner of choice for Dongbao's pipeline of products in Europe, and Dongbao will be the marketing and sales partner for selected Sobi's products in China.

Service Provider News

Wuxi PharmaTech gains GLP for its Suzhou toxicology facility

WuXi PharmaTech announced on November 8 that it had been awarded a Certificate of Good Laboratory Practice (GLP) compliance from the SFDA for its toxicology facility in Suzhou.

The certification covers single-dose and multiple-dose toxicology studies in both rodents and non-rodents, GeneTox studies (Ames, micronucleus, and chromosome aberration), and toxicokinetic studies. Receipt of this certification is necessary in order to perform toxicology studies to be filed in Investigational New Drug (IND) applications with the SFDA.

In September, WuXi announced that the Suzhou facility had received GLP certification from the Organization for Economic Cooperation and Development. WuXi's Suzhou facility is the only toxicology facility in China to have received certification from both the SFDA and OECD.

Tigermed to manage clinical trial and filing of D-Pharm's stroke drug candidate in China

D-Pharm, an Israeli specialty biopharmaceutical company that designs and develops innovative drugs for the treatment of the most devastating brain disorders, has selected Hangzhou Tigermed Consulting as the CRO to manage the regulatory filings and conduct the clinical trials of DP-b99, in China.

The agreement was signed together with Wanbang Biopharmaceuticals, as part of the D-Pharm - Wanbang codevelopment program for DP-b99 in China.

Discovered and developed by D-Pharm, DP-b99 is currently being tested in a pivotal Phase III multinational clinical study in ischemic stroke patients.

ChiMed division gets investment from Mitsui

Hutchison MediPharma, a subsidiary of China-based Chi-Med, has received US\$12.5 million via a private investment from Mitsui & Co to support the continued development of its pipeline of internally developed research and development programs.

Mitsui has invested US\$12.5 million in cash in return for new convertible Preference Shares giving Mitsui 12.2% of the enlarged share capital of Hutchison MediPharma.

Mitsui Global Investment Department GM Taro Inaba said Hutchison MediPharma is a unique combination of a highly productive integrated R&D platform, landmark strategic alliances with some of the leading multinational pharmaceutical companies and a first class leadership team.

Regulatory News

SFDA issues Guidelines for Ethical Review of Drug Clinical Trials

The SFDA issued a new regulation, *Guidelines for Ethical Review* of *Drug Clinical Trials*, on November 2 with effect immediately.

It is developed in accordance with relevant requirements in the "Provisions for Drug Registration", the "Quality Control Standards for Clinical Trial of Drugs" (GCP), the "Declaration of Helsinki" and CIOMS's "International Ethical Guidelines for Biomedical Research Involving Human Subjects".

The document seeks to streamline ethical evaluation practices by ethics committees in China. It provides that ethical committees must perform ethical evaluations independently, but adhere to government guidance and supervision. The rule also requires drug authorities to establish inspection and appraisal systems for ethical review of drug clinical trials.

The guidelines contains a total of nine chapters and 52 articles which provides general principles and set out rules for areas including organization and management of ethics committees, responsibilities of ethics committees, documentation and procedures for application and acceptance of ethical review, process of ethical review by ethical committees, the process of decision making and delivery for ethical review, post-approval surveillance and ethical review for clinical trial plan revisions, and documentation management by ethics committees.

This guidelines also contains three appendices which provide main contents of ethical review, a list of documents required for filing by ethics committees and a table of terminologies.

The new rule became effective on the date of its publication. For those ethics committees established before the issuance of this document, they should reorganize to meet requirements of the guidelines within one year and file with the State Food and Drug Administration as well as their respective local provincial food and drug administrations.

Full text of the new rule in Chinese can be downloaded from the SFDA website at the following address: *www.sda.gov.cn/WS01/CL0055/55613.html*.



SFDA issues lists of export-licensed drug and medical device manufacturers

In accordance with SFDA's "*Product Catalog for Drugs and Medical Devices under Export Supervision*" which became effective as of October 18, 2010, the SFDA announced a list of drug manufacturers and a list of medical device manufacturers which obtained licenses from the agency for export of products subject to the control of this Catalog.

Please download the two lists (in Chinese) from the SFDA website at: www.sda.gov.cn/WS01/CL0087/55735.html.

The SFDA issued the Catalog on October 18, 2008. The initial products contained in the Catalog include nine types of APIs and formulations as well as two types of medical devices.

Manufactures of the drug products in the catalog must possess "drug manufacture license", relevant product approvals and GMP certifications, according to the rules accompanying the product catalog. Export sales licenses must be obtained prior to their exports. Manufactures of the medical device products in the catalog must possess "medical device manufacture license" and relevant product approvals.

SFDA seeks comments on regulation for drug quality in medical institutions

The SFDA recently issued the draft of "*Rules for Supervision of Drug Quality in Medical Institutions*" again for public comments. The agency sought comments from provincial level drug administrations on the same draft regulation in July.

Full text of the regulation in Chinese can be obtained from the SFDA website at www.sda.gov.cn/WS01/CL0014/55221.html.

The proposed regulation represents the first attempt by the Chinese government to officially regulate drug quality in hospitals.

The regulation includes detailed provisions for purchase, storage, dispensing and formulation of drug products by medical institutions as well as relevant supervision mechanisms. It requires the medical institutions to terminate use of fake or substandard drugs immediately upon first knowledge. Additionally, the use of drug products with suspected quality problems should also be suspended and such cases should be reported to the local food and drug administrations.

Under the proposed regulation, medical institutions are banned from promoting or recommending drugs through medical advertisements, medical news, medical education programs or websites. They are also banned from selling hospital drug formulations through a variety of means including direct-mailing, voluntary medical services or trial usage.

Additionally, the new regulation prohibits the expanded use or sales of drugs under clinical trials. It also forbids involvement of hospital personnel in sales of drugs or hospital formulations.

Food and drug administrations are required by the proposed regulation to conduct routine inspections on the processes of medical institutions for drug purchase, storage, unpacking and formulation.



SFDA withdraws Sibutramine from the Chinese market

The SFDA issued an official notice on October 30 to terminate the production of Sibutramine bulk drug and formulations, as well as sales and clinical use of Sibutramine formulations. The decision was made following EMA and USFDA decisions to withdraw Abbott's Meridia (sibutramine) from European and U.S. markets and review of Chinese adverse drug reaction (ADR) data by the SFDA and its expert panels.

By March 2010, the National Drug ADR Monitoring Center under the SFDA received a total of 298 ADR reports for Sibutramine and these reports showed only minor side effects including dry mouth, constipation and insomnia.

Chongqing Taiji Group, the largest Chinese manufacturer and marketer of Sibutramine (under the brand name of Qu Mei), announced on October 29 it would recall all of its Sibutraminecontaining products from the Chinese market but said it had no plan for any consumer compensation. The annual sales of Qu Mei products are estimated to be around CNY 300 million.

Earlier, Abbott said it had already stopped sales of its Meridia in the country. The last import of Meridia by Abbott took place in June 2008 and all of the previously imported Meridia are reported to have been expired by January this year.

There are a total of 45 drug approvals for Sibutramine-containing drug products in China. All of these approvals are now withdrawn by the SFDA.

MOH to introduce rule for antibiotic use

The Ministry of Health is developing compulsory rules to control use of anti-infective drugs in order to curb widespread abuse of such drugs, according to Prof. Xiao Yonghong, head of MOH's national bacterial drug resistance monitoring network.

It is expected that the new rules will impose compulsory ceiling limits on the share of anti-infective drugs in total drug consumption of medical institutions.

Currently, 70% of hospital inpatients in China are on anti-infective medications, which is more than two times higher than the upper limit set by the WHO, Xiao said.

The 4th Joint ChP-USP International Symposium held in Hangzhou

As called for in the Memorandum of Understanding (MOU) between the Chinese Pharmacopeia Commission (ChP) and the United States Pharmacopeial Convention (USP), the 4th Joint ChP-USP International Symposium cosponsored by the ChP, the USP and the Zhejiang Food and Drug Administration was held in Hangzhou on October 21-22, 2010. Wu Zhen, Deputy Commissioner of the State Food and Drug Administration (SFDA), attended the symposium and delivered a speech.

Wu pointed out that the development of the global pharmaceutical industry needs enhanced international communication and cooperation in drug standards. Great efforts should be made to establish a mechanism for international pharmacopeia cooperation and coordination, to intensify the communication and cooperation in the aspect of drug standards and to hold regular international pharmacopeia symposiums, he said.

APIs/Bulk Drugs

Esteve Pharma forms API joint venture with Hangzhou Huadong Pharma

Esteve Quimica, a subsidiary of Spain's Esteve quimicofarmaceutico group, inaugurated its second new active pharmaceutical ingredient (API) facility in Shaoxing city, Zhejiang Province in joint venture with Yiwu Huavi Investment Group, a subsidiary of Hangzhou Huadong Pharmaceutical Group.

With 125 employees and an annual production capacity of 160 cubic meters, the plant has a building area of about 40,000 square meters on a premise of 80,000 square meters, making it the most important API manufacturing facility of Esteve in China. The new API facility called for an investment of EUR 40 million and its annual sales is expected to reach CNY 1.5 billion when the plant is in full operation.

The new plant is located around 200 km south of Shanghai in Paojiang Industrial Zone, Shaoxing city, Zhejiang Province. Its products will be mainly exported to established markets including the U.S., Europe and Japan. Additionally, the joint venture will also seek to supply the growing Chinese pharmaceutical market.

The initial entry into China by Esteve Quimica dates back to 2000, when the company established the first joint-venture with Yiwu Huayi Investment for intermediates and APIs in the town of Yiwu, about 300 km from Shanghai. The facility has a building area of 73,000 square meters, an annual production capacity of 270 cubic meters and 255 employees.

Pharma industry cooperation under discussion between leading Chinese and Indian trade groups

Indian Drug Manufacturers Association (IDMA) and Chinese Pharmaceutical Industry Association (CPIA) have finalized all the major clauses of cooperation between the two industry bodies as a prelude to formally signing a Memorandum of Understanding (MoU) at the exhibition venue of API China & Interphex China in Suzhou on November 9.

A delegation of IDMA led by its president, N R Munial and five others went to Suzhou for the purpose last week. The MoU is expected to be signed most probably in January next year.

The MoU is for a period of three years and will be jointly decided to renew the same after assessing the situation then. Talks for such an arrangement have been going on between these two industry bodies with the increasing trend of import of APIs, intermediates and other chemicals from China to India. A few Indian companies are also exporting some quantities of APIs and finished formulations to China.

Briefing about the MoU, Munjal said in Suzhou that as a part of first action of this initiative, IDMA will launch a website with regular uploading of Chinese laws relating to import & export, Indian drug regulations including latest notifications, FDI norms, etc. This is expected to help pharma companies, importers, exporters of both countries.

He said that apart from import and export of APIs and intermediates between the two countries, possibilities of industry collaboration in the form of joint ventures will also be explored by the associations as both the countries are strong global pharmaceutical players today. Some India's joint ventures with Aurobindo, Dishman and Dr.Reddy's are already operating successfully in China. At the same time there are no such ventures launched in India by the Chinese pharmaceutical companies as yet.



New report: pharma becomes more active in R&D in Asia-Pacific

In recent years, pharmaceutical companies have ramped up their clinical trial activity, patent challenges of brand name drugs and their development of new products in the Asia-Pacific region, according to report, *CMR International R&D Factbook*, released on November 2 by CMR International, a Thomson Reuters business.

"In 2002 53% of patients recruited into clinical trials globally were from North America - but by 2008 that figure was down to 32%," according to the report. "Asia Pacific, meanwhile, increased its share of clinical trial patients from 6% to 11%, while Europe showed marginal growth from 14% to 17%."

"U.S. and European pharmaceuticals are looking increasingly to place clinical work in Asian countries," said Hans Poulsen, head of life sciences consulting at Thomson Reuters. "It's a business decision. These economies are growing, people have more disposable income and they are spending more on health care, so the markets are growing," Poulsen added.

The report revealed "the number of new molecules in development by generic companies, particularly in India, reflects a strong inclination to invest in R&D," and "the number of patent challenges in the region indicates an increasingly aggressive approach to securing market share."

"The benefits to Asia Pacific in moving towards increased clinical trials and more drug development are clear: attracting more investment to the local pharma industry and earlier access to innovative medicines for the local population," Poulsen said, according to the press release. "It is not clear however, if this trend will be seen as an opportunity for collaboration, or an increase in competition for multinational companies," he added.

The information published in the Factbook is "based on primary sources covering major pharmaceutical companies which account for approximately 80% of the industry's global R&D expenditure," according to the press release.

Monitor Group: China to Become Life Science Powerhouse by 2020

Monitor Group, a global management consulting firm, released a new report, *China: the Life Sciences Leader of 2020*, finding that China is poised to become the global leader in life science discovery and innovation within the next decade.

At a time when the global life sciences and pharmaceutical industries are beset by major challenges, including patent cliffs, skyrocketing costs of drug approvals and failures in key trials for potentially landmark new drugs, China has developed a strategy of targeted government investments. Through a variety of national and regional programs, China is spending billions on a new health care "safety net", encouraging the growth of life science parks and startups, financing the development of a high-quality research infrastructure and luring back tens of thousands of Westerneducated Chinese researchers.

"In just a decade's time - a short-term horizon in the life sciences field - China will not only be a significant engine of innovation, but has the potential to create a new model for advanced drug discovery," said George Baeder, who runs Monitor's China life science practice from his office in Shanghai and co-authored the report. "Other industries have repeatedly failed to anticipate how quickly China can adapt and impact the global playing field." Baeder cautions that the pharmaceutical industry must now also pay attention.

Based on research and interviews with dozens of life science professionals in both the U.S. and China, the Monitor report finds that China's life sciences industry is today gathering a critical mass of highly-skilled talent, savvy and focused venture investors and growing government support as its market for drugs and medical devices escalates. China's domestic market is expected to overtake Japan and become the world's second drug market by 2015, and as global pharma firms are forced to slim down and cut research staffs, many now see China as a compelling destination to conduct cutting edge new research.

Among other findings, Monitor says that:

- At least 80,000 Western-trained PhDs in the life sciences have already returned to China to work in the industry or in academic institutes. The pace of repatriation of these highly-skilled scientists is likely to accelerate over the coming decade.
- China will unleash US\$124 billion between 2009 and 2012 alone to build new municipal as well as county-level hospitals as part of its broad-based health care reform.
- An exclusive Monitor survey of Chinese life science professionals now working in the United States finds that fully two-thirds contemplate either returning to China for good or becoming "sea turtles" - life science professionals who constantly circulate between China and the U.S. in pursuit of commercial and research opportunities. The report argues that such "sea turtles" and the "hybrid" firms they create will become important drivers of China's life sciences innovation as the biggest pharma firms are forced to specialize on core strengths and reduce head counts in areas where they have not succeeded in creating new therapies.

The report illustrates how key entrepreneurs, life science professionals and academias are developing innovative new models for pharmaceutical research and development in China, using Chinese-led clinical research organizations to fast-track their research in hopes of creating better drugs more rapidly.

The report also catalogues a series of risks and bottlenecks that could limit China's advance, however, including the ability of state regulators to encourage innovation while also ensuring that Chinese-made drugs are of the highest quality.



General Health

Vice Premier Li Kegiang pushes for steady healthcare reform progress

Li Keqiang, Vice Premier of China and Chairman of the State Council's Leaders Group for Deepening Reform of Pharmaceutical and Health Systems, chaired an official meeting of the Group on October 27 to reinforce the spirits of the fifth plenary session of the 17th Congress of the Chinese Community Party (CPC) which closed recently.

Li called for expedited and deepened healthcare reform, strengthened implementation of the five short-term tasks under the healthcare reform plan, steady progress of public hospital reform and establishment/perfection of the essential drug system.

The meeting reviewed various policies and documents relating to establishing/streamlining the essential drug purchase system, perfecting the compensation system for primary healthcare institutions, and encouraging/directing social capital in the development of the healthcare sector.

Li stressed the importance of government leadership in healthcare, further regulation of the hospital drug purchase tender system and adoption of multiple reform measures to ensure appropriate compensation and normal operation of primary medical institutions.

On the front of public hospital reform trials, Li stressed: 1) active exploration of effective means to separate government and institutions, public ownership and hospital management, medical institutions and drug sales, and for-profit and non-profit medical institutions; 2) establishment of a service division and mutual cooperation mechanism between public hospitals and primary healthcare facilities; 3) improving the internal management system of public hospitals to optimize patient-centered efficiency and strengthen regulation of healthcare practices; and 4) supporting market mechanisms in healthcare through encouraging social capital in healthcare provision to meet different levels of healthcare needs.

12th Five-Year Plan to emphasize primary healthcare

In a related development, China will focus on improving community healthcare services as its healthcare reforms gather pace in the next five years, said a recent CPC guideline document, Proposal for Formulating the 12th Five-Year Program for China's Economic and Social Development (2011-2015).

New health-care resources will be channeled to rural and urban communities, it said. China will encourage medical workers, especially general medical practitioners, to serve long terms in grassroots medical institutions with favorable policies, it added.

The government will further reform public hospitals so that larger hospitals in the cities can cooperate with grassroots medical institutions, it said. Private medical institutions will be encouraged to improve quality and efficiency of medical services through competition, and meeting the public's need for diverse medical services, the document said.

China will integrate different basic medical insurance programs

At the 5th Sino-European Social Security Roundtable Summit. Ying Weimin, Chinese Minister of Human Resources and Social Security, stated that China is working to integrate its different social security programs, which now cater for different groups of the Chinese population such as urban employees, urban residents and rural population, in the near future.

The plan will also cover integration of the urban employee basic medical insurance (BMI) program, the urban resident BMI program and the rural cooperative medical scheme.

The Chinese government has set it as an immediate priority to provide universal basic social security coverage to the entire Chinese population, Ying said. In addition, China will also raise the level of social security coverage to all gradually.

CHA: China's surveillance network for rational drug use in preliminary shape

China has established preliminarily a national network for surveillance of rational drug use covering 960 medical institutions in all Chinese provinces, autonomous regions and central municipalities, according to Hu Yin, Deputy Secretary General of the Chinese Hospital Association (CHA) at a recent conference for orientations of the National Formularies and surveillance of rational drug use.

The CHA is responsible for routine operations of the national level network for surveillance of rational drug use including data collection, compilation, summary, statistics and analysis related to drug usage and drug-related medical hazards, while provincial level governments are responsible for establishing and operating the provincial level networks.

The national network for surveillance of rational drug use is comprised of a number of subsystems including the clinical drug use surveillance sub-system, the prescription surveillance subsystem, the drug related medical hazard surveillance sub-system and individual major-disease surveillance sub-systems.

The existing 960 medical institutions covered by the network are mainly grade III hospitals which are supplemented by grade II hospitals. These medical institutions are at different levels including the national, provincial, municipal and district levels and include those affiliated to enterprises and the army. Information which needs to be submitted by these medical institutions to the network includes those covering clinical use of drugs, drug related medical hazards, prescriptions, first page of patient records and instructions, and drug therapies for major diseases.

On the basis of information collected by the network, different expert panels of the Committee for Rational Drug Use under the Ministry of Health will conduct classification, summarization, analysis and research, and subsequently submit their recommendations for relevant intervention measures or policies.

The provincial level networks of rational drug use are still in the process of being completed, according to Hu. It is planned that China will complete construction of its national network for rational drug use, which will cover all grade II or above medical institutions, before the end of 2012.

MOH launches new measures to fight rebound of commercial briberies in hospitals

There has been a rebound of commercial briberies in the process of hospital pharmaceutical sales in recent months, according to a senior official of the Ministry of Health (MOH).

In order to combat the situation, the MOH has introduced and reinforced a number of measures: 1) medical institutions are required to strengthen information management of drug and medical consumable sales data. Any prescription data collection/ analysis for commercial purposes (e.g. for calculating commissions or kickbacks) is strictly banned. Those who violate this rule will be severely punished with their department and hospital directors also held accountable; 2) the MOH will step up investigations and punishments of commercial bribery cases in medical institutions; 3) healthcare professionals who receive commercial bribes will be punished through disciplinary actions, dismissal and criminal prosecutions if applicable. Those physicians who are involved in serious commercial bribery cases will have their license suspended or withdrawn in accordance with the Licensed Physician Law: and 4) enterprises which are involved in commercial briberies will be banned from the relevant provincial level hospital drug purchase tenders for two years and have their violations recorded in relevant credit rating systems.

Shanxi adds 209 drugs to its essential drug list

Shanxi Provincial Health Department recently released its supplemental list to the National Essential Drug List (NEDL).

The new supplemental list contains 209 drugs including 132 chemical drugs and 77 formulated traditional Chinese medicines. All of the drugs on the list will be reimbursed by basic medical insurance programs as essential drugs at higher rates than nonessential drugs.

The list was developed by an expert panel of the province in accordance with drug consumption patterns and population health patterns in Shanxi province. It covers multiple disease areas and includes various leading antibiotics such as Ceftazidime, Cefotaxime and Azithromycin as well as cardiovascular drugs such as Felodipine.

Chongqing Drug Exchange begins member registration and operation

Detailed transaction rules of the Chongging Drug Exchange, a government-led third party online drug purchase transaction platform, were issued on October 20. At the same time, member registration initiated at the exchange and 133 common drug products were already listed for trading from October 25. These drug products were given entry prices on the basis of price investigations by the exchange of over 100 pharmaceutical enterprises. The exchange plans to list all non-essential drugs by the end of next year.

According to a recent official notice from the municipal government of Chongging, all public medical institutions in the city are required to purchase drug products, medical devices and relevant medical products through the exchange exclusively and all other purchase channels are banned.

Non-public medical institutions which are designated basic medical insurance facilities will also be required to purchase from the exchange in phases. Military hospitals, private medical institutions and clinics as well as retail pharmacies are encouraged to purchase from the exchange.

All pharmaceutical manufacturers, distributors and exclusive national agents of imported drugs must become members of the exchange in order to trade there. By October 20, over 600 pharmaceutical manufacturers and distributors had become members and 80% of them come from areas outside Chongging.

Local industry observers believe the new system of Chongging Drug Exchange will lead to an overhaul of the hospital drug purchase process in the city again and sharp price reductions (as much as 30%) are expected.

However, at least some executives are prepared to accept even a 30% price reduction because the rules of the exchange require payment by medical institutions within 60 days of order delivery. If 60-day payments can be secured, their companies will save substantial financial costs and gain healthy cash flow, they suggested.

Currently, many hospitals in Chongging hold back payments routinely and sometimes the settlements won't come for years.

MOH issues guidelines for colorectal cancer treatment

The Ministry of Health (MOH) issued the 2010 Edition of the "Guidelines for Colorectal Cancer Diagnosis and Treatment" on November 4. It is reported to be the first time the MOH issued such a guideline in oncology field.

The prevalence and death rate of colorectal cancers in China have been on the sharp rise in recent years with the medium age of such morbidity dropping to only 58 years of age, which is 12 to 18 years earlier than that in European and North American countries. As early screening of colorectal cancers has been weak, 60% to 70% of diagnosed Chinese colorectal cancer patients are already in mid- and late-stages.

The MOH is currently working hard to standardize oncology therapies in China and it recently established an expert committee for standardization of oncology therapies. The ministry is expected to issue more guidelines for diagnosis and treatment of common oncology diseases and implement these guidelines initially in selected trial sites including tumor hospitals, level III general hospitals and county hospitals. In addition, the MOH will establish a case registry of common oncology diseases and seek to improve quality control of oncology disease diagnosis and treatment in medical institutions.

CMA launches standard reference for clinical use of glucocorticoids

The Chinese Society of Internal Medicine, a branch of the Chinese Medical Association (CMA), launched a standard reference for clinical doctors, Rational Use of Glucocorticoids in Internal Medicine Diseases.

The reference material is the first publication of its kind in China which systematically teaches medical doctors about rational use of glucocorticoids. Because of the lack of such a standard reference and clear therapeutic guidance for glucocorticoids in the past, Chinese physicians have often been either overly conservative or aggressive in the prescription of such drugs, according to Prof. Zeng Xiaofeng with the Rheumatism and Immunity Department of Beijing Union Hospital.

The move is a part of the clinical education program for Chinese

physicians on the use of glucocorticoids drugs jointly initiated by the Chinese Society of Internal Medicine and Pfizer in 2007. The program seeks to train 30,000 clinical physicians in nine medical specialties nationwide. By the end of this year, the program will be expanded to 140 medium and small cities.

AIAP survey reveals high incidence of nasal allergies in Asia Pacific

Results from the landmark Allergies in Asia Pacific (AIAP) survey over adults and children of nine countries in the Asia Pacific (APAC) with nasal allergies or allergic rhinitis show that symptoms are severe enough to impair work performance and diminish quality of life. The large-scale AIAP survey, sponsored by global pharmaceutical company Nycomed, is the first of its kind to assess the extent to which bothersome nasal allergies impact mood, sleep, work productivity and ability to perform daily tasks.

Nasal allergies are among the most common chronic respiratory disorders globally with over 400 million people affected by allergic rhinitis worldwide. Incidence rates in Asia Pacific are estimated to be as high as 48% as societies become more urbanized and adopt urban lifestyles. Nearly two in five parents of children with nasal allergies say the discomfort their child experiences during an allergy attack is so severe that the child cannot tolerate it without relief. Overall, more than two out of five parents report that their child experiences runny nose everyday or most days in their worst months.

China's diabetes prevalence and medical expenditures soar

China has the highest number of diabetics in the world with an estimated 92.4 million sufferers, 61% of whom have yet to be diagnosed, experts warned on November 14.

People who go without being properly diagnosed are more likely to have blood glucose that is poorly controlled, which leaves them open to the risk of developing complications that affect their eyesight and kidneys, having a stroke or a limb amputated, experts said.

Those aged over 40, overweight or living in well-off urban areas are at a higher risk of developing diabetes, medical studies have shown. Overweight children are also susceptible to developing the disorder.

According to the latest study jointly conducted by the CDS and the International Diabetes Federation (IDF), 13% of the total medical expenditure in China, around US\$25 billion (S\$32 billion), is related to diabetes. The study is a follow-up to a study recently published in the New England Journal of Medicine which found that China had twice as many people with diabetes than previously estimated.

People with diabetes in China require three to four times more inpatient care, as well as outpatient and emergency room visits, than their healthy counterparts of the same age and sex, the study found.

Without intervention, "the cost of treating diabetes will rise rapidly in the next 10 to 20 years, as patients who have gone undiagnosed develop serious complications whose treatment will definitely cost more," Ji Linong, head of the Chinese Diabetes Society (CDS), said.

In emerging countries like China and India, phenomenal changes like rapid economic growth, new trends such as mass urbanization, different diets and increasingly sedentary lifestyles have all greatly increased the risk of developing diabetes.

Key Findings Of IDF-CDS Study

Approximately 5.000 people were interviewed between January 2008 and August 2010 in 12 sites for this nationally representative study. Early results from data based on 1,920 responses from 5 sites reveal the following key findings:

- CDS and IDF estimate that 13% of total medical expenditures in China are directly caused by diabetes: CNY 173.4 billion or US\$25 billion. People with diabetes in China report 3 to 4 times more in-patient care, out-patient visits, and emergency room visits than people without diabetes of the same age and sex.
- These numbers will increase rapidly over the next 10 to 20 years when approximately 50 million Chinese with undiagnosed diabetes enter medical care, and when they and the 50 million Chinese with diagnosed diabetes start developing preventable diabetes complications such as stroke, blindness and kidney disease.
- Health expenditures for people in China who have had diabetes for 10 or more years are 460% higher than for people who have had diabetes for 1 to 2 years.
- Urban Chinese with diabetes are so far well-protected from the financial impact of diabetes that often causes destitution in countries without health insurance systems. 89% of people with diabetes in the 5 Chinese cities studied have health insurance. Only 11% of their total household income is spent on medical care. However, they spend 9 times more than people of the same age and sex without diabetes. Persons who have had diabetes for more than 10 years spend 22% of their current household income for healthcare.
- Diabetes prevalence is skyrocketing in China. People are getting diabetes at a younger age. However, China has a window of opportunity to prevent an epidemic of serious diabetes complications, which will increase spending dramatically. Currently, fewer than 5% of Chinese people with diabetes have experienced stroke, heart attack and heart failure. Less than 5% report kidney disease, eye surgery, or problems with their feet or legs. Half the people interviewed use glucoselowering drugs but few use anti-hypertensives (16%), statins (1%), or aspirin (13%) which are inexpensive and highly effective and can together lower the risk of complications by 50% or more.

CDS releases survey of type II diabetes self-management by patients

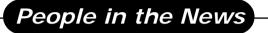
China Diabetes Society released recently its survey report for patient self-management of and various factors relating to type II diabetes.

The survey is sponsored by Novo Nordisk China and took more than three months to complete. It was participated by 5,961 type II diabetes patients with over one year history and 50 Chinese hospitals nationwide.

According to the survey report, the overall blood sugar control by Chinese type II diabetes patients is unsatisfactory with high prevalence of chronic complications and frequent incidence of hypoglycemia despite the fact that nearly 80% of such patients received some forms of related health education.

In addition, it is found that diabetes education in China is mainly focused on food intake, exercises and basic knowledge, while only 47% of type II diabetes patients were taught about diabetes complications and over 50% of such patients are not aware of the standards for glycosylated hemoglobin.

The survey found that one third of the type II diabetes patients in China who are on oral medications actually need to receive insulin therapies and they fail to follow physician suggestions due to various factors including inconvenience, fear for pain and addition, etc. Most of these patients are under the age of 50 and they are generally less motivated also for self-monitoring, regular checkups and health education.



Executive moves

PPD, Inc. announced on October 22 the appointment of *Dr. Andreas Tschirky* as leader of its newly acquired BioDuro. Dr. Tschirky spent the past 11 years with Roche, most recently serving as general manager of its R&D Center in China.

Aoxing Pharmaceutical announced on November 2 that *Hui* (*David*) *Shao* has resigned from his position as Chief Financial Officer to pursue other opportunities, effective on November 2010. *Guoan Zhang* has been appointed interim CFO, and will assume Mr. Shao's responsibilities. Mr. Zhang is currently the Controller for Aoxing Pharma's subsidiary, Hebei Aoxing Pharmaceutical.

ShangPharma Corporation announced on November 8 the appointment of **Benson Tsang** as a member of the Company's Board of Directors and Audit Committee, effective November 8, 2010. **Kevin Penghui Chen**, the Chief Financial Officer and Chief Operating Officer of ShangPharma, will resign as a member of the Audit Committee, but will remain as a member of the Board.

Former SFDA official tried in court for corruption

Wei Liang, a former division head level official with the SFDA, was on trial in Beijing's Dongcheng District People's Court recently for accepting bribes from 25 pharmaceutical and biological companies.

Wei was charged for accepting bribes totaling over CNY 1.47 million from 25 pharmaceutical and biological companies for his assistance in various applications relating to drug registration, regulatory amendments and licensing between 2006 and 2010 when he was division head level inspector with the Biological Products Division under the Drug Registration Department and the Production Supervision Division under the Drug Safety Supervision Department of the SFDA.

Wei pleaded guilty to these charges and therefore the court adopted an abbreviated procedure for his trial which lasted more than an hour. No judgments were issued at the court immediately after the trial.

It is reported that many of the 25 companies which bribed Wei were well-known companies. Two companies which were spotlighted in the trial are Shanghai Kehua Bio-engineering Co. Ltd., the largest medical diagnostics company in China, and Henan Puxin Bio-engineering Co. Ltd., a vaccine company originated from the Henan Provincial Center for Disease Control.

Wei was arrested in April this year. It was reported that a few other former officials, including Kong Fanzhong of SFDA's Drug Certification Administrative Center and Qi Zibo, Bai Jianshi and Chen Jiting of the National Institute for Control of Drugs and Biological Products were also detained or house-arrested around the same time in connection with Wei's case.

Other News

Upcoming events

Event: Wireless Healthcare Asia Summit 2011 *Dates*: March 24 - 25, 2011 *Venue*: TBD, Singapore *Weblink*: www.magenta-global.com.sg/whas11/index.php *Contact*: Patricia Chong *Tel*: +65 6391 2555, 6391 2555 *Email*: patricia.chong@magenta-global.com.sg

Event: World Pharma Manufacturing Summit 2011 *Dates*: March 14-16, 2011 *Venue*: TBD, Shanghai, China *Weblink*: www.wpms.org.cn *Contact*: Mr. Shia *Tel*: +86 21 6173 7668, 6173 7668 *Email*: ying.xia@hnzmedia.com

Event: OTC Pharma Asia 2011 *Dates*: January 17-18, 2011 *Venue*: TBD, Singapore *Weblink*: www.otcpharmaasia.com *Tel*: +65 6508 2401, 6508 2401

Event: The Safety Continuim In The Medical Product Life Cycle *Dates*: February 21 - 23, 2011 *Venue*: Sheraton Towers, Singapore *Weblink*: www.ibc-asia.com/drugsafety *Tel*: +65 6508 2401, 6508 2401 *Email*: register@ibcasia.com.sg

Event: Asia Pharma R&D Leaders 2011 *Dates*: March 24 - 25, 2011 *Venue*: InterContinental Pudong, Shanghai, China *Weblink*: www.aprdl.com *Contact*: Daniel Chen *Tel*: +86 21 3251 6046, 21 3251 6046 *Email*: daniel.chen@globaleaders.com



Feature Articles

Latest Updates on the Upcoming New Regulation for Drug Pricing

The National Development and Reform Commission (NDRC) is striving to release its new regulation for drug prices before the end of this year, according to Luo Yan, Deputy Director of Drug Price Division under the Price Department of the NDRC. At the same time, the NDRC is working on a price cut for essential drugs.

The proposed new regulation will seek to encourage drug innovation and pharmaceutical export, according to Luo.

According to a draft of the regulation, which was published for public comments in June, the NDRC can set the following prices individually: 1) Patented drugs and TCMs with state secretive recipes; 2) First-to-copy generic drugs; 3) Drugs with higher quality certified by the national drug regulatory authority or other designated institutions; 4) Formulated TCMs with higher quality which are certified by the national drug regulatory authority; 5) Drug products with national level awards from the State Council: and 6) Drugs produced in China but exported to international mainstream markets.

The bracket of "originator drugs" and individual pricing mechanism set to be eliminated?

Recent media reports quoting sources close to the NDRC suggest the agency has just completed the second draft of its Provisions for Drug Prices.

It is believed that the second draft contains neither the drug pricing bracket of and provisions for "originator drugs" (or "innovative category drugs") nor the individual pricing mechanism. Also, the NDRC is expected to gradually reduce the existing price gaps between originator drugs and their local generics during a fouryear transition period, according to a source who is a senior researcher with a large domestic pharmaceutical group. However, the source stressed that nothing is final before the agency releases the document.

The domestic pharmaceutical industry has been calling for the withdrawal of individual pricing mechanism for originator drugs for years and has won mainstream media support. Most recently the Chinese media has renewed its attacks on the large price gaps between off-patent originator drugs and their local generics.

But executives of multinational pharma companies say that the domestic pharmaceutical companies are targeting at the wrong aim. Their Chinese peers should seek to increase their prices (so as to ensure quality and boost innovation) rather than dragging the prices of foreign drug products down with their own, MNC executives told Pharma China.

Meanwhile, RDPAC, the industry association of research-based multinational pharma companies, has launched multiple media events recently to promote public awareness of drug quality and its correlations with drug pricing in order to generate support to a system of quality-based differentiated drug pricing.

RDPAC and its members submitted a response to the NDRC when the first draft of the Provisions for Drug Prices was released for public comments in April/May. The association also contracted Ernst Young to conduct a drug quality study which was recently concluded.

An RDPAC official, who is responsible for media relations, recently told Chinese reporters that he could not comment on the second draft of the Provisions for Drug Prices because he had not seen the document yet. But he expressed faith in that "the NDRC should be able to develop a pricing scheme under which interests of all stakeholders are taken into account and drug safety is secured."

Drug price manipulations through dosage form changes to be addressed in the new regulation

In a separate development, the head of the Drug Price Evaluation Center under the NDRC recently told participants of a pharmaceutical industry event that the upcoming drug pricing reform will target unreasonable drug price hikes in the drug distribution process.

The agency will center its efforts on preventing price hikes by pharmaceutical companies through changing dosage forms and/ or package sizes of their products, said the official. Such practices are reported to be widely adopted by pharmaceutical manufacturers and distributors to avoid government price surveillance and regulation.

NDRC will address this loophole with its new Provisions for Drug Prices under which rules for comparative pricing of different dosage forms and package sizes (for the same drug) will be introduced, according to the official.



Email: info@pharmachinaonline.com

Leading Drugs by Hospital Consumption in Six Major Chinese Cities in 2009

According to data from the Yangtze River Vicinity Hospital Drug Information Network, the hospital drug consumption in Shanghai, Hangzhou, Nanjing, Wuhan, Chengdu and Chongqing grew 21. 31%, 22.78%, 25.39%, 19.92%, 28.59% and 26.05% (year on year) respectively in 2009.

Anti-infectives is the largest therapeutic category in all six cities with market shares in Shanghai, Hangzhou, Nanjing, Wuhan,

2009	2008	Product Name	Sales	Share (%)	+/- (%)
Rank	Rank		(CNY Mln)		
1	4	Sodium Chloride IV solution	254.73	1.62	+38.22
2	1	Cefuroxime	250.29	1.59	+4.55
3	3	Thymic Peptide	248.91	1.58	+40.87
4	2	Omeprazole	238.57	1.51	+13.78
5	6	Cefotiam	215.91	1.37	+35.92
6	8	Ambroxol	174.03	1.10	+22.73
7	7	Ginko preparations	165.33	1.05	+1.36
8	5	Levo-ofloxacin	163.29	1.04	-4.56
9	9	Human Albumin	160.33	1.02	+22.95
10	14	Docetaxol	153.98	0.98	+41.88

Leading ten drugs by sales in 105 Shanghai representative hospitals 2009

Source: Yangtze River Vicinity Hospital Drug Information Network

Leading	Leading ten drugs by sales in 24 Hangzhou representative hospitals 2009					
2009	2008	Product Name	Sales (CNY MIn)			
Rank	Rank					
1	1	Thymic Peptide	110.72			
2	4	Omeprazole	89.50			
3	2	Human Albumin	80.71			
4	3	Pantoprazole	95.31			
5	5	Cefminox Sodium	63.69			
6	7	Sodium Chloride IV solution	62.68			
7	9	Levo-ofloxacin	57.52			
8	6	Cefotiam	56.80			
9	8	Ganglioside	56.57			
10	12	Oxaliplatin	56.37			

Source: Yangtze River Vicinity Hospital Drug Information Network

Less d'une des se deux de la		N		h it-l- 2000
Leading ten drugs b	y sales in 23	inanjing re	presentative	nospitais 2009

2009	2008	Product Name	Sales (CNY MIn)
Rank	Rank		
1	2	Omeprazole	80.10
2	3	Cefoperazone/Tapazole	80.08
3	1	Sodium Chloride IV solution	74.55
		Human Albumin	
4	9	Paclitaxel	49.75
5	4	Cefotiam	49.57
6	8	Docetaxel	44.55
7	10	Thymic Peptide	41.92
8	7	Levo-ofloxacin	40.08
9	6	Cefpiramide	38.49
10	15	Prostaglandin E1	37.88

Source: Yangtze River Vicinity Hospital Drug Information Network



Chengdu and Chongqing to be 21.35%, 25.40%, 27.21%, 32.16%, 26.85% and 28.69% respectively in 2009.

Oncology drug sales rose sharply in Shanghai, Hangzhou, Nanjing, Wuhan, Chengdu and Chongqing with growth rates of 25.61%, 30.09%, 23.79%, 21.60%, 32.80% and 37.65% respectively last year.

The following tables show the leading ten drugs by sales in these cities last year:

Leading ten drugs by sales in 27 Wuhan representative hospitals 2009

2009	2008	Product Name	Sales (CNY MIn)	
Rank	Rank			
1	3	Cefodizime	83.61	
2	2	Cefmandole	80.01	
3	1	Cefotiam	78.41	
4	4	Cefmenoxime	64.21	
5	6	Thymic Peptide	53.01	
6	8	Omeprazole	48.58	
7	11	Sodium Chloride IV solution	44.78	
8	13	Ceftezole	44.09	
9	10	Ganglioside	40.13	
10	15	Co-enzyme	37.99	
Courses Manathan Diversity (Incomited David Information Network)				

Source: Yangtze River Vicinity Hospital Drug Information Network

2009	2008	Product Name Sales (CNY Min)			
Rank	Rank				
1	1	Sodium Chloride IV solution	52.90		
2	2	Omeprazole	46.56		
3	5	Thymic Peptide Human Albumin	31.60		
4	23	Cefmtazole	30.21		
5	21	Cefoperazone/Tapazole	28.54		
6	50	Piperacillin/Sulbactam	28.46		
7	11	Piperacillin/Tapazole	27.84		
8	4	Glucose IV solution	26.99		
9	16	Cefathiamidine	25.44		
10	12	Cefminox Sodium	24.31		
Source	Vanatz	e River Vicinity Hospital Drug Inform	ation Network		

Leading ten drugs by sales in 17 Changdu representative bosnitals 2009

Source: Yangtze River Vicinity Hospital Drug Information Network

Leading ten drugs b	v sales in 29 Chongging	representative hospitals 2009

2009	2008	Product Name	Sales (CNY Mln)
Rank	Rank		
1	1	Sodium Chloride IV solution	68.53
2	2	Cefminox Sodium	62.94
3	3	Thymic Peptide	58.96
4	7	Aztreonam	46.44
5	9	Ganglioside	45.61
6	4	Cefepime	40.29
7	8	Omeprazole	39.76
8	5	Glucose IV solution	38.73
9	11	Mezlocillin/Sulbactam	37.71
10	6	Cefmenoxime	37.71

Source: Yangtze River Vicinity Hospital Drug Information Network



The 2009 China Pharmaceutical Rich List from Hurun Report

Landscape Reshaped by IPOs and Aggressive Valuations

Rupert Hoogewerf's Hurun Report recently released its 2009 China Pharmaceutical Rich List with Li Li & family of Shenzhen Hepalink topping the list with a The following table provides some details on the fortunes of the top 30 pharmaceutical entrepreneurs on the Hurun Report's 2009 China Pharmaceutical Rich List.

fortune of CNY 40 billion (approx US\$6 billion). He is trailed by Li Jinyuan of Tiens Group, the richest pharma entrepreneur in 2007 and 2008, a personal fortune of CNY 20. 0 billion (up from CNY 17.5 billion last year).

Li Li & family caused a sensation when drug maker Shenzhen Hepalink Pharmaceutical went public in May, propeling him straight into the second place on Hurun's 2009 China Rich List. Li Li, 46 years, his wife Li Tan and her cousin Shan Yu founded the business in 1998 and together they own a 75.6% stake. Hepalink makes heparin, a blood thinner purified from pig intestines, which is used to prevent blood clots. This is the first time a pharmaceutical tycoon made it into the Top Five of Hurun's China Rich List underlining the rise of local drug companies.

Rupert Hoogewerf said the rapid pharmaceutical market growth bumped the number of pharmaceutical tycoons with personal fortune over CNY 10 billion to six this year. By comparison, only Li Jinyuan who topped the China Pharmaceutical Rich List 2008 had a personal fortune above this landmark figure. All of the 50 pharmaceutical entrepreneurs on the list have at least personal fortune of CNY 1.5 billion.

The combined personal fortunes of the top 30 pharmaceutical entrepreneurs on the list grew 76% and 157% respectively compared with those in 2008 and

Rank	Fortune (CNY bn)	Name	Company	Industry
1	40.0	Li Li & Family	Shenzhen Hepalink	API
2	20.0	Li Jinyuan	Tiens Group	Health foods
3	12.7	Ye Chenghai Family	Salubris Pharma	Pharma
4	11.0	Xiu Laigui	Xiuzheng Pharma	TCM/API/pharma
5	10.6	Li Zhenjiang Family	Shineway Pharma	TCM/pharma
6	10.4	An Kang Family	Hualan Bio	Biopharma
7	8.5	Zhu Baoguo Family	Joincare Group	TCM/health foods
8	7.4	Sun Piaoyang	Hengrui Pharma	Biopharm/pharma
9	6.9	Zhao Buchang & son	Buchang Group	TCM/API/pharma
10	6.8	Ma Xingtian	Kangmei Pharma	TCM/pharma
11	6.6	Liu Gexin	Kelun Pharma	Pharma
12	5.9	Lei Jufang	Qizheng Tibetan Med	Tibetan medicine
13	5.7	Hu Bofan Bros	NHU Group	API/health food
14	5.2	Mr. & Mrs. Pu Zhongjie	Lepu Medical	Medical device
14	5.2	Xie Bing	China Biopharma	Biopharm/pharma
16	5.1	Chen Xueli	Weigao Group	Medical device
17	5.0	Chen Fazhu	Yunnan Baiyao	TCM
17	5.0	Mr. & Mrs. Zhu Jiman	Gloria Pharma	Pharma
19	4.8	Guo Jiaxue	Topsun Group	TCMs/API/Med.
20	4.7	Xu Jingren	Yangtze River Pharma	TCM/Pharma
21	4.6	Wu Guangming & son	Yuyue Group	Medical device
21	4.6	Zou Jieming	Sanjin Pharma	TCM
23	4.5	Jiang Wei & family	Guizhou Bailing	TCM
24	4.1	Zhang Huawei	Weigao Group	Medical Device
25	4.0	Guo Guangchang	Fosun Group	Pharma/biopharm medical device
25	4.0	Li yihai	Jiming Kexing Group	TCM/pharma
27	3.4	Yang Wenlong	Renhe Pharma	TCM/pharma/ health foods
28	3.2	Zhu Wenchen	Furen Pharma	API/pharma
29	2.9	Que Wenbin	Duyiwei Biopharm	TCM/TibetanMed
30	2.7	Chen Bang	Aier Ophthalmology	Medical service
30	2.7	Chen Jinxie	Yongjin Group	Pharma/TCM

2.7 Source: Hurun Report

30

2007, according to Rupert Hoogewerf. He believes the sharp growth is related to the fast-rising number of IPOs by Chinese pharmaceutical companies last year.

CON	China	Phar	mace	utical	Guide	2010
M	中	E	医	药	指	南

API/pharma

DiAo Group

Li Bogang