

In This Issue

NCPC and Jointown to form a pharma trading/distribution JV

The deal will facilitate NCPC's expansion into pharma distribution and help Jointown penetrate better in northern China. P13

Merck sets up R&D Asia HQ in BJ

Merck establishes its Asia R&D headquarters in Beijing as a part of its US\$1.5B China R&D investment commitment over the next five years. P15

AstraZeneca acquires Chinese generic drug company

AstraZeneca will buy Guangdong BeiKang Pharma, a generic injectable antibiotic producer, for an undisclosed amount. P15

Pfizer looks to expand R&D in China through local partnerships

Pfizer will expand its R&D team in China and is exploring possible collaborations with Chinese research outfits. P16

Cardinal Health China acquires Wuxi Xishan Medicine

Cardinal Health will buy Jiangsu Wuxi Xishan Medicine through setting up an 80%-Cardinal-owned JV. P16

BMS expand research partnership with Sincere to cardiovasculars

The companies agreed to co-develop BMS-795311, BMS's preclinical small molecule CETP inhibitor. P17

Boehringer Ingelheim to invest Euro 70M for manufacturing expansion in China P17

C O N T E N T S

Editorial

- Long term outlook remains positive for MNCs despite pricing pressures and uncertainties 2

News in Focus

- NDRC issues new rule for ex-manufacturer drug price survey 6
- NDRC issues "Rules for Differential and Relative Pricing of Drug Products" 7

The Market

- Chinese acute coronary syndrome drug market to top US\$448M by 2015 10
- MNC peers challenge the lead of Bayer's Glucobay 10
- RNCOS: Chinese drug market to grow 20% CAGR through 2014 10
- BCG and Deloitte: Chinese drug market to sustain strong but more modest growth 11
- New report predicts sustained double-digit Chinese pharma growth thru 2022 11

Industry News

- SMEI ranks top 100 Chinese retail pharmacy chains 2011 11
- China releases its 12th Five-Year Plan for Biotechnology Development 12
- MIIT to issue the 12th Five-Year Plan for the Chinese Pharma Industry 13
- Local company news 13
- Foreign company news 14
- Service provider news 18

Regulatory News

- SFDA releases its 2010 Annual Statistical Report 18
- SFDA issues Guidelines on Management of Phase I Clinical Trial of Drugs 18
- SFDA issues Guidance on Management of Laboratory for Drug Clinical Trial Biological Sample Analysis 19
- SFDA seeks additional comments for its drafted rule on DMF filing of APIs/IPIs 19
- State Council passes the National Drug Safety Plan (2011-2015) 20
- SFDA demands XiAn Janssen to take risk control actions on CAELYX and Velcade 21

- SFDA demands prosecution of pharma companies involved in making fake drugs 21
- Guangdong to revise prices of 99 Western medicines 21

Legal/IPR News

- Foreign companies have an upper hand in the Chinese biopharma patent landscape? 21
- Sihuan Bio sues Vitapharm for patent scam 22

API/Bulk Drugs News

- Huahai Pharmaceutical to raise CNY 1.3B for expansion 22
- Sinochem DSM builds a new semi-synthetic cephalosporin plant in Shandong 22

Product and R&D News

- TCM found to be more effective for female infertility than pharma options 22
- Sino-Danish researchers discover anti-cancer compounds from mushroom 22
- Two new pharma research institutions established in China 23

General Health

- State Council reaffirms healthcare reform direction with review of new documents 23
- MOH outlines cost containment measures 23
- BMI agency to take over essential drug purchase tendering in Shanghai 24
- CDS initiates clinical research of base insulin 24
- New study: Increased Western medicine practices at TCM hospitals in China 24
- Essential drugs to be traded in CDE 25
- China's HIV/AIDS-infected estimate 25

People in the News

- SFDA Deputy Commissioner prosecuted 25
- Chongqing's drug purchase tender official sentenced five years for corruption 25
- Recent official and executive moves 25

Other News 26, 27

Stop Press 29, 31

Feature Articles

- Review of Chinese Pharma Industry Performance in the First Three Quarters 28
- China's Healthcare Outlook in 2012 30
- Chinese Physicians Are More Digitally Savvy Than You Think 32

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: 13 distinguished industry leaders

US Head Office:

311 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 5885-7333 ext 0260
 Cell: 18601267831 e-mail: dxue@pharmaguys.com

Subscriptions (2011):

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
 311 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 re-
 trieval system, or transmitted in any form or by any other
 means, electronic, mechanical, photocopying, record-
 ing 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.

Editorial**Long term outlook remains positive for MNCs
despite pricing pressures and uncertainties**

James J. Shen

The winter in Beijing is chilling as usual. In the past, one could probably hope for some warmth from the heated Chinese economy and flamboyant Christmas decorations everywhere around downtown, but things seem to be a bit different this year.

I began my year-end fact-finding trip to China in early December and felt the subtle difference in the air soon after I arrived - it is probably to do with the falling level of anticipation, confidence and even enthusiasm of the Chinese as a result of the country's broad social-economic realities, coupled with the sense of powerlessness over the upcoming leadership changes and political wrestles, which stalls a lot of things before the 18th CPC Congress and creates certain anxieties over the country's future direction.

Economy cools as the government begins to switch gear

"The march of the Chinese dragon is relentless. However, it is not immune to the economic morass of its major trading partners and is experiencing a slowdown in growth rate that is more rapid than anticipated," said Zacks Investment Research in a recent article.

Yet for all its successes, there are several imbalances in China's model of a mixed economy, the article went on to suggest. The government's search for a Goldilocks economy - not too hot, not too cold - may have backfired somewhat. Latest statistics indicate that overall export growth was sharply lower on a month-over-month basis, although the composite growth rate at 15.9% was still respectable, partly on account of buoyancy in Latin American markets.

There are other telltale signs of a slowdown. The economy grew at 9.1% year over year in the third quarter, which represents the slowest growth rate in the past couple of years. Then, in November, the Purchasing Managers' Index touched 49, its lowest point since 2009. In fact, it was the first time in nearly three years that this measure went beneath the critical 50 level.

The Chinese government has reacted to the challenges, although it does not want to signal a sharp policy shift in the open. It has cut the cash reserve ratio to infuse liquidity and announced in low profile an initiative to pour CNY 10 trillion into seven so-called "strategic sectors" (including biopharmaceuticals) over the coming five years. Among other measures, a politburo member has asked local officials to enhance their social management skills in order to curb social unrest and labor strikes.

Better social management skills? I don't know how effective that is to abate instability, but hopefully it will at least help the Mandarins learn to negotiate and find consensus better in order to get us out of the current healthcare reform ditch which is hurting all stakeholders.

Besides, the government has also been busy with more five-year plans (FYPs) lately. In addition to the four pharmaceutical-related FYPs issued in the first half, one more was released recently for the development of the biotechnology sector and a few more are still on the way. While some U.S. officials recently expressed their admirations for the abilities of the Chinese government to plan ahead, I have not been so impressed with the growing number of such plans, many of which increasingly resemble documents in the "Great Leap Forward" era with hollow slogans, unsubstantiated growth quotas and idealistic goals. Nonetheless, these documents do offer considerable value for detecting government policy directions.

The good news is that many government programs and funding/investment schemes are increasingly open to foreign companies, so MNCs with substantial China presence can expect to receive some direct policy and financial support from the Chinese government.

Tough healthcare market realities despite optimistic outlook

My conversations with Chinese pharma executives, healthcare policy experts and government affair insiders during this trip have turned out to be rather demoralizing with rising frustrations over the present state of the Chinese pharmaceutical market and healthcare reform.

Most executives on the ground see challenges with organic growth in the short term and complain about the scarcity of desirable M&A targets. Restructuring of acquired local companies is very challenging as anticipated and I heard about headaches at Sanofi with integration of the newly acquired BMP Sunstone. Invariably, all are disappointed with the healthcare reform progress and direction from their own perspectives.

Crooks in the pharma industry are further complicating an already complex situation in China healthcare after some of them were caught by the Chinese media for manipulating prices of little-known drug products with suspicious regulatory and tender records. As if this is not enough, an industry whistleblower published a website in mid-December exposing ex-manufacturers of more than 10,000 drug products. These put significant pressure on the NDRC to slash drug prices further.

I have long predicted the rise of fake and counterfeit drug products, given the benign civil and criminal penalties for making them. By comparison, the legal risks in promoting and selling authentic drugs to hospitals could be much higher at times. In just a few months, the Chinese government seized CNY 2 billion worth of fake and counterfeit drugs in a recent campaign and the confession of a ring leader reveals that the fake drug business is "as profitable as narcotics, but not nearly as risky" and the favorite place for promotion of fake and counterfeit drugs is in fact pharmaceutical industry trade shows. Reportedly, the ring even hired a professional sales force and provided routine medical-related trainings to them to ensure "excellent customer service".

On the other hand, repeated price cuts and cost containment measures have hurt the pharma industry bottom line this year. The profit of the API, pharma formulation and biological product sub-sectors grew only 10%, 13% and 7% respectively in the first three quarters, but that of formulated TCMs and herbal crude drugs continued to surge 39% and 63% respectively indicating unsuccessful cost containment in these two areas.

State-owned, collective and foreign-invested pharmaceutical companies took the hardest hit from recent cost containment measures with -13%, -2% and +3% profit growth respectively in the period, while that of private, shareholding and other companies showed sharp profit growth at 46%, 28% and 33%.

However, the output value and sales growth of the API, pharma formulation, biological product sub-sectors continued to show steady growth rates between 23% and 29% in the first three quarters, while those were higher for formulated traditional Chinese medicines (TCMs) at 33% and 36% respectively. Meanwhile, herbal crude drugs experienced the sharpest sales growth of all at 53%.

Again, state-owned pharmaceutical companies and foreign-invested enterprises underperformed in the first three quarters with the lowest sales growth at 18% and 21%, while shareholding and other enterprises fared slightly better at 27% and 31%. Nonetheless, private and collective companies did much better with 43% and 35% revenue growth.

The industry performance this year shows a market trend of continuously rising demands at lower profit margins in the backdrop of intensified government cost containment. The poor

performance of state-owned and foreign-invested companies, despite government policy preference of such companies, was most likely a result of imbalanced regulatory and cost containment policy enforcements, a general lack of business flexibilities on the part of big pharma companies, superior maneuverability of smaller private enterprises and incompetence of the government to control irregular players.

On a positive note, at least the outlook for vaccines remains to be bright with good visibility. The Chinese vaccine market growth is going to be around 20% and its size will reach CNY 12 billion next year, according to estimates of Chinese investment research firm CI Consulting. The planned government investment into vaccine supply infrastructure, which totals CNY 9.4 billion, is expected to further stimulate growth of the sector.

A number of MNCs are already well positioned for the sector's opportunities and they are working to bypass various policy restrictions on foreign companies through partnerships with Chinese players. Novartis successfully completed the acquisition of Zhejiang Tianyuan Bio early this year, while GSK formed a joint venture with Neptune Interlong Bio which it eventually has acquired. Besides, MSD China entered into a strategic alliance with SinoPharm Group in July to co-market a number of therapeutic vaccines and they are reportedly exploring the idea of a joint venture together.

Pharma industry experts also continue to maintain long term positive view of the Chinese pharma market. A number of forecasts were released by well-established sources in December.

Boston Consulting Group estimates that the annual size of the Chinese drug market will grow to US\$85 billion in 2015, driven by rising demands from healthcare reform and faster growth of primary healthcare. The firm expects the primary medical institutions to contribute about one third of the Chinese drug market by then.

In the meantime, Deloitte published a new report, *The Next Phase: Opportunities in China's Pharmaceuticals Market*, which expects continued strong but modest growth for Chinese pharma between 2011 and 2015 at around 15%. The report predicts the CAGR of patented drug sales in China to sustain at 25% in the next five years.

A new report by Visiongain also forecasts sustained double-digit growth in the Chinese pharmaceutical market from 2011. Overall pharma revenues gained in China will rise to US\$116.8 billion in 2015, the report says. At the same time, a new study of RNCOS anticipates the pharmaceutical market in China to reach US\$87.2 Billion by 2014, growing at an impressive CAGR of around 20% during 2011-2014.

Finally, we have invited two pharma industry experts, Herman Schwiertert of VDS Healthcare and Jingyi of InterChina Consulting, to share their views over Chinese healthcare market outlook next year. In summary, they anticipate another 25% healthcare market growth in 2012 and expect that the OTC market and hospital sales of prescription drugs and medical devices will grow dramatically as more hospitals are constructed across China.

Healthcare reform in paradox

Talking to a few government affairs insiders on this latest China trip, my prior suspicion was confirmed that the politics of succession will most likely stall any major healthcare reform progress in the near future. Although the reform is now stagnant with many unsettled debates, it is unlikely new experiments or directions will be taken seriously at the national level before the new term of Chinese government falls into place.

Popular speculations predict Vice Premier Li Keqiang to succeed Premier Wen Jiabao after the CPC's 18th Congress next year. Li's academic training is in law and economics, which is a bit unusual compared with the overwhelming science and engineering background of the past and present Chinese leaders including Premier Wen. Some analysts believe this may make a difference as to how Li will lead, govern and make decisions.

Li has recently been seen as increasingly taking the frontline and the driver seat of the healthcare reform, while Wen seems to be less visible than before. Last month I talked about Li's high profile article on CPC ideology journal *Qiushi* reaffirming the current line of healthcare reform, and most recently Li chaired a full meeting of the State Council's Leaders Group for Deepening Pharmaceutical and Health System Reform laying out the direction for the next phase of healthcare reform.

As before, Li upheld the core reform principles of 1) healthcare as a public welfare item; 2) essential and universal coverage of the BMI system; and 3) restructuring healthcare mechanisms with emphasis on prevention, rural healthcare and co-existence of traditional Chinese and Western medicines. He said the objectives for the next phase of healthcare reform will move from "expanding coverage" to "raising quality" of the BMI system, from "strengthening" to "full development" of primary healthcare, from "conducting trials" to "full implementation" of the public hospital reform, and from "upgrading hardware" to "centering on service improvements" of the healthcare system.

While the political statement of the meeting repeats many well-known reform doctrines, I do pickup a few new signals including 1) prevention is raised to a new height; 2) raising quality of healthcare and BMI services is to become a new objective of reform; and 3) full implementation of the public hospital reform is now on the agenda.

I am a bit surprised with the State Council's push for full public hospital reform implementation at this point and time, as experiments of such reform has so far failed to offer any consensus over future direction. In fact, the entire healthcare reform is now stuck with the core public hospital reform task of "separating medicine from sales", without which all reform progress achieved so far is simply scratching the surface of China's healthcare trouble. On the other hand, failure of the local Chinese governments to substantiate adequate financial support to medical institutions makes the objective an unattainable empty promise. It is actually unfair for the central government to lay most of the healthcare reform funding burden on local governments which have limited tax income. Local government revenues have been further weakened after the central government put a lid on land sales to curb housing bubble which has served as the primary revenue source of local governments.

Under the circumstance, it is almost unrealistic to expect local governments, particularly those in less-developed areas, to come up with substantial funds to pay the bills of healthcare reform, especially the price of "separating medicine from drug sales". The only thing left to do, it seems, is to find face-saving ways to redefine the objective. In the words of the Ministry of Health, "separating medicine from sales" should mostly mean "reform of the BMI reimbursement system".

Other than that, the central government has been talking about raising medical fees and increased medical fee reimbursements by the BMI. They are likely to be pies in the sky also, as any meaningful medical fee will be objected by the public and, without sharp central government funding increase and BMI premium raise, the entire BMI funding at the present level is probably just a

tiny cookie to the expanded appetites of hospitals and physicians who have been more than well-fed with drug profits in the past two decades.

At a recent pharma industry summit, Zhu Youdi, a former senior official with the State Council's Research Center, blasted the Chinese physicians as "the biggest group of drug dealers in thousands of years of human history". Zhuang Yiqiang, Deputy Secretary General of the Chinese Hospital Association, quickly responded to defend his constituents. He blamed the government for not funding the hospitals sufficiently and said the medical institutions had been forced to survive on drug sales. "Hospital directors have no choice but to lead their physicians to make money, or they will be starved to death", he proclaimed without any guilt. Sun Zhigang, Vice Minister of NDRC in charge of healthcare reform, had to muddle through the tension with stereotypical Mandarin lines that "the government will increase fiscal subsidies and pay for raised medical fees, through BMI, before medicine can truly be separated from drugs sales". Well, I suggest that Mr. Sun should check with the Ministry of Finance before writing a check on behalf of the central government.

Despite the intensifying dog fights among stakeholders and unavoidable reform standstill, a notable event spotlighting at least a new healthcare reform development took place in Shanghai, where the BMI agency under the city's department of human resources and social security will take over governance of Shanghai's hospital drug purchase tender system from the city's health department. The move seeks to remove the conflict of interests of the health department, which oversees and operates public hospitals, in such tenders and to reflect the important role of the BMI agency as the public payer. This does indicate a new healthcare reform direction and may soon be replicated by other local governments. However, it is probably not good news to pharmaceutical companies as the BMI agency may be more motivated to contain costs as opposed to offering better quality healthcare.

NDRC under more pricing pressure as SFDA steps up regulation of drug registration and research

We spoke earlier about recent media exposure of price manipulations by some pharmaceutical companies and this has created new pressures on the NDRC to slash drug prices. Many analysts began to talk about another round of price cut, but I tend to expect such actions, if any, will unlikely be comprehensive and are going to be targeting at certain types of products only, such as selected TCMS.

The NDRC "responded" to public outrage recently with the release of two more drug pricing related regulations covering ex-manufacturer drug price surveys and differential/relative pricing of drug products. Although the two regulations have long been planned, releasing them now will at least reduce the heat on the agency somewhat.

While the earlier rule poses considerable impacts on NDRC's development of drug prices, the latter regulation has aroused more industry attention and panic. Many subscribers checked in with me about my observations, indicating a high level of anxiety among MNC executives and financial analysts. However, my take is that the regulation will have limited impacts on MNCs, as it is primarily targeted at price manipulation by irregular local players through changes of dosage forms, specifications and packaging. In fact, the rule could even benefit MNCs indirectly as it is likely to curtail a range of irregular competitive practices by some local players.

On the drug regulation front, the SFDA has been active in the past month releasing a number of new regulations including two

new clinical research rules, namely the *Guidelines on Management of Phase I Clinical Trial of Drugs* and the *Guidance on Management of Laboratory for Drug Clinical Trial Biological Sample Analysis*. In a related development, Deputy SFDA Commissioner Wu Zhen told a recent national conference on clinical trial quality control that China will initiate a classified management system for clinical research facilities starting with those conducting phase I trials. He stated that there are now 333 designated clinical research institutions in China and, among them, only those approved will be allowed to conduct phase I studies.

Notably, the agency also issued its second draft for "*Rules for Filing Regulation of Active Pharmaceutical Ingredients (APIs) and Inactive Pharmaceutical Ingredients (IPIs)*" and is now seeking additional public comments on it. The rule is the Chinese equivalent of the Drug Master File (DMF) system for APIs and IPIs in many Western markets. It is expected to streamline and strengthen SFDA's regulation of the full pharmaceutical manufacturing process starting from raw materials.

MNCs continue to raise its Chinese bet as government prepares more FYPs

The Ministry of Science and Technology came out with one more five-year plan, the *12th Five-Year Plan for Biotechnology Development*, in late November. The Plan seeks to boost development of the Chinese biotechnology sector with emphasis on biopharmaceuticals, bio-agriculture, bio-manufacturing, bio-energy and bio-environmental conservation. Focus areas within the biopharmaceutical subsector include technologies and products for major infectious diseases such as AIDS, viral hepatitis and tuberculosis; key technologies for clinical diagnosis, forecast and early warning (of healthcare trends), vaccines, and clinical emergency medicine; and R&D of new diagnostic reagents and vaccines which help reduce incidence and death rates of AIDS, viral hepatitis and tuberculosis.

Similarly, the *12th Five-Year Plan for the Chinese Pharmaceutical Industry Development (2011-2015)* will soon be released, according to the Ministry of Industry and Information Technology (MIIT). The Plan's key objectives include 20% average annual growth for pharmaceutical industry output value, 16% average annual growth for industrial value-added, strengthened drug innovation, increased industry consolidation, and improved international competitiveness in the plan period.

On the front of industry trends, there were few major developments with leading domestic players in the past month, except a couple of M&A moves by SinoPharm in southern China to prepare for war with dominant regional drug distributor Guangzhou Pharmaceutical Group, which also has planned six major acquisitions next year and an ambitious expansion of its retail pharmacy business to a chain with 10,000 retail-outlets nationwide.

One noteworthy trend is the integration of upstream domestic pharmaceutical manufacturers with downstream distributors. Showcasing the tendency is the deal between North China Pharma (NCP) with Jointown Group to create a joint venture for international trade, national hospital drug distribution, essential drug delivery, regional pharmaceutical distribution and logistics services. According to NCP, the joint venture will facilitate its expansion into pharmaceutical distribution and logistics, while Jointown believes the deal will help it penetrate better into northern China regions especially Hebei province.

Two major MNC drug distributors are also on the move to boost their China presence. Following its US\$470-million acquisition of

Zuellig Pharma China last November, Cardinal Health made two more acquisitions in China including a regional pharmaceutical distributor in Chengdu back in August and Jiangsu Wuxi Xishan Medicine Co. Ltd. lately. Cardinal Health is expected to undertake more acquisitions in China so as to get some regional scale and expand into new areas, but further down it will have to grow organically. In the meantime, Alliance Boots, the largest European pharmaceutical distributor, has also been actively pursuing business expansion in China. Despite MNC entries, Chinese giants like SinoPharm and Shanghai Pharma do not seem to be threatened, as there are still a few restrictions in place which bottleneck the development of foreign players in China's drug distribution sector.

In the meantime, poor visibility and interim turbulences of the Chinese healthcare marketplace have not undermined the confidence of MNCs with the country. Bayer chief executive Marijn Dekkers told a German newspaper that his company is confident about the sustainability of growth in China and "there is so much demand in China, I couldn't imagine what would interrupt our sales growth there," he said.

I hope I could be as optimistic as Dekkers, but there are concerns which cannot be discounted easily, especially when foresight is poor. Nonetheless, he is right in the sense that, despite problems, China healthcare continues to offer more opportunities and better hope than any other parts of the world, which are either in deeper trouble or too small to matter for the struggling MNCs.

Probably guided by this consideration, a number of leading big pharma companies raised their bets on China further recently.

Top of the list is Merck, which opened an Asia R&D headquarters for innovative drug discovery and development in Beijing on December 6 as a part of its US\$1.5 billion commitment for R&D in China over the next five years. Similarly, Pfizer said it would expand its R&D team in China and is exploring possible collaboration with Chinese research outfits, while BMS expanded its research partnership with Simcere Pharma to a new cardiovascular drug.

In the meantime, AstraZeneca PLC announced recently a further push into China with the purchase of privately-held Guangdong BeiKang Pharmaceutical Company Ltd, a Chinese maker of generic injectable antibiotics, for an undisclosed amount. By comparison, Boehringer Ingelheim released a plan to invest 70 million Euro to expand its manufacturing plant in the Zhangjiang High-Tech Park of Shanghai into a strategically important supply center for China. As opposed to some of its MNC peers like AstraZeneca which have been embracing generic drugs through joint ventures with or acquisitions of Chinese players, Boehringer Ingelheim said it is more interested in bio-similars which have higher technological barriers. The company is under discussion with the Shanghai government about a proposed biosimilar project which carries an investment tag of Euro 30 million.

Indeed, MNCs are increasingly looking to acquisitions of or joint ventures with Chinese generic drug companies in order to gain better access to low tier markets. There are already plenty of prior examples in the past two years, including Sanofi's acquisition of BMP Sunstone, GSK's purchase of Nanjing Meirui, Nycomed's deal with Guangdong Techpool, and various joint ventures between Novartis and Huhai Pharma, Pfizer and Zhejiang Hisun, and MSD and Simcere Pharma.

Conversely, Eli Lilly CEO John Lechleiter told Dow Jones that his company would continue to build China business with its portfolio of innovative drugs, as the company launched its blockbuster osteoporosis drug Forsteo in China. Two Lilly China

executives also played up the prospects of Cialis in China as a fast-growing rival to Pfizer's Viagra on the sidelines.

In close - future remains rosy for MNC players

I have repeatedly sounded alarm about problems in China healthcare in recent months, but by no means am I discounting the huge potential of the market. My warnings are meant to prevent companies from being overly-preoccupied with long term optimisms, thus failing to grasp Chinese healthcare realities and neglecting short term challenges.

As I close this editorial and offer my usual New Year greetings, I would like to go over where things stand for MNCs in the Chinese pharmaceutical marketplace.

On the bright side, the Chinese government remains committed to drug innovation at the macro policy level, with few but slowly growing moves by both central and some local governments to provide funding and policy support to drug innovation. These government programs, especially at the local level (though unevenly implemented nationwide), are increasingly accessible to MNCs operating locally. In addition, China's planned CNY 10 trillion stimulus package for strategic industries supports innovation by research-based companies in the country. Besides, the government generally stands by large pharmaceutical companies in consideration of better regulation and quality control.

As China's economy continues to grow, the government will be able to invest more into healthcare and people can afford to pay more for higher quality healthcare. Maturity of the country's commercial health insurance system will eventually unleash currently-bottlenecked healthcare demands, which is capped under 5% Chinese GDP at present.

The strength of MNCs lies with their innovative product portfolio and expertise in quality control, although diversification will help companies benefit from the broad range of opportunities China offers and meet massive lower tier healthcare demands. A recent study of the State Intellectual Property Office of China (SIPO) of biopharmaceutical patents in China shows that, by many measures, foreign companies have an upper hand with biopharmaceutical patents in China especially in the area of oncology drugs. Foreign companies have filed a total of 14,930 Chinese patent applications in the biopharmaceutical sector and 3,865 patent approvals have been issued to them.

MNCs also possess significant strength in certain market segments such as the urban hospital market, certain sophisticated therapeutic areas, the vaccines and the OTC drugs.

The ongoing Chinese pharmaceutical industry consolidation, which is encouraged by the government, also benefits MNCs as small irregular players are forced out of business and the order of healthcare marketplace returns. In addition, the industry restructure provides good opportunities for MNCs to acquire local businesses so that they can expand to previously inaccessible territories and diversify into new markets. Diversification can help MNCs broaden their business base and weather out short term turbulences.

Undeniably, however, MNCs face many serious challenges along the process of the Chinese healthcare reform. All pharmaceutical companies are caught in the reform process, and for MNCs, irrational cost containment measures, especially uneven price control moves and unpredictable policy swings, probably hurt the most. Poor drug regulatory enforcement, overemphasis on prices in the hospital tender process, and rampant corruption in pharmaceutical sales also undermine the market prospects of high quality drug products, especially those premium-priced.

As margins of off-patent originator drugs narrow, MNCs face the serious challenges of not being able to replenish their innovative pipeline in time, which are often attributable to the slow approval process of innovative drugs by the SFDA.

There are also a number of issues which cloud the long term prospects of MNCs in China healthcare. The healthcare reform has the tendency of preferring low-cost generic drugs, as premium products of MNCs are frequently beyond the reach of China's BMI system which seeks to provide essential but universal healthcare coverage. Although the government can be expected to increase its healthcare funding as the Chinese economy grows, there is so far no sign to show that it wants to pick up a much bigger share of the country's overall healthcare expenditures. Additionally, there are uncertainties in the Chinese economy itself and also the danger that the country may turn to the left politically, thus putting socialized medicine on the table again. Such chances are rather slim but should not be entirely overlooked.

The long term prospects of premium healthcare products lie with the development of a sound commercial health insurance system, without which China's healthcare expenditures can be expected to remain at around 5% of GDP and most of it will be consumed on low-cost generic drug products. This is exactly why the overall market share of MNCs remains to be small despite a fast-growing healthcare pie.

The building of a commercial health insurance system is supported by Chinese policies and some initial groundwork has been carried out. But the sector's development is largely tied with the healthcare reform progress and its outlook is still blurry. The MNCs are advised to provide meaningful support to the development of this sector.

On my way back home in Princeton, I was pleased to see the familiar blue-lighted Christmas tree on the neighboring Novo Nordisk site - this reminds me that the New Year is just around the corner again! Well, it is time to forget about all the complexities of life for a short while, keep fingers crossed and wish for our own "Good Fortunes" in 2012.

Merry Christmas and Happy New Year to all our readers and their families!

News in Focus

NDRC issues new rule for ex-manufacturer drug price survey

In an attempt to streamline practices and processes of ex-manufacturer drug price surveys and strengthen drug price control, the NDRC recently released its "*Rules for Ex-manufacturer Drug Price Survey (Interim)*".

Full text of the regulation and relevant forms in Chinese are available from NDRC's website at http://www.sdpc.gov.cn/zcfb/zcfbtz/2011tz/t20111122_445871.htm.

The following is a through summary of the regulation by Pharma China for its subscribers only:

The new regulation has a total of 25 articles. The first two articles describe the legal basis of the regulation and its applicability to cover ex-manufacturer price surveys of drug products under regulation by the NDRC.

Article 3 stipulates that the ex-manufacturer drug price surveys are facilitated by NDRC's drug price evaluation center or provincial level price authorities, while Article 4 defines such surveys as "field investigations of actual ex-manufacturer prices of domestically-made and repackaged imported drugs". Article 5 lays out the principles of objectivity, accuracy and transparency in such surveys.

Articles 6 and 7 provide the NDRC with the power to investigate pharmaceutical companies during survey periods for ex-manufacturer prices of selected drug products which are under its regulation. Scope of such surveys includes facts relating to ex-manufacturer drug prices and sales.

Article 8 requires pharmaceutical manufacturers to truthfully fill out the "survey form for essential facts of pharmaceutical manufacturers and their products" and the "survey form of ex-manufacturer drug prices", and provide other relevant information including 1) declaration of legal accountability and truthfulness; 2) relevant company licenses, drug approvals and labor contracts; 3) relevant drug innovation information such as new drug approvals, patents, awards, etc.; 4) documents relating to sales such as contracts; 5) financial information such as financial statements, detailed sales records, invoices, employee rosters and salary records; and 6) other information as deemed necessary for the surveys.

According to Articles 9, 10 and 11, investigators should verify information supplied by pharmaceutical manufacturers for their essential facts and overall financial situations. Investigators are required to conduct such verifications by selecting one to two representative drug specifications and in accordance with their actual production situations. In addition, they should verify current retail prices of drug products against rules and documents of pricing authorities and pharmaceutical companies.

Article 12 wants investigators to classify sales models of pharmaceutical companies according to their sales policies as follows: 1) self-managed sales model - under which pharmaceutical manufacturers manage their sales and marketing to retailers directly; 2) agency sales model - under which sales and marketing to retailers are conducted by pharmaceutical distributors on behalf of pharmaceutical manufacturers; 3) contract manufacture model - under which pharmaceutical manufacturers are contracted to produce drug products for other parties which conduct sales and marketing activities themselves; and 4) other models.

Investigators should verify drug sales volumes and revenues through inspections of detailed sales records, incoming/inventory/outgoing records and delivery documents; and they should verify the number of drug sales personnel by checking employee rosters, salary records and labor contracts, according to Article 13.

Under Article 14, investigators should verify the highest and lower ex-manufacturer prices of drug products against detailed sales records; calculate the average ex-manufacturer drug price of a drug product using weighted-average of all ex-manufacturer prices (of the same drug product) in the survey period; and check truthfulness and accuracy of ex-manufacturer prices through sample inspection of drug sales invoices.

Articles 15 and 16 demand investigators to fill in relevant verification forms, provide necessary explanations and hear opinions and explanations of pharmaceutical companies about investigation circumstances and conclusions. Explanations of pharmaceutical manufacturers can be attached if necessary.

Article 17 requires investigators to verify relevant situations such as zero sales, production changes and manufacturer changes

with explanations from pharmaceutical companies. As to manufacturers which conduct accounting manually, investigators should verify their biggest monthly sales.

Articles 18 through 22 provide reporting, paperwork and submission requirements for investigators after they conclude ex-manufacturer drug price surveys. They are required of objectivity and are warned against conflicts of interests and corruption.

All violations of pharmaceutical enterprises, including refusal to report as well as fake and omitted information, will be penalized according to relevant laws and regulations, Article 23 stipulates.

Article 24 provides that provincial level price authorities can, in accordance with this regulation, organize surveys of ex-manufacturer prices of drugs under their regulation or develop local rules for ex-manufacturer drug prices on the basis of local realities and price control needs.

The regulation becomes effective on December 1, 2011 as mandated by Article 25.

NDRC issues "*Rules for Differential and Relative Pricing of Drug Products*"

In an effort to improve drug pricing rationale and transparency, the National Development and Reform Commission (NDRC) released its revised "*Rules for Differential and Relative Pricing of Drug Products*" on December 1. The regulation will become effective on January 1, 2012 and replace the existing edition of the same rule issued by the NDRC on January 7, 2005 and other previously-issued relevant rules.

The regulation has a total of 22 articles. Pharma China has prepared an exclusive through summary of this regulation in English as follows for our subscribers only.

Full text of the regulation in Chinese is available at the NDRC's website (http://www.ndrc.gov.cn/zcfb/zcfbtz/2011tz/t20111201_448827.htm).

Article 1 - The regulation is developed to streamline government pricing of drug products and to raise rationale and transparency of drug product.

Article 2 - The regulation is applicable to drug products which are subject to government pricing and government guidance prices.

Article 3 - The "differential/relative price" in this rule refers to the price differences and relative pricing ratios for different dosage forms, specifications and packaging of the same drug. Specifically, there are dosage form differential/relative prices, specification differential/relative prices, and packaging differential/relative prices.

Article 4 - The relative pricing of drug products will take into consideration of average social costs, clinical efficacy, treatment expenditures, level of production technology, ease of use, industrial development direction, etc.

Article 5 - Different dosage forms and specifications of the same drug should be priced in accordance with stipulated relative pricing ratio on the basis of the representative product.

Article 6 - In order to determine a representative product, a representative dosage form should be ascertained, followed by the selection of a representative specification.

1) The representative dosage form should be determined as follows - conventional tablet should be the representative dosage

form of oral solid dosage forms and conventional hard capsule should be the representative dosage form when conventional tablet form does not exist; small volume liquid injection should be the representative dosage form for injectable dosage forms and conventional powder injection should be the representative dosage form when small volume liquid injection does not exist; when all of the above dosage forms do not exist for a given drug, the dosage form of the drug contained in the Chinese Pharmacopoeia (ChP) or in the national standard for its API will be adopted as the representative dosage form; and when such dosage forms are not listed in the ChP or the national standard for its API, the first dosage form approved for marketing, which must be still in active production and sales, should be used as the representative dosage form.

2) The representative specification should be ascertained as follows - among all approved specifications, that with content and filling matching conventional single dose and with medium packaging quantity should be used as the representative specification.

3) For situations which are not covered by the above methods, the following factors should be considered to determine representative (dosage forms and specifications).

a. Commonly-used clinically - the representative dosage form and specification should match the drug's main indication, have a long history of clinical use and are produced by multiple manufacturers.

b. Commonly-used internationally - the representative dosage form should be a mainstream dosage form internationally for the drug.

c. Reasonably-priced - the representative dosage form and specification should have reasonable actual market prices.

Article 7 - The dosage form differential/relative price in this rule refers to the price difference and relative pricing ratio between different dosage forms of the same drug. Refer to Appendix I and II for details.

Article 8 - The specification differential/relative price in this rule refers to the price difference and relative pricing ratio between different specifications of the same dosage form of the same drug. Specifically there are content differential/relative price and filling differential/relative price.

Article 9 - Content differential/relative price is applicable when there is a clear relativity between labeled content and daily therapeutic dose. When other conditions are the same, the price of non-representative product = the price of representative product x content relative ratio. The formula of the content relative ratio is $K=a^{log_2 X}$ (where K=relative ratio, X=content of non-representative product divided by content of representative product, and a = content relative coefficient). The highest content relative coefficient is 1.7. The large volume injection products for electrolyte balance with content differences should be at the same price. For a compound formulation of chemical drugs with the same formula and indication but different ingredient contents, their prices should be calculated on the basis of the sum of all ingredient contents.

Article 10 - Filling differential/relative price is applicable when there is a clear relativity between labeled filling and daily therapeutic dose. When other conditions are the same, the price of non-representative product = the price of representative product x filling relative ratio. The formula of the filling relative ratio is $K=1.9^{log_2 X}$ (where K=relative ratio and X=filling of the smallest pack of non-representative product divided by filling of

the smallest pack of representative product). The prices of chemical drugs and biological products under 10 ml with different fillings should be at the same price. For chemical drugs and biological products above 10 ml with different fillings, CNY 0.05 should be added to/deducted from their prices for each 10 ml more or less.

Article 11 - Content and filling differential/relative prices are not applicable when there is no clear relativity between the labeled contents and fillings of drug products (which are the same drug in the same dosage forms) and daily therapeutic dose. Such prices should be calculated using the same principles for daily medical expenses. The calculation formula is: minimal unit price of the non-representative product = minimal unit price of the representative product x daily therapeutic dose of the representative product divided by daily therapeutic dosage of the non-representative product.

Article 12 - The packaging differential/relative price in this rule refers to the price difference and relative pricing ratio among different packing quantities, packaging materials and packaging patterns of the same drug with the same dosage form and the same specification. Specifically there are packing quantity differential/relative price, packaging material differential/relative price, and packaging pattern differential/relative price.

Article 13 - Packing quantity differential/relative price. When other conditions are the same, the prices of minimal retail pack of oral tablet and oral capsule are calculated as follows: $K=1.9^{log_2 X}$ (where K=relative ratio and X=pack quantity of non-representative product divided by pack quantity of the representative product). For drug products of chronic diseases and those that need to be taken over a long period of time, if their pack size is less than the three-day therapeutic dose (calculated on the basis of the highest adult single dose for their main indications), a reduction coefficient of 0.9 should be multiplied on packing quantity differential/relative prices. For dosage forms of other categories, the price of minimal retail packing quantity should be calculated using the price of minimal independent package or minimal unit x pack number.

Article 14 - Packaging material differential/relative price.

1) The oral solid dosage form drug products with different containers or packaging materials should have the same prices.

2) For the prices of small-volume injectable biological products using single-dose prefilled syringes, when other conditions are the same, CNY 3 can be added on the basis of the conventional injection price. Chemical drugs, formulated TCMs and natural medicines adopting the above packaging should not be given differential prices.

3) For large volume injection products, the prices of plastic bottle and soft bag packaging will be added CNY 1 and 4 respectively on top of the glass bottle packaging of the same specification. No price differentiation is granted for differences in materials and specific shapes/designs of glass bottle, plastic bottle and soft bag packaging.

Article 15 - Packaging pattern differential/relative price. The price of combination packaging made up by multiple drug products should not be higher than the sum of the prices of drug products in the packaging. No differential pricing is granted to combinations of drug, injectable solvent and syringe.

Article 16 - When a combined calculation of multiple differential/relative prices is required, the order of dosage form, content, filling, pack size, packaging material and packaging pattern should be followed.

Article 17 - Under one of the following special circumstances,

differential/relative prices can be calculated using independent representative products:

1) The delivery route and dosage form of the representative and non-representative products are the same, but they have different indications or therapeutic functions (excluding addition or deduction of indications or therapeutic functions).

2) The non-representative product is for pediatric use only.

3) The content difference between non-representative and representative products is over 8 times.

Article 18 - Under one of the following special circumstances and when there are major clinical significances, differential/relative prices should be calculated using independent representative products:

1) Injection and aerosol which allow patients to self-administer drugs using special drug delivery devices.

2) There are changes to indications or therapeutic functions which are of major clinical significance.

3) When the representative oral tablet and capsule are in single-dose packaging, and the non-representative product is in multiple-dose packaging and its price is not higher than the single dose packaging of the same drug with the same dosage form and specification.

4) Due to their own nature, the dosage form or specification changes have major impacts on drug efficacy and safety.

Article 19 - When calculating retail prices using differential/relative ratios, those under CNY 1 should be rounded to Fen, those between CNY 1 and 100 should be rounded to Jiao and those above CNY 100 should be rounded to Yuan.

Article 20 - Definitions of terms in this regulation are as follows:

1) "Same drug" refers to drug formulations with the same active ingredients. Among them, chemical drugs and biological products with active ingredients under the same Chinese generic drug name or INNs are considered the same drugs. Those with the same active ingredients but with different names, acid, base, metal, crystalline form, crystalline water content, formula, solvent and other inactive ingredients are also considered the same drug. Formulated TCMs and natural medicines with the same name and same formula in the national drug standards are considered the same drug.

2) "Representative product" means the base dosage form and specification which are used to calculate prices of other dosage forms and specifications of the same drug.

3) "Content" refers to the amount of active ingredient, index element or activity unit in the minimal measurement of a drug formulation as specified in national drug standards.

4) "Filling" means the area, volume or weight of drug formulation in the minimal individual unit (of a drug).

5) "Daily therapeutic dose" refers to the average value of daily doses of a drug matching its main indications and therapeutic functions as indicated in the package insert.

6) "Packing quantity" means the number of drug formulation product by minimal measurement in each minimal retail packaging of the drug.

7) "Packaging material" refers to the medicinal packaging material in direct contact with drug formulation in each minimal independent packaging unit.

8) "Single dose packaging" refers to the sealed packaging

unit containing no more than a single dose of a drug formulation in the minimal retail packaging.

9) "Multi-dose packaging" means multiple single doses of a drug formulation are packed in the minimal retail packaging of a drug.

Article 21 - Those differential/relative prices or ratios which are not covered by this regulation should be developed temporarily by provincial price authorities according to Article 4 of this regulation and filed with the NDRC.

Article 22 - The regulation is to take effect on January 1, 2012 and to replace the existing edition of the "Rules for Differential and Relative Pricing of Drug Products (Interim)" issued by the NDRC on January 7, 2005 and other previously-issued relevant documents.

Appendix I - Differential/Relative Ratios for Common Formulations of Chemical Drugs & Biologicals

Category	Dosage Form	Code	Unit	Formula	Relative Ratio	Note
Tablets (Oral)	Conventional Tablets	(1)	Per tablet	-	1	Including plain tablets, sugarcoated tablets, film-coated tablets, abnormal tablet, scored tablets, etc.
	Chewable Tablets	(2)	Per tablet	(2)÷(1)	1.05	
	Buccal tablets (inc. Soluble Tablets)	(3)	Per tablet	(3)÷(1)	1.05	
	Enteric-coated Tablets	(4)	Per tablet	(4)÷(1)	1.1	
	Dispersible Tablets	(5)	Per tablet	(5)÷(1)	1.2	
Capsules (Oral)	Effervescent Tablets	(6)	Per tablet	(6)÷(1)	1.3	
	Hard Capsules	(7)	Per capsule	(7)÷(1)	1	
	Enteric-coated Capsules (Capsule Shell)	(8)	Per capsule	(8)÷(7)	1.1	
	Soft Capsules (Soft Gelatin Capsules)	(9)	Per capsule	(9)÷(7)	1.2	
Granules/Solution (Oral)	Granules	(10)	Per bag	(10)÷(1)	1.2	Including soluble granules, suspension, etc.
	Powders	(11)	Per bag	(11)÷(10)	0.9	
	Oral Solution (Drops)	(12)	Per vial	(12)÷(10)	1	Including oral suspension
	Dry Suspension	(13)	Per bag	(13)÷(10)	1.1	
	Effervescent Granules	(14)	Per bag	(14)÷(10)	1.1	
Plasters (External Use)	Ointments	(15)	Per packet	-	1	
	Pastes	(16)	Per packet	(16)÷(15)	1	
	Creams	(17)	Per packet	(17)÷(15)	1.1	
	Gels	(18)	Per packet	(18)÷(15)	1.1	Including emulgels and mucilage.
Injections	Small Volume Injections, Powder Injections	(19)	Per vial	-	1	Benchmark: specs of 10ml filling
	Freeze-dry Powder Injections, Menstruum Crystal Powder Injection	(20)	Per vial	(20)-(19)	CNY 2.5	Indicated in the valid documents issued by SFDA, if not, should be Powder Injections.
	Large Volume Injections	(21)	Per bottle	(21)-(19)	CNY 4.5	Benchmark: specs of 50ml filling

Source: NDRC ** Filling≥50ml = Large Volume Injection; filling< 50ml = Small Volume Inj.

Appendix II - Differential/Relative Ratios for Common Formulation of TCMs and Natural Drugs

Category	Dosage Form	Code	Unit	Formula	Relative Ratio	Note
Pills (Oral)	Honeyed Pills	(1)	Average Medical Expense per day	-	1	
	Water-honeyed Pills	(2)	Average Medical Expense per day	(2)÷(1)	1.2	
	Watered Pills	(3)	Average Medical Expense per day	(3)÷(1)	1.3	
	Condensed Watered Pills	(4)	Average Medical Expense per day	(4)÷(1)	1.4	
Tablets (Oral)	Sugarcoated Tablets	(5)	Average Medical Expense per day	-	1	
	Plain Tablets	(6)	Average Medical Expense per day	(6)÷(5)	0.9	
	Film-coated Tablets	(7)	Average Medical Expense per day	(7)÷(5)	1.1	
	Enteric-coated Tablets	(8)	Average Medical Expense per day	(8)÷(5)	1.1	
	Dispersible Tablets	(9)	Average Medical Expense per day	(9)÷(5)	1.2	
	Effervescent Tablets	(10)	Average Medical Expense per day	(10)÷(5)	1.3	
Capsules (Oral)	Hard capsules	(11)	Average Medical Expense per day	(11)÷(5)	1	
	Soft Capsules (Soft Gelatin Capsules)	(12)	Average Medical Expense per day	(12)÷(5)	1.4	
Granules/Solution (Oral)	Granules (Sugar), Dry Syrups	(13)	Average Medical Expense per day	(13)÷(5)	1.25	Sugar refers to all oligosaccharides including glucose in hydrolysates. Low sugar-based formulations to implement the price of sugar-based formulations in this table.
	Granules (Sugar-free)	(14)	Average Medical Expense per day	(14)÷(13)	1.1	
	Oral Liquid (Sugar), Mixtures (Sugar), Syrups	(15)	Average Medical Expense per day	(15)÷(13)	0.9	
	Oral Liquid (Sugar-free), Mixtures (Sugar-free)	(16)	Average Medical Expense per day	(16)÷(15)	1.1	
	Effervescent Granules	(17)	Average Medical Expense per day	(17)÷(13)	1.1	

Source: NDRC

The Market

Chinese acute coronary syndrome drug market to top US\$448M by 2015

The acute coronary syndrome (ACS) drug market in China will grow from US\$326 million in 2010 to US\$448 million in 2015, according a new report, *Acute Coronary Syndrome in China*, from Decision Resources.

The report indicates that AstraZeneca's Brilinta (ticagrelor) will exceed sales of Sanofi's Plavix (clopidogrel) in the treatment of ACS, making Brilinta the top Western brand in the ACS therapeutic market in China in 2015.

According to the report, the success of Brilinta in China will be due to its efficacy, premium price and potential reimbursement coverage. Brilinta is expected to launch in China in 2012 and to be included on the next National Drug Reimbursement List, which should publish by 2014.

Meanwhile, market share of Sanofi's Plavix will decrease between 2010 and 2015 because of the adoption of more efficacious adenosine diphosphate (ADP) receptor antagonists Brilinta and Eli Lilly's Effient (prasugrel) following their launch, and the increasing use of generic clopidogrel.

"China's ACS drug market will surpass that of any of the major European markets in 2015," said Decision Resources Analyst Jing Wu. "Because the ACS drugs used in China are priced comparable to their average prices in the EU, the large patient pool in China greatly contributes to the market's size."

The new report features extensive primary research with Chinese cardiologists as well as a market outlook by drug and class through 2015 and acute coronary syndrome epidemiology through 2020.

MNC peers challenge the lead of Bayer's Glucobay with a new generation of diabetes drugs

As diabetes rates soar in China, drugmakers including Merck & Co., Sanofi and Eli Lilly & Co. are trying to unseat Bayer AG and Novo Nordisk A/S as the biggest providers of diabetes medicines. At stake is a market that may triple to US\$2.1 billion in annual sales by 2019 from US\$700 million in 2009, says Yifi Liu, an analyst for Datamonitor in Shanghai.

"You should continue to expect double-digit growth in China's diabetes market for many years to come," Kare Schultz, COO of Novo Nordisk, said in a telephone interview. The Copenhagen-based drugmaker is the country's top seller of insulin, which diabetes patients lack to convert blood sugar into energy.

Beyond insulin, the pill to beat is a 17-year-old Bayer drug called Glucobay, little used in the West but dominant in China. Glucobay sales there surged 22 percent to CNY 1.8 billion (US\$283.4 million) last year, according to Bayer. The medicine, now a generic, only garnered a fraction of that, or US\$9.7 million in revenue, in the U. S. in the first nine months of this year, according to data research firm IMS Health.

"We're still winning market share" with Glucobay in China, Bayer Chief Executive Officer Marijn Dekkers said at a dinner with journalists in Shanghai.

The medicine, a so-called starch blocker intended to cut blood

sugar after meals, is unpopular in the U.S. because it's not potent enough to justify its side effects, according to Tom Donner, head of the diabetes center at Johns Hopkins University.

Yet it's a logical option for a population with a diet high in carbohydrates like that of China, said Datamonitor's Liu. Combined with Bayer's marketing savvy, that may help explain why the drug is so famous locally it has reached the status of "pharmaceutical myth", according to Liu.

Bayer also kept prices low, making Glucobay an affordable option for a disease with few insurance-reimbursed therapies.

In addition, the company worked with physicians and health authorities to help draft guidelines for diabetes treatment. The company held round-table talks on diabetes with influential doctors. It also set up Bayer Diabetes Community Center houses, where people can get free drugs and prevention literature and participate in patient activities, all under the auspices of the Bayer brand name, Liu said, "adding that the loyalty to the brand Glucobay is very strong." said Liu.

Meanwhile, the new generation of drugs that may relieve sufferers and supplant Glucobay has already begun its march into China.

Merck's Januvia went on sale last year, and Novo's Victoza became available in October. Lilly and Amylin Pharmaceuticals Inc.'s Byetta won approval in 2009. All three work in different ways to prompt the pancreas to make insulin, the hormone that diabetics need to break down the sugar that builds up in their blood stream.

Bayer's dominance, while under threat, probably won't evaporate overnight. Next-generation drugs take about five to six years to penetrate the market, delayed by requirements for clinical testing inside China, according to Novo's Schultz. Once the medicine goes on sale, demand tends to pick up only after it's added to insurance reimbursement lists.

"The sales are insignificant until we get on the reimbursement", Schultz said. Until then, only the fewer than 10% of the population willing to pay out-of-pocket will be able to buy Victoza, he said.

Sanofi introduced its Lantus insulin in 2004. The French drugmaker said local sales had doubled in the third quarter of 2011 after the medicine was included in reimbursement lists in Shanghai last December and Beijing in July.

The first new therapies are likely to be added to insurance payers' lists by 2013, according to Datamonitor's Liu.

By 2016, newer classes of drugs will be the fastest-growing diabetes medicines in China, estimates Vineet Kashyap, an analyst for IMARC Group in New Delhi. Medicines such as Januvia, Victoza and Byetta are likely to hold 17 percent of the market by then, approaching the one-quarter share estimated for drugs in Glucobay's class of starch blockers, Kashyap said.

RNCOS: Chinese drug market to grow 20% CAGR through 2014

According to a new research report from RNCOS titled "*Emerging Pharmaceutical Markets Globally*", China has witnessed rapidly increasing growth in the pharmaceutical markets, owing to emergence of a strong economic nation in the world. The growth of the industry will be driven by the high population base, healthcare spending, and high prevalence of chronic diseases. The pharmaceutical market in China is likely to reach US\$87.2 Billion by 2014, growing at an impressive CAGR of around 20% during 2011-2014.

The pharmaceutical market in the E7 countries has continued to witness rapid growth over the last few years, owing to their increasing healthcare spending, disease profile, and favorable government initiatives.

The report suggests that fast growth in population and increasing income levels will still be the prevailing factors for the high growth in the coming years. Also, increasing penetration of health insurance has constructed a suitable platform for stronger pharmaceutical market growth.

BCG and Deloitte: Chinese drug market to sustain strong but more modest growth in the next five years

Driven by rising demands from healthcare reform and faster growth of primary healthcare, the annual size of the Chinese drug market will grow to US\$85 billion in 2015, according to Cherry Che, head of Boston Consulting Group China at a recent pharma industry event.

Che expects the Chinese primary healthcare institutions to contribute about one third of the Chinese drug market by then. She predicts the market shares of county level medical institutions and urban hospitals to be at around 23%-25% and 50% respectively.

She is optimistic about the growth of China's primary healthcare sector under the ongoing healthcare reform, which seeks to strengthen grass-root healthcare access. Once the government investments to primary healthcare facilities are in place, the lower tier pharmaceutical market will enter into a phase of accelerated growth with limited cost containment pressure within the scope of essential drugs, she suggests.

In the meantime, Deloitte published a new report, *The Next Phase: Opportunities in China's Pharmaceuticals Market*, on December 1. The report suggests that China's pharmaceutical sales surged at 25.7% CAGR between 2007 and 2010, and expects continued strong but modest growth in between 2011 and 2015 at around 15%. The report estimates the CAGR of patented drug sales in China between 2007 and 2010 to be as high as 35.7%, while the trend will sustain at 25% in the next five years.

On the other hand, Deloitte China life science and healthcare leader Yvonne Wu stated that the average M&A deal size within the Chinese pharmaceutical industry has risen from US\$38.6 million in 2005 to US\$113.6 million in the first half of 2011. The number of pharmaceutical M&A deals rose to 28 in 2010 compared with 12 in 2006, according to M&A advisory firm Mergermarket.

New report predicts sustained double-digit growth for Chinese pharma thru 2022

A new report by visiongain, a London-based business information company, predicts sustained double-digit growth in the Chinese pharmaceutical market from 2011. National healthcare reforms will stimulate sales of drugs there. Overall pharma revenues gained in China will rise to US\$116.8bn in 2015. That analysis appears in Chinese Pharmaceutical Market 2012-2022, published in December 2011.

In 2010, the overall Chinese pharmaceutical market generated US\$53.3bn, nearly a quarter of which came from anti-infective drugs. With China's chronic disease burden increasing, and its

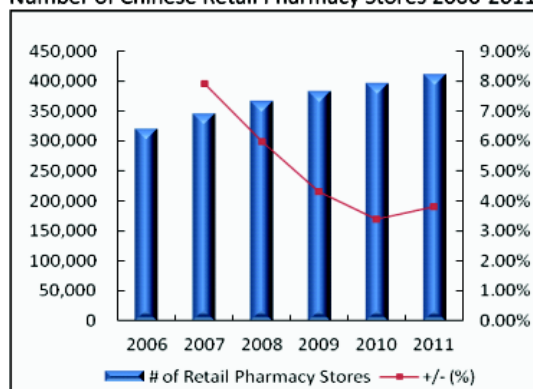
population ageing, revenue from 2012 to 2022 will increasingly come from treatments for cancer, cardiovascular and cerebrovascular diseases, diabetes and central nervous system (CNS) disorders. Sales of vaccines will also contribute to the overall growth, the study also notes.

Industry News

SMEI ranks top 100 Chinese retail pharmacy chains 2011

China had a total of 409,249 retail pharmacy stores at the end of June 2011, up 15,010 stores or 3.81% year on year, according to the Southern Medicine Economic Institute (SMEI) under the SFDA. Among the total, around 266,000 are independent stores, while the rest are controlled by retail pharmacy chains.

Number of Chinese Retail Pharmacy Stores 2006-2011



Source: SMEI

SMEI recently announced its ranking of the top 100 Chinese retail pharmacy chains 2011 (by number of directly-owned stores). Limited by space, we will only cover the top 20 of them as follows.

Top 20 Chinese retail Pharmacy Chains in 2011

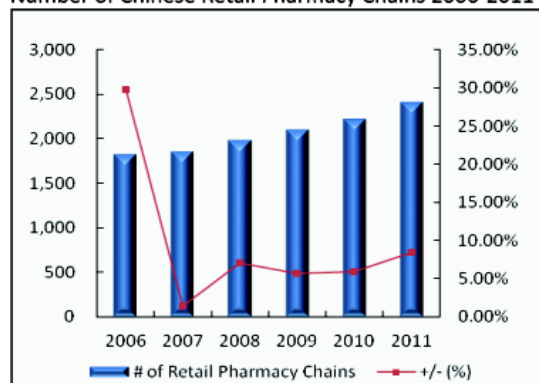
Rank 2011	Company Name	Owned	Franchised	Total	Rank 2010
1	Nepstar Drugstore	2,969	0	2,969	1
2	Sinopharma Guoda Pharmacy	1,820	90	1,910	5
3	Chongqing Peace Drugstore	1,740	772	2,512	2
4	Yunnan Hongxiang Yixintang Pharmacy	1,453	0	1,453	4
5	Chongqing Tongjunge Pharmacy	1,272	6,438	7,710	7
6	Shanghai Huashi Pharmacy	1,187	495	1,682	11
7	Guangdong Dashenlin Drugstore	1,043	0	1,043	6
8	Guangdong Dongguan Guoyao Group	900	0	900	8
9	Liaoning Chengda Fangyuan Pharmaceutical Chain	800	0	800	14
10	LBX Pharmacy	567	0	567	15
11	Shenzhen China Zhonglian Pharmacy	560	0	560	12
12	Jiangxi Huangqing Renzhanhuashi Drugstore	504	6	510	9
13	Yifeng Pharmacy	459	0	459	23
14	Sichuan Derentang Pharmacy	458	347	805	24
15	Jilin Yihe Pharmacy	439	0	439	16
16	Shandong Guoda Renhetang Drugstore	380	84	464	-
17	Jilin Great Drugstore	355	327	682	30
18	Yunnan Dongjun Pharma	350	1,250	1,600	17
19	Chifeng Rongjitang Pharmacy	330	0	330	18
20	Harbin Pharma Group Holding Co Ltd (Harbin Renmin Tongtai Pharmacy)	310	50	360	21

Source: SMEI

There were 2,409 retail pharmacy chains at the end of June 2011, up 187 or 8.42% year on year. However, the average number of retail outlets per chain was down to 60 in 2011 from 69 in 2006.

By comparison, the average number of retail stores owned by the top 100 Chinese retail pharmacy chains rose to 278 in June this year, up 13.47% year on year. The top 100 chains owned a total of 27,890 retail pharmacy outlets in June 2011, an increase of 13.75% year on year.

Number of Chinese Retail Pharmacy Chains 2006-2011



Source: SMEI

Among the top 100, there were seven chains with more than 1,000 retail stores each, five chains with 500 to 999 retail outlets each, 16 chains with between 200 and 499 outlets each, 41 with 100 to 200 outlets each, and 31 with less than 100 outlets each.

Number of Outlets Owned by the Top 100 Chains 2010-11

# of Outlets Owned by Each Chain	Top 100 in 2010		Top 100 in 2011	
	# of Chains	Total Outlets	# of Chains	Total Outlets
≥1000	5	8,499	7	11,484
500-999	7	4,467	5	3,331
200-499	15	4,715	16	4,956
100-199	31	4,137	41	5,701
<100	42	2,701	31	2,418

Source: SMEI

SMEI found the pharmaceutical retailing sector in Chongqing and Shanghai to be relatively more consolidated, while that in Shandong and Jiangsu provinces to be much less chained.

The leading retail pharmacy chains by outlet growth in the period were Shanghai Huashi Pharmacy, SinoPharm Holdings Guoda Pharmacy, Chenda Fangyuan Pharmacy Chain and Chongqing Tongjunge Pharmacy Chain, Yifeng Pharmacy, Sichuan Derentang Pharmacy Chain and Jilin Pharmacy.

Top 10 Chinese Retail Pharmacy Chains by Outlet Growth in 2011

Rank	Company	2010	2011	+/-	+/- (%)	Driver	Rank
1	Shanghai Huashi Pharmacy	600	1,187	587	+97.83	M&As	6
2	SinoPharm Guoda Pharmacy	1,295	1,820	525	+40.54	Capital Injection	2
3	Liaoning Chengda Fangyuan Pharmacy Chain	451	800	349	+77.38	Model shift from franchise to own	9
4	Chongqing Tongjunge Pharmacy	923	1,272	349	+37.81	Brand promotion	5
5	Sichuan Derentang Pharmacy Chain	260	458	198	+76.15	Business model change	14
6	Yifeng Pharmacy	282	459	177	+62.77	Equity investment	13
7	Jilin Great Drugstore	183	355	172	+93.99	Regional expansion	17
8	LBX Pharmacy	400	567	167	+41.75	VC investment	10
9	Beijing Tongrentang	112	265	153	+136.61	Brand/product Strength	22
10	Zhaoqing Tiantian-bang Pharmacy	65	170	105	+161.54	Regional expansion	35

Source: SMEI

Some retail pharmacy chains were growing rapidly during this period. 53 chains boosted the number of their directly-owned retail pharmacy stores and 20 of them had outlet growth over 50% in the year ending June 2011.

China releases its 12th Five-Year Plan for Biotechnology Development

The Ministry of Science and Technology released China's 12th Five-Year Plan for Biotechnology Development on November 28. The Plan seeks to boost development of the Chinese biotechnology sector with emphasis on biopharmaceuticals, bio-agriculture, bio-manufacturing, bio-energy and bio-environmental conservation. It plans to make biotechnology a pillar industry of the Chinese economy by 2015 with cumulative annual growth rate (CAGR) of over 15%. It also wants to make China the top country in the world in terms of biotechnology human resources.

Focus areas within the biopharmaceutical subsector include technologies and products for major infectious diseases including AIDS, viral hepatitis and tuberculosis; key technologies for clinical diagnosis, forecast and early warning (of healthcare trends), vaccines, and clinical emergency medicine; and R&D of new diagnostic reagents and vaccines which helps reduce incidence and death rates of AIDS, viral hepatitis and tuberculosis.

The Plan also seeks to achieve the following specific objectives including 1) development of new technologies for large-scale and fast-turnaround production of vaccines and antibodies, systems for assessment of vaccine quality and efficacy, and production/optimization technologies for humanized antibodies; and 2) upgrading and improvements of traditional vaccines, development of new vaccines and antibody drugs for major and common infectious diseases, and R&D of therapeutic vaccines and antibody drugs for major non-communicable diseases including cancers, cardio- & cerebro-vascular diseases, metabolism diseases and autoimmune diseases.

12 core biotechnology fields for development are identified by the Plan including "-omics" technologies, bio-synthesis technologies, bio-information technologies, stem cell and regenerative medicine, gene and cellular therapies, molecular grouping and personalized medicine, biochip and bio-imaging technologies, bioprocess engineering, biocatalysis engineering, medicinal target discovery and molecular designing technologies, and animal/plant species design and bio-safety technologies.

In order to achieve the above objectives, the Plan calls for the development of a special government fund for development of strategic emerging industries, strengthened government investments into biotechnology, and relevant tax incentive policies. It also encourages the participation of private capital through a variety of means including bonds, venture capital and private equity investments. In addition, perfection of intellectual property right protection, incentive schemes for talents, and international cooperation are also cited as important measures to develop the biotechnology sector.

The output value of the Chinese biotechnology sector was CNY 1.5 trillion in 2010, according to the document.



MIIT to issue the 12th Five-Year Plan for the Chinese Pharmaceutical Industry Development

The *12th Five-Year Plan for the Chinese Pharmaceutical Industry Development (2011-2015)* will soon be released, according to Wang Xuegong, an official with the Pharmaceutical Division under the Department of Consumables of the Ministry of Industry and Information Technology (MIIT).

The Plan's key objectives include 20% average annual growth for pharma industry output value, 16% average annual growth for industrial value-added, strengthened drug innovation, increased industry consolidation, and improved international competitiveness.

Specific targets include increased R&D investment equaling at least 5% of revenues by major pharma enterprises, over 30 innovative drugs with new drug certificates, over 30 new generic drugs, and manufacture upgrading of 200 major drugs by 2015.

In addition, the Plan wants the pharmaceutical industry to consolidate, expand and secure the supply of essential drugs with the top 20 essential drug manufacturers accounting for 80% of the essential drug market.

The Plan seeks to promote international regulatory compliance of Chinese pharmaceutical industry and it wants at least 200 bulk drugs achieving USFDA and COS certifications and 80 pharmaceutical formulation manufacturers gaining GMP certifications from developed countries or the WHO by the end of the plan period.

Industry consolidation continues to be encouraged in the plan period and there should be at least five and 100 Chinese pharmaceutical enterprises with revenues over CNY 50 billion and CNY 10 billion respectively. The top 100 companies should account for at least 50% of the Chinese pharma industry revenues.

Internationally, the plan seeks to achieve an average annual growth of at least 20% for drug exports in the period, and improve drug export composition through registration of at least 200 generic drugs in developed markets. Besides, at least 10% drug export should come from finished drug products. Furthermore, it hopes that at least 50 Chinese pharma companies will establish overseas R&D centers or production facilities by 2015.

In order to realize the above objectives, ten major tasks are laid out by the plan including strengthened new drug innovation capabilities, elevated drug quality and safety level, improved essential drug supply security, boosted technical upgrading, optimized pharmaceutical industry structure, enhanced regional distribution of pharmaceutical operations, accelerated business globalization, improved environmental conservation, better IT infrastructure, strengthened drug reserve by the state, and building of an emergency response system.

The plan advocates the development of five major areas including modernized TCMS, biopharmaceuticals, new chemical drugs, advanced medical devices and new types of pharmaceutical inactive ingredients, packaging materials and machineries.

Local company news

SinoPharm initiates a new acquisitions to step up business in south China

Accord Pharma, a pharmaceutical distribution subsidiary of SinoPharm Holdings, recently announced that it had acquired

two local distributors, Guangxi Wuzhou Huawu Crude Drugs Co. Ltd. and Zhaoqing Hexin Pharmaceutical Co. Ltd., in south China for CNY 4.5 million and CNY 5.1 million respectively.

The move is believed to be an initial step by SinoPharm to consolidate and expand its pharmaceutical distribution business in south China, where SinoPharm's archrival is Guangzhou Pharmaceutical Group. Accord Pharma has reportedly been selected by SinoPharm as the platform to restructure its pharmaceutical distribution businesses in south China region and it will subsequently be renamed SinoPharm Accord Pharmaceutical Co. Ltd.

Faced with double competitive pressures from SinoPharm and Shanghai Pharmaceutical Group, Guangzhou Pharmaceutical Group plans to pull off six major M&A projects next year in order to fend off its rivals from the north. Revenues of Guangzhou Pharma were CNY 27.5 billion, among which CNY 18.3 billion was from distributor sales.

On the other hand, Accord Pharma's revenues last year reached over CNY 13 billion, among which over CNY 12 billion was from distributor sales. Meanwhile, a source in SinoPharm Holdings disclosed that the company's revenue target this year of CNY 100 billion is expected to be achieved before the end of the year.

In a separate development, SinoPharm announced recently that it had acquired Beijing Caishikou Pharmaceutical Co. Ltd. to further strengthen its dominant position in Beijing.

NCPC and Jointown to form a pharma trading and distribution JV

North China Pharmaceutical Corporation (NCPC), the largest Chinese antibiotic manufacturer, announced on December 8 that it had reached an agreement with Jointown Pharmaceutical, the fourth largest Chinese pharmaceutical distributor, to form a joint venture.

Following the agreement, Jointown will inject new capital into NCPC's fully-owned subsidiary NCPC International with specific amounts to be determined by financial audits of the company. Subsequently, NCPC will own 51% and Jointown will own 49% of the joint venture.

Both parties will seek to build NCPC International into a major player for pharmaceutical import and export, national hospital drug distribution, essential drug delivery, regional pharmaceutical distribution including Hebei province and drug related logistics services.

NCPC said the joint venture deal will facilitate its expansion into pharmaceutical distribution and logistics, while Jointown believes the deal will help it penetrate better into northern China regions including Hebei province.

Sihuan begins construction of a major new production and R&D facility

Sihuan Pharmaceutical announced the construction of new production and R&D centre in the Zhangwan Development Area, Tongzhou District, Beijing. The new facility will commence production in August 2013.

The first phase will comprise production lines with an annual capacity of 300 million vials of small volume liquid for injection, 20 million vials of lyophilised powder for injection and 20 million vials of sterile powder for injection.

The facility will comply with the new Chinese Good Manufacturing

Practice (GMP) standards and selected production lines will also conform with US Food and Drug Administration (FDA) standards, the company said.

Sihuan chairman and CEO Che Fengsheng said the new production plant and R&D center will strengthen their production capacity and R&D capabilities thereby enabling their growth.

"To ensure that our products are of the highest quality and conform to the new GMP requirements, we are also upgrading our biological medicine and traditional Chinese medicine production plant in Jilin," Fengsheng added.

Tasly Pharma selects ICON for global phase III trial for botanical cardiovascular drug T89

ICON plc has been selected by Tasly Pharmaceuticals to conduct a global Phase III trial for T89, a botanical product being studied for the treatment of chronic stable angina pectoris due to coronary heart disease. The drug is also known as Dantonic pill, and, if approved, would be the first traditional Chinese medicine to gain FDA approval.

Tasly is conducting two global Phase III trials for the Dantonic pill and ICON has been awarded the three-arm Phase III trial and will also be providing IVRS, data management and central laboratory services for both global trials.

TaiGen gains worldwide rights of Nemonoxacin from Warner Chilcott

TaiGen Biotechnology, a leading development stage pharmaceutical company based in Taiwan with a wholly-owned subsidiary in Beijing, mainland China announced recently that Warner Chilcott will transfer the worldwide rights for Nemonoxacin, a novel non-fluorinated quinolone antibiotic under development for treatment of antibiotic-resistant infection, to TaiGen. With the transfer of the compound, a complete regulatory package and related intellectual property rights, TaiGen will hold the worldwide exclusive rights for development, manufacture, commercialization and sub-licensing of nemonoxacin.

TaiGen originally licensed nemonoxacin product rights in ten Asian countries and worldwide development rights through Phase II from Procter & Gamble Pharma, which was acquired by Warner Chilcott in October 2009. In August 2010, Warner Chilcott regained all rights outside the TaiGen territories after TaiGen obtained positive data, including effective eradication of MRSA and quinolone-resistant MRSA in two Phase II trials for community acquired pneumonia (CAP) and diabetic foot infection under a US IND.

Conba Pharma acquires 84% of Yunnan Xiongye Pharma

Zhejiang Conba Pharmaceutical (600572), the maker of Qianliekang tablets and Tianbaoning capsules, intends to acquire an 84% stake in Yunnan Xiongye Pharmaceutical from China Yunnan Xiongye Group, according to a company filing.

Xiongye Pharma, which produces formulated traditional Chinese medicines (TCMs) and western medicines, recorded a loss of CNY 4.69 million last year on revenue of CNY 7.76 million. During the first 10 months of 2011, it posted a loss of CNY 4.78 million on revenue of CNY 5.07 million. Through the end of October, the target company had total assets of CNY 45.94 million and negative net assets of CNY 2.9 million.

According to Conba Pharma, the current acquisition will help to improve its product structure. Xiongye Pharmaceutical currently has five types of exclusive TCMs and some of its products are included in China's national essential drug list.

Leading Chinese generic drug player fined CNY 6.3M for GMP violations

Sichuan Shuzhong Pharmaceutical, a leading supplier of generic drugs and traditional Chinese medicines (TCMs) in China, was fined a total of CNY 6.3 million (including forfeit of sales income and penalties) for GMP violations at its TCM manufacturing facility (e.g. not following approved production processes).

The company's violations were found during site inspections by the SFDA and Sichuan Provincial Food and Drug Administration in April this year. Subsequently, the GMP certification of Shuzhong Pharma's TCM facility was withdrawn and its TCM production was suspended. The firm undertook corrective measures in the past six months and won back its GMP certification this November.

Shuzhong Pharma has a comprehensive product portfolio composing of more than 200 approved drug products in six dosage forms. Its annual sales turnover was CNY 2 billion in 2010.

Foreign company news

Lilly gears up on China and blames smaller Chinese presence on IP concerns

Eli Lilly and Co. will continue to build its business in China, even as it faces intellectual property theft, Lilly CEO John Lechleiter told Dow Jones Newswires in an interview published Nov. 20.

Though Lilly sees the country as a linchpin of growth in coming years, China remains a small market for Lilly. It generated US\$320 million in sales for the company in 2010, just 1.3% of its US\$23 billion in sales worldwide. In the third quarter, Lilly's revenue from China grew 31%, compared to 9% worldwide. Sales of a number of off-patent drugs like Prozac, Vancocin and Zyprexa grew 22%, 40% and 22% respectively in China last year.

While the firm is also targeting markets in South Korea, Taiwan and Australia, China and Japan "are clearly our focus in Asia," Lechleiter told Dow Jones.

Lechleiter joined a group of other CEOs in a meeting with Chinese President Hu Jintao at the Asia Pacific Economic Cooperation summit in Hawaii this month. He said China had shown "remarkable progress" in anti-counterfeiting efforts, though he acknowledged that intellectual property theft remains a problem. Whereas in the past, intellectual property concerns made Lilly more reluctant than its peers to move aggressively into China.

Lilly upbeat about prospects of its ED drug Cialis in China

Although Pfizer continues to be the dominant player on the Chinese market for Western erectile dysfunction (ED) medicines, Eli Lilly is working hard to catch up with the ambition to have its Cialis overtaking Viagra in China eventually.

Two senior executives of Eli Lilly, Di Lu, Vice President of Lilly China, and Jialin Chen, Vice President of Lilly China's anti-infective and specialty product sales, recently talked with the Chinese press in high profile about the sharp growth of Cialis in recent years

and imminence of the product to surpass Viagra internationally. Since the Chinese approval of Cialis for retail sales, the product experienced almost 100% revenue growth in China last year and most of the increase came from retail sales channels, according to Chen.

According to Chen, his company has invested heavily into retail sales channels and more funds will be poured in the next few years so as to beef up the competition with Pfizer. Lilly will expand to more cities and broaden channel coverage in regional markets in future, he added.

According to conservative estimates by pharma industry experts, the Chinese ED drug market is about CNY 8 billion. But 90% of the market is controlled by formulated traditional Chinese medicines (TCMs) as people are reluctant to visit hospitals for such medicines due to cultural reasons. Prescription ED medicines like Viagra and Cialis account for only 10% of the overall ED drug market.

On the other hand, IMS Health, which monitors larger Chinese hospital drug sales, suggests that Viagra has a 50% market share in hospital sales of all ED medicines including Western medicines, formulated TCMs and healthcare products.

Lilly launches osteoporosis drug Forsteo

Eli Lilly announced recently the launch of its blockbuster osteoporosis drug, Forsteo (Teriparatide injection), in China. The drug was approved in China in March this year for serious osteoporosis in post-menopausal women.

Eli Lilly already has a deal with Synthes, a Swiss medical device company recently acquired by Johnson & Johnson, for co-promotion of Forsteo and development of its additional indications worldwide. The two companies will co-market the product in China too. Worldwide sales of Forsteo was US\$3.7 billion last year.

China is estimated to have around 70 million osteoporosis patients now and, as incidence rate of the disease rise sharply, such patient population is expected to reach 300 million in the near future. Current prevalence rates of osteoporosis are 50%-70% and 100% for Chinese women aged 60 to 69 and over 70, and 30% among Chinese senior males.

Bayer Healthcare initiates trials and registration of Regeneron's AMD drug

Bayer HealthCare has commenced a new phase III clinical study of Regeneron's Eylea (VEGF Trap-Eye) for the neovascular form of age-related macular degeneration (wet AMD).

This latest trial is being conducted in China in association with partner Regeneron Pharmaceuticals, with the aim of further strengthening the drug's clinical profile and making it more widely available.

Named Sight, the new phase III study will involve around 300 patients and will be the largest retinal trial conducted in the Asian nation, with safety and efficacy results to be compared to photodynamic therapy with verteporfin.

Dr Kemal Malik, head of global development and member of the Bayer HealthCare executive committee, said: "After reporting positive data from our large View programme in wet AMD, we look forward to potentially bringing this new treatment to patients with wet AMD in China."

If the drug is approved in China, Bayer will market Eylea and the companies will split the profits.

Merck sets up R&D Asia HQ in Beijing with US\$1.5B investment commitment

Merck & Co., known as MSD outside the United States and Canada, announced on December 6 the establishment of an Asia R&D headquarters for innovative drug discovery and development located in Beijing, China. The new facility is part of a US\$1.5 billion commitment the company has made to invest in R&D in China over the next five years.

"The establishment of the MSD Asia R&D headquarters represents an important milestone as we implement our strategy of building capabilities, and relationships to succeed in fast growing geographic regions," said Peter S. Kim, Ph.D., president, Merck Research Laboratories. "By strategically locating in China, we are able to complement our existing R&D capabilities, and facilitate new collaborations with scientists in the region and across emerging markets."

Located in Wangjing Park, one of Beijing's rapidly expanding science and technology parks, the facility will consist of 47,000 square meters of office and laboratory space. The first phase of construction, scheduled to be completed by 2014, will provide capacity for approximately 600 employees working in the areas of drug discovery, translational research, clinical development, regulatory affairs and external scientific research programs.

In addition to building an Asia R&D headquarters in Beijing, some of the funds will be put into establishing collaboration arrangements with local counterparts, academic institutions and other types of partners, said Kim. Possible partners would be assessed on whether they could add value and play a complementary role, stated Michel Venatosis, president of MSD China. The executives said the new R&D headquarters in Beijing could be a platform for many kinds of collaboration.

MSD has entered into a number of alliance agreements with local partners recently. It has signed a research deal with Shenzhen-based BGI in September, aiming to combine BGI's sequencing techniques with a new generation of personalized therapies.

The company also formed a joint venture with Simcere Pharmaceutical Group in July and signed an agreement with Sinopharm Group for vaccine development and distribution earlier.

AstraZeneca acquires Chinese generic drug company

AstraZeneca PLC announced on December 8 a further push into China with the purchase of a Chinese maker of generic injectable antibiotics for that massive market. The company said it would buy privately-held Guangdong BeiKang Pharmaceutical Company Ltd for an undisclosed amount.

The Chinese firm's five injectable treatments for fighting infections, mainly antibiotics, will be marketed under the AstraZeneca brand once they are manufactured to AZ's standards. AstraZeneca said it aims to manufacture them to its global standards and make them commercially available under AstraZeneca brand names by mid-2013.

News of the acquisition follows AstraZeneca's decision, announced in October, to invest US\$200 million investment in a new manufacturing facility in Taizhou, Jiangsu province, representing the British company's largest ever investment in a single manufacturing facility globally.

Mark Mallon, president of AstraZeneca's Asia-Pacific region, said "AstraZeneca continues to invest in the key emerging markets

such as China where the combination of growing populations, elevated levels of chronic diseases and increasing income are driving demand and expectations for better healthcare treatment."

Overall, AstraZeneca expects emerging markets to make up a quarter of its global sales by 2014 and its China strategy is a key plank in that strategy. It currently generates around 17% of total sales in emerging markets.

Negative studies of Sanofi's Lantus may undercut the product's potential in China

Results of a study presented at the San Antonio Breast Cancer Symposium suggest that people who used Sanofi's Lantus (Insulin Glargine) had a 2.9-fold greater risk of developing cancer. The research, based on medical records of 23,266 patients in southern Sweden, also found that those taking metformin had an 8% lower chance of developing cancer.

The study is flawed, according to Riccardo Perfetti, head of medical affairs at Sanofi's diabetes unit. In the meantime, Sanofi presented fresh data which it says reinforces the safety profile of Lantus (insulin glargine). The French giant unveiled new meta-analysis data at the World Diabetes Congress in Dubai, which it says adds to "the wealth of evidence resulting from more than 80,000 patients enrolled in clinical trials and 38 million patient years of treatment exposure to Lantus".

It remains to be seen if the latest negative results will impact the Chinese sales of Lantus and if the SFDA decides to respond in any way, but the related news was already widely covered by the Chinese press, thus raising public concern.

Sanofi is the No.2 insulin market leader in China after Novo Nordisk and the Chinese sales of Lantus is currently in a phase of steep growth. The product was included in Beijing's BMI drug reimbursement list this July and recently entered into the national drug reimbursement list. Its Chinese sales surged 41% to CNY 700 million in 2010.

Lantus can be reimbursed 90% by China's basic medical insurance (BMI) system at a unit price of CNY 257, which is nearly five-folds of regular insulin products, reports the Chinese press.

Pfizer looks to expand R&D in china through local partnerships

According to Pfizer, it will expand its research and development team in China and is exploring possible collaboration with Chinese research outfits as it seeks to tap the country's vast talent pool and emergence as a major market.

The company, which moved its regional emerging markets headquarters for Asia to Shanghai from Hong Kong last year, has a total of about 600 researchers in Beijing, Shanghai and Wuhan.

"(The number) is growing consistently. We have been here for six years; on average it's been about 100 people per year," Lingshi Tan, vice-president for Pfizer's worldwide development operations and general manager of Pfizer's R&D center in China, told Reuters in an interview on December 10.

Salomon Azoulay, senior vice-president for Pfizer's medical and development in emerging markets and established products, said in the interview that Pfizer is open to collaborating with Chinese research companies.

"We are exploring with a number of companies ... there are many

ways of collaborating. One is looking at what Chinese R&D is producing and seeing if there is anything of interest for Pfizer," said Azoulay.

Pfizer, the number one foreign drug company in China by revenue, signed a memorandum of understanding for a potential strategic partnership in April with Shanghai Pharmaceuticals.

"Another option is to out-license or co-develop products. China has interesting products, especially target products in oncology and other areas, which we may be interested in," Azoulay said. He added that it is critical to involve China as early as possible in new global drug projects.

"If you do not include China early on in a global project, you will need to do a specific programme for China and that delays approval. That's why we try to involve China as early as possible in the global development plan to have (Chinese) patients and minimise the gap," he said.

The company hopes to file for Chinese approval for a number of new drugs including Tofacitinib for rheumatoid arthritis, and Eliquis or apixaban, which it developed with Bristol-Myers Squibb for stroke prevention.

Cardinal Health China acquires Wuxi Xishan Medicine

Cardinal Health announced on December 9 that it had entered into an agreement with Jiangsu Wuxi Xishan Medicine Co. Ltd. (Wuxi Xishan) to acquire the latter through setting up a joint venture which is more than 80%-owned by Cardinal Health.

Wuxi Xishan is a mid-size regional pharmaceutical distributor in Wuxi City, Jiangsu province with annual sales of CNY 360 million in 2010. The top two pharmaceutical distributors in Wuxi were reportedly acquired by SinoPharm and Shanghai Pharma earlier.

Cardinal Health plans to replicate its business model in the U.S. and thus extend the business scope of Wuxi Xishan to include not only drug products but also medical devices, medical consumables, healthcare supplements and more, said Eric Zwisler, President of Cardinal Health China.

Following its US\$470-million acquisition of Zuellig Pharma China last November, Cardinal Health also acquired a regional pharmaceutical distributor in Chengdu back in August through establishing a CNY 25-million joint venture, Sichuan Hwei Pharmaceutical Consultancy Co. Ltd., in order to expand its business in Sichuan province.

In the meantime, Alliance Boots, the largest European pharmaceutical distributor, has also been actively pursuing business expansion in China. In March, the company announced new capital injection of CNY 150 million into its 50:50 joint venture Guangzhou Pharmaceutical to facilitate its fast growth in southern China, and it signed a letter of intent with Nanjing Pharmaceutical to form a joint venture in July.

China plans of MNC pharmaceutical distributors may clash with those of Chinese giants like SinoPharm and Shanghai Pharma. But an executive with SinoPharm said the company is not particularly threatened by the recent MNC moves as there are still a few restrictions in place which bottleneck the development of foreign pharmaceutical distribution business in China.

Meanwhile, Zwisler said that the Chinese pharmaceutical distribution market is big enough for more than just a few players, and Cardinal Health does not exclude the opportunities to collaborate with Chinese giants like Shanghai Pharma.

BMS expands research partnership with Simcere to a cardiovascular candidate

Bristol-Myers Squibb Company and Simcere Pharmaceutical Group announced on December 13 that the companies had expanded their strategic partnership formed last year to include a second collaboration in a different therapeutic area. The companies agreed to co-develop BMS-795311, Bristol-Myers Squibb's preclinical small molecule inhibitor of the Cholesteryl Ester Transfer Protein (CETP). This collaboration is expected to accelerate the delivery of clinical Phase IIa proof-of-concept by leveraging the complementary strengths of a premier Chinese pharmaceutical company and a global biopharmaceutical company.

Under the terms of the agreement, Simcere will receive exclusive rights to develop and commercialize BMS-795311 in China while Bristol-Myers Squibb will retain exclusive rights in all other markets. The companies will together determine the strategic development plan to explore the potential of BMS-795311 to treat and prevent progression of cardiovascular disease. Simcere will run and fund initial development work. Financial terms were not disclosed.

"Simcere was the first company with which Bristol-Myers Squibb created a partnership under our Oyster Strategy to seed companies in key markets with promising investigational medicines of continued interest from our early pipeline," said Francis Cuss, M.D., senior vice president, Research, Bristol-Myers Squibb. "That partnership, focused on an oncology compound, has gone extremely well and we are excited to expand our relationship to include a second collaboration in another therapeutic area. Working together we are building on the strengths of both organizations to develop potential medicines and help patients."

Boehringer Ingelheim to invest Euro 70M for Chinese manufacturing expansion

Boehringer Ingelheim announced on December 14 that the company intends to invest 70 million Euro to expand its manufacturing plant in the Zhangjiang High-Tech Park in Shanghai into a strategically important supply center for China. The goal of this project is to bring more health to more patients and to continuously improve Boehringer Ingelheim's product competitiveness and enlarge its market share.

With the expansion until end of 2013, the number of employees will rise significantly from 240 today to 400, the production capacity will be doubled.

"We want to expand our Zhangjiang plant, primarily to meet the demand for more health in China. It also shows our continuous commitment to China and specifically Shanghai," said Professor Dr Wolfram Carius, responsible for the Corporate Board Division Operations and Human Resources. "Our vision is to transform our Shanghai plant into a launch site in Boehringer Ingelheim's global Operations network."

The project intends to build a modular and lean manufacturing facility on the current production site. It will be able to produce marketed products and new pipeline products. The objective to have world-class production through a lean manufacturing approach will be supported by the optimisation of material flow and by its highly qualified employees.

In the first phase, which will be completed by the end of December

2013, a packaging center for ampoules and solids and a new automatic warehouse will be constructed. Furthermore, a new laboratory building for development activities will be set up on the site. In the second phase, to be concluded until the end of 2014, the existing solids manufacturing facility will be revamped and upgraded with new technologies.

"We are committed to meeting the growing demand of China's pharmaceutical market and to bringing more health to patients and their families," said David Preston, Chief Executive Officer of Boehringer Ingelheim China.

Preston told the Chinese media that, as opposed to some of its MNC peers which have been embracing generic drugs through joint ventures with or acquisitions of Chinese players, Boehringer Ingelheim is more interested in bio-similars which have higher technological barriers. He revealed the company is under discussion with the Shanghai government about a proposed biosimilar project which carries an investment tag of Euro 30 million.

Since it entered the Chinese market in 1994, Boehringer Ingelheim has expanded its product range to cover respiratory, cardiovascular, central nervous system and other important therapeutic areas. In the forthcoming years, the company will continue to expand, including the therapeutic areas diabetes, oncology and stroke prevention.

Gedeon Richter gains China rights of myoma drug from HRA Pharma

HRA Pharma and Gedeon Richter Plc. recently announced that Richter had been recently awarded the exclusive distribution and marketing rights for the innovative product, Esmya (ulipristal acetate), indicated for the treatment of uterine fibroids (myoma), in China, Russia and other CIS republics.

This new arrangement follows Richter's 2010 acquisition of PregLem, a privately held Swiss pharmaceutical company specializing in the treatment of benign gynaecological conditions. As a result of the acquisition, Gedeon Richter Plc. procured the distribution and marketing rights that HRA Pharma had granted PregLem for Esmya, the lead product in PregLem's portfolio, across the European Union and in North America.

SciGen may sell its Chinese HepB vaccine plant following recent FDS deal

UK drugmaker FDS Pharma has recently bought the hepatitis vaccine manufacturing facility in Israel operated by Singapore biopharmaceutical concern SciGen along with license rights for the manufacture and sale of SciGen's vaccine against hepatitis B - for US\$2 million in addition to 5% royalties on sales, according to a SciGen stock exchange announcement. SciGen is a subsidiary of Polish biotechnology concern Bioton, and has been under financial pressure of late.

SciGen is reportedly also considering selling off a subsidiary in China which owns a secondary filling and packaging facility that is in the process of being commissioned to supply insulin into Asian markets.

The company sells insulin manufactured by Bioton in Asia-Pacific markets, but company secretary Jenny Low said the sale of the Chinese plant would be considered "provided the company will recover its cost of investment and at the same time reduce the operating expenses of the group for the next 12 months".

Service provider news

ICON to acquire Beijing KendleWits to expand clinical research capability in China

ICON plc announced on December 13 that it had agreed, subject to closing conditions, to acquire Beijing Wits Medical Consulting Ltd., a leading CRO in China. The transaction is expected to close in the first quarter of 2012.

BeijingWits offers full-service clinical development capabilities and has a strong track record in clinical trial execution in China. The company is a renowned expert in Chinese regulatory processes and a leading advocate of ICH GCP in China. In addition to boosting ICON's service capabilities in the region, BeijingWits will also strengthen ICON's presence through the addition of over 100 highly qualified and experienced professionals in Beijing, Shanghai, Chengdu, Guangzhou, Wuhan and Hong Kong.

Quintiles kicks off its Chinese CRO Kun Tuo

Further deepening its commitment to China, Quintiles announced on Dec. 13 the launch of Kun Tuo, a local contract research organization (CRO) built to service the unique needs of the Chinese biopharmaceutical industry and multinational biopharma companies operating in China.

Kun Tuo will provide a full range of services, including comprehensive clinical trial management, regulatory submission preparation, biostatistics and data management. Kun Tuo will tap Quintiles' global resources and expertise to develop customized offerings in key therapeutic areas, along with vaccines, late phase studies, medical devices and diagnostics.

"Kun Tuo will leverage Quintiles' quality and training systems to offer customized, high-quality solutions best suited for local Chinese biopharma, as well as global biopharma local affiliates," said Ling Zhen, General Manager, Quintiles China. "We have an aggressive growth plan for China and anticipate doubling Quintiles total staff during 2012 as we look to provide our customers with the solutions they need to succeed in one of the world's most dynamic marketplaces."

Regulatory News

SFDA releases its 2010 Annual Statistical Report

The State Food and Drug Administration released its 2010 Annual Statistical Report on November 2. The publication contains the following drug regulatory information:

Essential food and drug regulation information

By the end of 2010, China's food and drug regulatory system had, at central and all local levels, a total of 2,898 food and drug agencies and 1,076 institutions. They employed a total of 45,393 officials including 17,164 inspectors, among whom 39 GLP inspectors, 198 GCP inspectors, 2,843 GMP inspectors and 14,084 GSP inspectors.

All levels of food and drug agencies accepted a total of 117 administrative appeal cases and Chinese courts accepted a total of 70 lawsuits against such agencies last year.

Drug registration

The SFDA issued a total of 243 clinical trial approvals for new drugs (CTAs), two new drug certificates, 27 new drug production approvals (NDAs), and 58 new drug certificates+NDAs.

The agency granted three NDAs and 30 CTAs for class I new chemical drugs last year, while it gave out one NDA and 13 CTAs for class I new biological products in 2010.

It approved 153 clinical trials of copy drugs and production of 657 such products. The agency also approved 308 clinical trial applications and 183 marketing applications for imported drugs. SFDA also approved 2,325 supplemental applications while provincial level food and drug departments approved 9,009 supplemental applications.

Pharmaceutical manufacturers/distributors

There were a total of 4,678 manufacturers of APIs and drug formulations in China at the end of 2010.

414,840 businesses held pharmaceutical distribution licenses including 13,461 wholesalers, 2,310 retail pharmacy chains with 137,073 outlets, and 261,996 independent retail pharmacy stores.

Administrative protection

The SFDA terminated one pharmaceutical administrative protection last year. There were 1,395 traditional Chinese medicine products under protection.

SFDA issues Guidelines on Management of Phase I Clinical Trial of Drugs

To enhance the management of the Phase I clinical trial of drugs, effectively safeguard the rights, benefits and safety of trial subjects, and improve the research quality and management of the Phase I clinical trial of drugs, the State Food and Drug Administration (SFDA) issued on December 2 the *Guideline on Management of Phase I Clinical Trial of Drugs (interim)* in accordance with the *Drug Administration Law of the People's Republic of China*, the *Provisions for Drug Registration and the Good Clinical Practice (GCP)*.

The Guideline contains 54 articles under 14 chapters, which specifies the responsibilities, conducting requirements, management systems and standard operating procedures, quality assurance, risk management, contracts and agreements, trial protocols, management of subjects, management of investigational products, management and analysis of biological samples, data management and statistical analysis for the management of the Phase I clinical trial of drugs. The Guideline went into effect as of the date of promulgation.

Full text of the Guidelines in Chinese is available from the SFDA website at the following link: <http://www.sda.gov.cn/WS01/CL0844/67396.html>.

In a related development, Deputy SFDA Commissioner Wu Zhen told a recent national conference on clinical trial quality control that China will initiate a classified management system for clinical research facilities starting with those conducting phase I trials.

He stated that there are now 333 designated clinical research institutions in China and only those approved will be allowed to conduct phase I studies.

Wu disclosed the SFDA's pilot IT system for regulatory information of drug clinical trials has achieved initial success and its trial will soon be expanded following certain modifications. The

system, which collects dynamic information on both clinical trials and clinical research facilities, will eventually be implemented nationwide, he said.

SFDA issues *Guidance on Management of Laboratory for Drug Clinical Trial Biological Sample Analysis*

In accordance with the requirements of the *Provisions for Drug Registration*, the *Guidelines for Quality Control of Drug Clinical Trials (GCP)* and *Guidelines for Quality Control of Non-clinical Research (GLP)*, the SFDA issued on December 2 the *Guidance on Management of Laboratory for Drug Clinical Trial Biological Sample Analysis (Interim)*.

The document has a total of nine chapters and 47 articles covering requirements for organization structure & personnel, laboratory facilities, instruments & materials, contract management, SOP, experiment implementation, data management and quality control of analytical laboratories for biospecimens in drug clinical trials.

Full text of the document in Chinese is available from the SFDA website at the following link: <http://www.sda.gov.cn/WS01/CL0844/67395.html>.

SFDA seeks additional comments for its drafted rule on DMF filing of APIs and IPIs

SFDA issued its second draft for "*Rules for Filing Regulation of Active Pharmaceutical Ingredients (APIs) and Inactive Pharmaceutical Ingredients (IPIs)*" on December 5 and is now seeking additional public comments on it (before December 20, 2011). The rule is the Chinese equivalent of the Drug Master File (DMF) system for APIs in many Western markets.

Full text of the drafted rule (second draft) in Chinese is available from the SFDA website at the following link: <http://www.sda.gov.cn/WS01/CL0778/67394.html>.

The first draft for the rule was released by the agency on September 16, 2010 and the SFDA solicited the first round of public comments then. Subsequently, the agency reviewed all comments and revised the rule into the second draft.

According to SFDA's explanatory notes accompanying the second draft, the following important changes were made to the first draft after taking into considerations of all public comments received.

1. Activation mechanism for DMF file numbers - The second draft established an activation mechanism for DMF file numbers of APIs and IPIs referencing similar provisions in foreign DMF management systems. The mechanism activates and publicizes relevant API and IPI DMF file numbers when their related drug formulations are approved.

2. Filing of IPIs - There were many comments about difficulties in defining "IPIs for injection" and "new types of IPIs" provided in the first draft. To address this, the second draft stipulates that IPIs should be filed and approved in relation to their drug formulations. Following approvals of their related drug formulations, DMF file number of relevant IPIs will be activated. Alternatively, the dossiers for IPIs can be submitted together with

the registration applications of their related drug formulations.

3. Mechanism for authorized linking and referencing DMF files - In consideration of comments on dossier confidentiality, the second draft 1) establishes an authorization mechanism from manufacturers of APIs and IPIs to producers of drug formulations; 2) provides that technical review/regulatory departments should only link/reference relevant confidential DMF information with proper authorizations; and 3) sets out confidentiality requirements for IT systems and relevant operating procedures.

4. Transparency and publication provisions - The second draft improves the definitions of filed information and confidential requirements, adds limitations to publicized information, and clarifies relevant authorizations and scope of use for each part of the DMF file.

5. Issues relating to changes (to the DMF file) - As the management of file modifications is complex, the second draft provides only the principles for file modifications rather than detailed rules. Classified control of file modifications and a system of annual report is established. As such file modifications are related to the supplemental applications for drug formulations, relevant technical guidelines (for drug registration) can be referenced over such requirements.

The second draft of the rule is divided into six chapters and 31 articles. A thorough summary of the draft is prepared by Pharma China exclusively for its subscribers in the following:

Chapter I provides the general principles of the rule. The scope of the rule covers APIs, traditional Chinese medicine extracts, IPIs as well as packaging materials and containers in direct contact with drug products which are used in approved drug products or those under registration. Filing of APIs and IPIs refers to the process under which the producers of APIs and IPIs used in approved drug formulations and those under applications file their required documentations through the API/IPI information filing platform established by drug regulatory authorities.

APIs as well as packaging materials and containers in direct contact with drugs should be subject to registration and filing regulation. Dossiers of IPIs can either be filed or submitted as a part of the drug formulation registration application.

The SFDA is responsible for establishing the API/IPI filing information platform, while the Center for Drug Evaluation (CDE) under the SFDA is responsible for maintaining it. Provincial and below levels of food and drug administrations are responsible for ensuring filings by API and IPI producers in their areas.

Chapter II stipulates the basic requirements for filing. Information on locally-made APIs and IPIs should be filed by their legal Chinese producers, while that on imported APIs and IPIs should be filed by the representative offices or designated agents of their legal foreign manufacturers. Filing manufacturers are responsible for the truthfulness of filed information and should accept audits of formulation manufacturers and inspections of drug authorities which do not review filed information individually. Drug formulation manufacturers should sign contracts with API/IPI manufacturers, define each other's responsibilities and are responsible for auditing APIs/IPIs they use.

Drug regulatory authorities should keep filed API/IPI information confidential through encrypted IT system and SOPs. Employees of drug authorities are responsible for keeping filed information confidential. Drug evaluation departments should reference relevant filed information according to API/IPI file numbers provided in the drug formulation applications and with authorizations from such file holders.

Chapter III deals with the procedures for filing submission and modifications. APIs and IPIs used for the first time in approved drug formulations are required to file within the required timeframe. Relevant information about drug formulations using such APIs and IPIs should be filed together with other required information.

APIs and IPIs used for the first time in drug formulation (under application) are required to file within 30 days of their related drug formulation application submission. The filing numbers of APIs as well as packaging materials and containers in direct contact with drugs are activated only when their related drug formulation and drug packaging material registrations are approved. API/IPI producers are required to file information including starting materials, intermediates, production processes, quality standards and analytical methods. File numbers are generated automatically by the platform upon filing of API/IPI information.

Modifications to the API/IPI files can reference relevant published technical guidelines for approved chemical drugs, while guidelines for modifications of other API/IPI files not covered can be developed separately if there are special requirements. Filed API/IPI information should be updated annually and annual reports should be submitted to the filing platform by producers. Warning indicators will appear in files when producers fail to submit annual reports for two years consecutively, thereafter if such files are not updated for three more years, they will be indicated as inactive and will no longer be publicized on the platform. When files of APIs and IPIs need to be changed, their producers should conduct relevant research to evaluate impacts on quality.

Files need to be updated timely with relevant research information and appraisal reports when critical changes occur. Relevant drug formulation manufacturers should be notified prior to any file modifications. Drug formulations manufacturers should be aware of any changes to APIs and IPIs used, conduct relevant research and appraisals, submit relevant applications in accordance with related drug registration regulations and conduct auditing of APIs/IPIs following changes.

Chapter IV governs the use of filed information. It is provided that all drug formulations under registration must provide filing numbers of their APIs/IPIs and those applications using unfiled APIs/IPIs will not be accepted. Filed information will be used in the evaluation process of drug formulations and researchers/manufacturers of drug formulations under registration should conduct audits of API/IPI suppliers and their QA/QC systems. Starting materials and intermediates can be audited if necessary. Drug regulatory agencies can use the filed information to investigate API/IPI origins when inspecting approved drug formulations.

Chapter V covers the management of filed information which is composed of open part, limited-open part, confidential part and filing numbers. Open part is accessible by the public, while drug formulation manufacturers can retrieve the limited-open part with authorizations from API/IPI producers and drug regulatory agencies can use the confidential part following confidentiality SOP after verifying holder authorizations.

APIs/IPIs used by drug formulation manufacturers must match with the filed information. Formulation registration applications and production should be suspended whenever such discrepancies are found. Producers filing untruthful information will have their file numbers withdrawn, publicized and banned from filing with the platform for five years.

Filed APIs and IPIs should be submitted together with drug formulation applications and status of such files will be activated when their related drug formulation applications are approved.

Filed APIs and IPIs not used in any drug formulations will be shown as "inactive". Filed APIs and IPIs inactive for more than five years will have their files withdrawn.

Chapter VI, the appendix, provides that any disputes between pharmaceutical formulation manufacturers and API/IPI suppliers should be resolved among themselves or through the court system. It also states that the filing and format requirements for different categories of APIs/IPIs, e-format and requirements of the filing platform, as well as the confidentiality SOP will be formulated separately.

State Council passes the *National Drug Safety Plan (2011-2015)*

An executive meeting of the State Council passed the proposed "*National Drug Safety Plan (2011-2015)*", according to a statement released on December 7 after the meeting presided over by Premier Wen Jiabao.

The 2011-2015 plan sets the general goal of "sharply" boosting the safety level and people's satisfaction with drugs by ensuring that all pharmaceutical products meet the standards of a newly revised regulation on medical product quality management by the end of 2015, the statement said.

The plan sets forth overall objectives and major tasks of drug safety in the 12th Five-Year Plan period. The seven primary drug safety tasks in the period include:

- *Raising national standards*: Harmonizing Chinese standards for chemical drugs and biological products with the international norm, and leading the development of international standards for traditional Chinese medicines.
- *Improving the system for drug testing and examinations*: Stepping up infrastructure building for national level institute for control of drugs and enhancing the laboratory facilities of provincial and prefectural level institutes.
- *Strengthening quality control of drugs and medical devices throughout the full manufacturing process*.
- *All drug products approved for marketing should be regulated under a standard coding system and e-regulation should cover all drug products*.
- *Boosting drug safety monitoring and early alert*: Refining surveillance of adverse drug reactions and drug abuse, and improving post marketing appraisal of drugs.
- *Elevating the supply capabilities of national essential drugs*: Strengthening sampling, tender, procurement, use and quality control of such drugs.
- *Establishing a long term drug safety regulatory mechanism*: Perfecting the product recall system for problem and exiting drugs. Developing credit rating of pharmaceutical enterprises, and banning serious violators and companies with poor credit from the pharmaceutical industry.
- *Deepening reform and improving legal framework*: The system reform of drug related approvals should be deepened with stringent standards and streamlined processes. The order of pharmaceutical distribution sector should be regulated and the layers of drug distribution process should be reduced.

SFDA demands XiAn Janssen to take risk control actions on CAELYX and Velcade

China's State Food and Drug Administration (SFDA) warned on December 7 of safety risks related to the use of the AIDS-related cancer-fighting medication Caelyx and Velcade, drugs used for treating myeloma and lymphoma.

The warning came after European Medicines Agency gave interim recommendations to deal with shortcomings in the quality of the two medications produced at Ben Venue Laboratories.

A joint GMP inspection of the Ben Venue Laboratories' manufacturing site in Ohio, USA (where a number of sterile medicines are manufactured) by the UK and French medicines regulatory agencies together with the USFDA in November 2011 highlighted several shortcomings in the quality management system. During the inspection, Ben Venue decided to cease all manufacture and distribution of medicines from its site. Ben Venue is a unit of Boehringer Ingelheim.

Two products manufactured at the facility, Caelyx (Doxorubicin Hydrochloride Liposome Injection) and Velcade (Bortezomib for Injection) are currently marketed in China by XiAn Janssen Pharmaceutical. While there are Chinese producers of Bortezomib for injection, Velcade is the only approved Bortezomib injection product in China.

Following the U.S. and European actions, the SFDA has conducted risk assessments of the two products. It has recently requested XiAn Janssen to 1) voluntarily recall all batches of Caelyx and stop new sales of Velcade immediately; and 2) notify potential risks to physicians and patients, advise patients on Caelyx to switch to other similar drugs and continue use of Velcade with existing patients only with their consents.

According to SFDA, XiAn Janssen is already taking actions in accordance with its requests.

SFDA demands prosecution of pharma companies involved in making fake drugs

The SFDA issued a statement on December 9 demanding local food and drug authorities to prosecute a number of pharmaceutical manufacturers and retailers which were caught to make or distribute fake and counterfeit drugs in the latest campaign of the Ministry of Public Security for cracking down on such products.

Among all those caught, the SFDA exposed the names of six drug retailers and four pharmaceutical companies including Wuhu Sanyi Pharma, Jiangxi Furentang Pharma, Sichuan Taishan TCM Crude Drug and Sichuan Jinyuntang TCM Crude Drug.

Guangdong to revise prices of 99 WMs

After slashing prices of over 500 formulated traditional Chinese medicines, Guangdong's price authorities recently announced that it is revising prices of 99 Western medicines of 441 specifications, all of which are OTC drugs and products under provincial price regulation.

Among all, prices of 307 drug product specifications were reduced by an average of 22%, while the rest 134 are kept at the same price.

It is reported that supplemental medicines for immune-regulation were impacted the most by the price cut.

Legal/IPR News

Foreign companies have an upper hand in the Chinese biopharmaceutical patent landscape?

The State Intellectual Property Office of China (SIPO) recently organized a research of biopharmaceutical patents in China, according to an article in the *International Business Daily*, a leading Chinese business newspaper under the Ministry of Commerce. Categories of Chinese biopharmaceutical patents covered include vaccines, diagnostic reagents, recombinant protein drugs, therapeutic antibody drugs, nucleotide drugs and blood products.

The research outcome shows that, at least by some measures, foreign companies have taken the biopharmaceutical patent high ground in China especially with therapeutic antibody drugs. In the biopharmaceutical sector, foreign companies have filed a total of 14,930 Chinese patent applications and 3,865 patent approvals have been issued to them thus far.

Schering AG, Novartis, Wyeth (now part of Pfizer), Genentech and Hoffman La Roche are among the most active foreign biopharmaceutical patent applicants, and their patent applications in the past three years represent respectively 45%, 41%, 39%, 51% and 48% of their total number of biopharmaceutical patent applications in China.

Foreign companies are especially strong for patents of therapeutic antibody drugs with 1,449 patent approvals so far, which is 1.6 times of Chinese patent approvals (932) for the category. Schering AG, Genentech, Novartis, Chugai Pharma and Wyeth are the top five leaders in terms patent applications in this category with 181, 150, 104, 96 and 90 such applications.

On the other hand, domestic applicants have filed a total of 16,914 biopharmaceutical patent applications in China and they have received 4,693 approvals, accounting for 54% and 55% of all Chinese biopharmaceutical patent applications and approvals.

Chinese applicants have slightly higher number of patent approvals in the categories of diagnostic reagents, recombinant protein drugs, nucleotide drugs and blood products. Leaders of Chinese biopharmaceutical patent holders are: Suzhou Aijie Biotech (826 approvals), Fudan University (623), Zhejiang University (323), Shanghai Human Genome Research Center and Zhongshan University (160).

Although Chinese companies have prevailed with more Chinese biopharmaceutical patent applications and approvals, few such patents are industrialized or commercialized, the research suggests. In addition, the general quality of such patent applications and approvals is not high with their protection scopes being rather narrow, the study found.

WiCON

China Pharmaceutical Guide 2011

中国医药指南

Sihuan Bio sues Vitapharm for patent scam

Jiangsu Sihuan Bioengineering Co., Ltd. recently filed a lawsuit against Beijing Vitapharm Technology Development Co., Ltd., claiming the licensing deal between the two companies to be a patent scam of the latter, according to a recent company filing by Jiangsu Sihuan Bio. The litigation was already accepted by the Beijing No.1 Intermediate People's Court.

Jiangsu Sihuan Bio announced last September that it entered into a technology transfer and licensing agreement with Beijing Vitapharm under which the latter would transfer the China rights of its Australian-patented sublingual delivery technology for IL2, IFN and other bio active tablets to Beijing Sihuan Biopharmaceutical Co. Ltd., a subsidiary of Jiangsu Sihuan Bio. In return for the technology transfer and license, Jiangsu Sihuan Bio agreed to transfer a 45% stake of Beijing Sihuan Biopharma, which was valued at CNY 100 million, to Beijing Vitapharm.

Jiangsu Sihuan Bio now claims that it transferred the said stake of Beijing Sihuan Biopharma to Beijing Vitapharm following the contract signing, but has yet to receive any technology transfer. Furthermore, the company only discovered recently that the supposedly Australian-patented technology under the contract is not patented at all in Australia and it only has a patent application number which was already expired in 2008.

Subsequently, Jiangsu Sihuan Bio filed the above lawsuit demanding return of the 45% stake of Beijing Sihuan Biopharma from Beijing Vitapharm and withdrawal of the above contract between the two parties. In addition, the company also reported the case to the police, requesting criminal prosecution of Thomas SaiYing Ko (高世英), the owner of Beijing Vitapharm. Chinese reporters were unable to reach Ko for his response to the case.

The management of Jiangsu Sihuan Bio has been widely criticized by investors and analysts for its incompetence in this case and failure to carry out appropriate due diligence before entering into major contracts.

APIs/Bulk Drugs

Huahai Pharmaceutical to raise CNY 1.3B for expansion

Zhejiang Huahai Pharmaceutical (600521) plans to issue up to 100 million new shares to raise a maximum of CNY 1.33 billion, according to a company filing. Proceeds will be invested into the production of blood thinner crude drugs and pharmaceutical formulations.

Huahai Pharmaceutical's operating revenue rose 109% year-on-year to CNY 920 million in the first half of 2011, while net profit increased 122% year-on-year to CNY 132 million. Revenue generated from sartans, a series of blood thinner bulk drugs, surged 130% year-on-year.

Sinochem DSM builds a new semi-synthetic cephalosporin plant

Sinochem DSM Pharmaceutical, a joint venture of Sinochem and DSM, laid foundation on December 9 in Zibo city, Shandong

province of a new plant which will manufacture new types of semi-synthetic cephalosporins (SSCs) using innovative biotechnology processes.

The new plant is expected to become operational in early 2013. Compared with the traditional manufacturing processes, the new proprietary enzyme technology and processes to be employed at the new facility are expected to slash energy consumption, waste disposal and industrial air emission by 66%, 90% and 50% respectively.

Sinochem DSM specializes in the R&D, production and distribution of raw materials, intermediates and APIs of anti-infective drugs. It already has a manufacturing facility in Zibo city for the first generation of cephalosporins.

Sinochem DSM has recently introduced a new China business growth strategy which seeks to strengthen its beta-lactam products and expand the share of APIs.

Product and R&D News

TCM found to be more effective for female infertility than pharma options

Australian researchers at Adelaide University have created hope for women suffering from infertility as a recent study sheds new light on effectively treating women with infertility issues with Traditional Chinese Medicine. The research, titled "Efficacy of Traditional Chinese Herbal Medicine in the Management of Female Infertility: A Systematic Review" concluded that using TCM methods improved pregnancy rates as much as 2-fold in just a 4-month period in comparison with Western Medical fertility enhancement drug therapies.

The research, funded by the Australian government, involved reviewing 30 previously conducted studies that included more than 1,800 women with fertility challenges.

In addition, the Australian study also concluded that the use of specific herbal treatments tailored to treat the individual's reproductive systems and particular fertility challenges played a crucial role in the success of the treatment.

Sino-Danish researchers discover anti-cancer compounds from mushroom

A Sino-Danish research team has identified a new class of compounds in a common mushroom, which could be used to develop cancer-beating drugs, the University of Copenhagen said on December 8.

According to Soeren Broegger Christensen, a professor of natural products research at Copenhagen University's Faculty of Pharmaceutical Sciences (Pharma), whose team led the research, the mushroom's unique chemical structure could make it a potent weapon in the battle against cancer cells. The team isolated certain active compounds from the mushroom, which are particularly aggressive towards cancer cells.

According to Christensen, the mushroom is 100 times less active, and significantly less toxic, towards benign human cells than malignant cancer cells, based on laboratory models.

Two new pharmaceutical research institutions established in China

Three institutes under the Chinese Academy of Medical Sciences (CAMS), including the Institute of Materia Medica (IMM), the Institute of Medicinal Biotechnology (IMB) and the Institute of Medicinal Plant Development (IMPLAD), have agreed to merge into the new Academy of Materia Medica under the CAMS.

The move seeks to strengthen R&D capabilities of the three institutes through resource consolidation and research integration.

The new academy was officially inaugurated on December 17 and its first president is Jiang Jiandong, the president of IMM.

In a separate development, 19 leading pharmaceutical and traditional Chinese medicine companies in Quizhou province established a private drug research platform, Guiyang Modern Pharmaceutical Research Institute. Core sponsors of the institute include Quizhou Yibai Pharma and Quizhou Tongjitang Medicine.

The 19 pharmaceutical enterprises hope to build the institute into an advanced drug innovation service platform which is open to all drug companies in Guiyang city, capital of Guizhou province.

General Health

State Council reaffirms healthcare reform direction with review of new documents

The State Council held a full meeting of its Leaders Group for Deepening Pharmaceutical and Health System Reform on November 29 and Vice Premier Li Keqiang chaired the meeting.

Li acknowledged the healthcare reform progress in the past three years and demanded consolidation of the reform achievements and completion of the *Plan for Deepening Pharmaceutical and Health System Reform during the 12th Five-Year Period (2012-2015)*.

The meeting reviewed the above plan as well as a few other important healthcare reform documents including the "Guiding Opinions for Reform Trials of County Level Public Hospitals" and the "Mid-term Assessment Report of the Implementation Plan for Deepening Pharmaceutical and Health System Reform (2009-2011)".

The meeting claimed success over the five primary tasks in the above implementation plan with expansion of the basic medical insurance system (BMI) to cover 1,295 million or 95% of the Chinese population, initial establishment of the national essential drug system in primary healthcare, reduction of essential drug prices by an average of 16.9%, improvements of primary healthcare system infrastructure, rising patient visits to primary healthcare institutions, increased government investments into essential and major public health services, as well as reform trials and phased reform implementation at urban and county level public hospitals respectively.

Li upheld the core reform principles of 1) healthcare as a public welfare item; 2) essential and universal coverage of the BMI system; and 3) restructuring healthcare mechanisms with emphasis on prevention, rural healthcare and co-existence of traditional Chinese and Western medicines.

He said the objectives in the next phase of healthcare reform will

move from "expanding coverage" to "raising its quality" of the BMI system, from "strengthening" to "full development" of primary healthcare, from "conducting trials" to "full implementation" of the public hospital reform, and from "upgrading hardware" to "centering on service improvements" of the healthcare system.

Li also called for increased government subsidies of the BMI system on the basis of its continuous coverage expansion, exploration of a major medical coverage mechanism, active development of commercial health insurance, expansion of the national essential drug system to village clinics and non-public primary healthcare institutions; establishment of a new order for pharmaceutical production and distribution, and streamlining of drug pricing mechanisms.

In a related development, the National Audit Office of China reported findings of its recent field survey of primary healthcare infrastructure building in ten provinces or central municipalities for the past three years. The survey was conducted through financial auditing and meetings with primary healthcare professionals and local officials.

Problems discovered in the field survey include 1) positioning of primary healthcare remain unclear despite improved facilities and hardware (as rural population is now very transient and access to county hospitals are easy); 2) primary healthcare institutions find it hard to retain talents; and 3) financial difficulties are experienced by primary healthcare institutions following introduction of the zero-margin policy on essential drug sales (as promised government support of such institutions is not fully facilitated in many localities).

MOH outlines cost containment measures implemented at public hospitals

In an effort to showcase to the public that it has taken concrete actions on cost containment of healthcare expenditures, the Ministry of Health (MOH) issued a statement on December 13 to outline the five areas of cost containment measures implemented by health departments at different levels in public hospitals.

Firstly, health departments have adopted measures including overall hospital expenditure control, itemized expenditure limits, and expenditure target control to set goals of healthcare cost containment and to assign responsibilities to hospitals and their personnel. In addition, health departments also established cost containment contracts with public hospitals which link government subsidies and income of hospital directors with cost containment performance.

Secondly, internal hospital management has been strengthened to train physicians about cost containment and professional ethics. Clinical pathways, drug prescription evaluation, medical service information publication, innovative healthcare services, and new hospital accounting and financial control systems were implemented.

Thirdly, measures including improved centralized drug purchase tender system, crackdown of corruptions in drug sales, approval mechanism for high-end medical equipment, prioritized use of essential drugs, promotion of appropriate medical technologies, and mutual recognition of test results by hospitals at the same level were adopted in public hospitals to cut costs of healthcare services.

Fourthly, incentive and penalty mechanisms including strengthened inspections, early alert system for drug usage,

programs against antibiotic abuse, and auditing of hospital finance were established or improved. Additionally, experiment of BMI medical expenditure reimbursement reform models including disease-related group (DRG), headcount-based reimbursement and lump-sum prepayment were carried out by various local governments.

Fifthly, the medical service provision was restructured to encourage initial patient visits to primary healthcare and classified medical services through primary healthcare infrastructural improvements, BMI reimbursement policy revision, as well as mutual referral schemes between hospitals and primary healthcare institutions.

Furthermore, the MOH reported that China's outpatient and inpatient medical expenditures grew 0.3% and fell 0.1% respectively in the first half of this year, indicating progress of its cost containment efforts.

BMI agency to take over essential drug purchase tendering in Shanghai

As the reform of China's hospital drug purchase tender system staggers with little progress and increasing disputes, a fresh development has emerged recently, offering a glimpse of hope to at least some.

According to Shanghai's Municipal Health Department and Municipal Human Resource and Social Security Department, the city's basic medical insurance (BMI) agency will take over the responsibility of essential drug purchase tendering from next year. It is likely that the move will be expanded to tender purchase of all drug products under the national drug reimbursement list (NDRL) under the BMI system.

Hospital drug purchase tendering has always been the territory of health authorities, not BMI agencies which are under human resources and social security departments. The move by Shanghai is a courageous experiment which has no precedence nationwide and therefore indicates a new reform direction for hospital drug purchase tendering.

Stakeholders have mixed feelings of the new direction. Pharmaceutical companies are wary of the possibility that the BMI agency in Shanghai may over-emphasize drug prices, while health department officials question the professional competence of human resource & social security officials in drug quality assessment and assurance. Meanwhile, the arguments in support of this move are indeed centered on BMI agency's vested interest in cost containment.

But it remains to be seen how this change will strengthen control of drug expenditures, after-all, the drug prescription right continues to be in the hand of physicians as some pharma executives point out.

The latest development in Shanghai has actually long been planned under the city's healthcare reform plan, according to Gao Jiechun, Director of the Hospital Management Institute under the Fudan University.

Gao disclosed that the city's BMI agency will only take charge of the essential drug purchase tendering at the frontline and medical institutions will eventually decide what and how much to purchase. He said that medical institutions would negotiate with suppliers again before making purchases and claimed that such practices of "secondary tendering or negotiations" are legal under the *Government Procurement Law of PRC*.

Nonetheless, the central government's new drug purchase tender policies specifically seek to eliminate such secondary tendering and negotiation practices.

Gao, on the other hand, proclaims that this measure is in fact derived from Shanghai's "Minhang model" for hospital drug purchase tendering which has won support of the State Council.

CDS initiates largest clinical research of base insulin in China

The Chinese diabetes Society (CDS), a part of the Chinese Medical Association, initiated the largest ORBIT registry research of base insulin therapy in China on November 23.

The research seeks to assess efficacy and safety of the base insulin therapy in Chinese type II diabetes patients (after six months of treatment) who do not respond well to oral blood glucose lowering drugs. A total of 20,000 such patients nationwide will be enrolled.

The research also hopes to discover a series of factors affecting efficacy and safety of base insulin therapy in such Chinese patients.

Preliminary outcome of the research project is expected to be released before the end of 2013.

New study: Increased Western medicine practices at TCM hospitals in China

Scientists from the Research Institute of Health Development Strategies in Fudan University in China have published a comparison of Chinese hospitals practicing traditional Chinese medicine and those practicing conventional Western medicine.

The study generated the fascinating trends and observations: "Western medicine has become a vital revenue source for TCM hospitals in the current Chinese health care environment where government subsidies to health care facilities have significantly declined. Policies need to encourage TCM hospitals to identify their own special and effective services, improve public perception, increase demand, strengthen financial sources, and ultimately make contributions to preserving one of the national treasures."

Key findings of the study are as follows:

For TCM hospitals, the percentage of service revenue from Western medicine increased from 44.3% to 47.4% while the percentage of service revenue from TCM declined from 26.4% to 18.8% from 1999 to 2004. Percentages of revenue from laboratory tests and surgical procedures for both types of hospitals increased and the discrepancy between the two types of hospitals was narrowed from 1999 to 2004. Revenues of TCM hospitals from laboratory tests increased from 3.64% to 5.06% and those from surgical procedures increased from 3.44% to 7.02%.

General hospitals' TCM drug revenue in outpatient care declined insignificantly from 5.26% to 3.87%, while the decline for the TCM hospitals was significant from 19.73% to 13.77%. The national statistics from 1999 to 2008 showed similar trends that the percentage of revenue from Western medicine for TCM hospitals increased from 59.6% in 1999 to 62.2% in 2003 and 66.1% in 2008 while the percentage of revenue from TCM for TCM hospitals decreased from 18.0% in 1999, 15.4% in 2003, and 13.7% in 2008.

Essential drugs to be traded in Chongqing Drug Exchange

The Chongqing Drug Exchange (CDE) will initiate trading of all essential drugs from December 29, according to a recent essential drug procurement conference of Chongqing city. Subsequently, medical institutions can only purchase essential drugs through the CDE.

Currently all primary healthcare facilities in Chongqing have already implemented the zero drug sales margin policy, while prices of essential drug products were reduced by an average of 30.48% this year. However, there are still unresolved issues including short supply of drug products with excessively-low prices and poor delivery capability to remote areas.

The situation will be improved following trading of essential drugs thru the CDE, said Qian Qiu, director of the city's health department.

Qiu said the CDE will set reference prices on essential drugs after conducting surveys of their actual ex-manufacturer prices on the market and all transactions must be kept below reference prices. The essential drugs will be centrally purchased, delivered, settled and regulated after being listed at the CDE, he added.

The CDE will classify essential drug products into three separate lists, namely the list of common essential drug products, the list of low-priced essential drug products and the list of elective essential drug products, which are designed to meet diverse demands of different areas.

The CDE will also request the BMI system and the government to advance funds ahead of each round of centralized essential drug purchase in order to ensure payments to suppliers within 60 days after acceptance of their deliveries by medical institutions.

In addition, the CDE will establish credit rating and penalty systems to prevent irregularities including document forgery, price manipulation, poor quality and failures to supply drugs according to contract terms.

The CDE disclosed that all 182 county level and above public medical institutions are now members of the CDE after trading of non-essential drugs began last December. The prices of such drugs have been reduced by an average of 28% this year.

China's HIV/AIDS-infected population estimated to account for one-fifth of the world total

China currently has 346,000 registered HIV carriers and AIDS patients, although the actual number is predicted to hit 780,000 by the end of 2011, according to an expert panel consisting of members from China's Ministry of Health (MOH), the World Health Organization and UNAIDS.

The panel estimated that the country will have 154,000 AIDS patients by the end of 2011, with 48,000 new infections and 28,000 deaths this year, according to a statement released by the MOH on November 29.

China has been boosting distribution of HIV/AIDS tests among spouses of carriers and others who have close contact with them, the statement said, adding that a total of 67.45 million HIV tests were conducted across the country between January and October, up 16.5 percent year-on-year. These tests found 61,000 HIV carriers and AIDS patients.

People in the News

Former SFDA Deputy Commissioner prosecuted for corruption

Zhang Jingli, former SFDA Deputy Commissioner, was recently prosecuted at Beijing's No.2 Intermediate People's Court for corruption, fabricating lies about/framing others and profiting from illicit businesses.

Specific charges by the prosecution include bribes totaling CNY 1.18 million and illegal revenues of over CNY 23 million from sales of more than 43,000 sets of a TCM health preservation publication authored by Zhang. In addition, he is accused of being behind more than 1,300 letters sent to the disciplinary inspection agencies and the Chinese leadership to frame other officials, specifically SFDA Commissioner Shao Mingli.

Zhang was present in the court and pleaded guilty to only some of the charges which were unspecified by local press reports. However, he pleaded not guilty to other charges.

Chongqing's drug purchase tender official sentenced five years for corruption

Deng Xianbi, a deputy inspector with the Chongqing Municipal Health Department and the Director of Chongqing Municipal Drug Purchase Tender Office, has recently been handed a sentence of five year imprisonment for accepting bribes in the amount of CNY 95,000 between 2008 and 2010. In return for the bribes, Deng provided assistances to help the two bribing pharmaceutical companies prevail in the drug purchase tender process.

Deng pleaded guilty to all charges and returned his illegal incomes. He did not, at this point, indicate if he will appeal for lighter sentences.

Recent executive moves

Jingsong Wang has recently been appointed Head of China R&D and Head of Translational Medicine Asia Pacific at Sanofi. He was previously Liaison to BMS China R&D Center, Discovery Medicine & Clinical Pharmacology and Director, Discovery Medicine at Bristol-Myers Squibb, Princeton, New Jersey.

Zhang Ming-Qiang joined Merck as vice president and site head of MSD R&D Asia earlier this year. He was formerly chief technology officer at Roche's R&D Center in Shanghai.

Weiping Yang has resigned from the position of Chairman and CEO, Fresenius Kabi China to pursue personal interests. He was succeeded by **Luc Depotter** who was CEO of Fresenius Kabi Taiwan. Yang has worked with Fresenius since 1994 holding many important positions. Between 2003 and 2005, Dr. Yang left Fresenius briefly to become the President of Beijing Double Crane Pharmaceutical Ltd.

WiCON

China Pharmaceutical Guide 2011

中国医药指南

Jianqiu Ge has resigned from his post as Vice President in Shanghai Pharmaceutical Holding Co., Ltd. He used to be a director with Credit Suisse, a Senior Vice President in Shanghai Site of BNP Paribas, Executive Director in Shanghai Site of UBS AG. He holds a Bachelor's degree in International Law from East China University of Politics and Law, and a Master's degree in Law from Columbia University.

ShangPharma Corporation announced on December 13 that its President and Chief Operating Officer, **Kevin Chen**, has resigned from his executive posts to pursue new professional opportunities effective early December 2011. He will continue to serve on ShangPharma's board of directors.

Evan Goldberg has been promoted to Senior Director, Strategy & Business Development at Pfizer China from previously Director, Strategy & Business Development. He was Director, Strategic Planning & New Business Development with Wyeth Pharmaceuticals China before the company was taken over by Pfizer.

Jeffrey Jian has been appointed Marketing Director at AstraZeneca China this month. He was with Pfizer China for more than four years previously as a senior marketing manager. Before joining Pfizer China again in 2007, Xiong was a group product manager with BMS China and a product manager with Pfizer China and Novartis China.

Roche China has promoted **Eric Zhan** to Head of Market Access Strategic Team from the previous position of Strategic Project Manager, National Market Access. Before Roche, he was an Associate Strategic Project Manager with GSK China.

Gorden Chen has recently been promoted to Associate Director at MSD China. He was previously Marketing Manager, Portfolio Management & New Product Planning. Before joining MSD, he was a Senior Business Development Manager with GSK China and Baxter China respectively, and before that the Head of Marketing at Nutricia China.

Xiaoliang Fu has been promoted to Project Portfolio Manager for PS site at Novo Nordisk China. He was a project manager with the company.

Dr. Taiming Chu has become Director of Tailored Product-Growth Platform, Surgical Devices at Covidien and she is based in Shanghai. Before joining Covidien, she was VP of Business Development at AspireTech Solutions, Inc.

Medtronic China has recently appointed **Clement Chan** as its Marketing Manager. He continues to hold the position of Senior Marketing Manager at Medtronic.

ICON announced that its Development Solutions division had appointed **Dr Daniel Tang** as General Manager, Asia Pacific. Prior to joining ICON, Dr Tang was Vice President of Operations and Bioassay/DMPK at Frontage Laboratories Inc. and Vice President DMPK at ChemPartner Inc.

Hogan Lovells has strengthened its Greater China IP practice with the latest hire of **William "Skip" Fisher** in Shanghai. His move follows on from the recent hire of outbound China IP partner **Song Zhu** based in San Francisco.

Other News

China to pump CNY 10 trillion into seven strategic industries over five years

China confirmed to visiting U.S. officials that Beijing plans to pour CNY 10 trillion (US\$1.7 trillion) into the so-called "strategic sectors" over the coming five years, U.S. Commerce Secretary John Bryson told reporters on November 22. The package is 2.5 times as big as the eye-popping CNY 4 trillion fiscal stimulus launched during the global financial crisis in 2008.

The confirmation of the huge sum of money showed Beijing's ambition to shift the growth engine of the world's No.2 economy to cleaner and hi-tech sectors while also boosting domestic growth as the global economy struggles.

The targeted sectors include alternative energy, biotechnology, new-generation information technology, high-end equipment manufacturing, advanced materials, alternative-fuel cars and energy-saving and environmentally friendly technologies.

To fulfill the spending target, the central Chinese government itself would most likely not deliver the bulk of the money, but would seek to spur spending by corporations, investment by local governments and lending by banks.

Chinese media initiates another wave of bashing "excessively high drug prices"

Chinese media, led by the state-owned CCTV, recently started a new wave of exposing "excessively high drug prices". In a CCTV investigation that lasted a year, the investigative journalists reportedly picked 20 drug products at random and found their profit margins (between ex-manufacturer prices and final retail prices) to be over 500%.

The CCTV report quoted a number of pharmaceutical industry whistleblowers as saying that such margins are common industry-wide and some products can have margins as high as 3,000%. They also revealed to the CCTV detailed insider-rules and business practices throughout the pharmaceutical distribution process.

Furthermore, the said insiders provided the CCTV with product catalogs of over 100 pharmaceutical manufacturers involving more than 10,000 drug products and many common medicines for pneumonia, gastritis and pain were found to have margins over 400%.

In two extreme cases, the margins (between ex-manufacturer prices and hospital retail prices) of 2 ml/4 mg-Lappaconitine Hydrobromide injection of Tianjin Pharmaceutical Group's Xinzheng Co. and 2 ml/20 mg-Nefopam Hydrochloride injection of Shandong Fangming Pharma were found to be over 6,500%.

WiCON

China Pharmaceutical Guide 2011

中国医药指南

WiCON

China Pharmaceutical Guide 2011

中国医药指南

"Wikileaks of Chinese pharma" reveals sensitive ex-manufacturer drug price info online

A whistleblower who published ex-manufacturer prices of thousands of drugs online claims to have received threats from pharmaceutical companies. The site, which is dubbed by some as the Wikileaks of Chinese pharma, lists ex-manufacturer and retail prices of more than 14,000 commonly used medicines.

The founder of the Jiangyaojia.com website goes by the alias "Wei Baixing" - which translates as "for the people". Wei, who claims to be a former executive with a drugs firm, launched the site this month, vowing "to disclose the real cost of drugs" and calling on people "to reject expensive medicines".

Many visitors to the website were shocked to discover that the retail prices of most of the drugs listed were more than 10 times their factory prices, Chinese media reported. One web user said: "a cough medicine was only CNY 3.3 at the ex-manufacturer price, but I paid CNY 46 for it!"

Wei claims to have received several threatening letters from pharmaceutical companies. One company asked him to delete the prices, otherwise they would shut down the site, Wei claimed.

"I publish the prices of drugs to support calls for the country's health care system to be reformed and to benefit the public. I will stick to it," Wei told the media. He hopes the website will put pressure on hospitals and pharmacies setting retail prices.

Upcoming events

Event: 2nd Annual OTC Pharma Asia 2012
Dates: March 14 - 16, 2012
Venue: Grand Copthorne Waterfront Hotel, Singapore
Weblink: www.otcpharmaasia.com
Tel: +65 6508 2401
Email: register@ibcasia.com.sg

Event: Antibodies Asia 2012
Dates: February 20 - 23, 2012
Venue: Grand Hyatt Shanghai, China
Weblink: www.antibodiesasia.com
Tel: +65 6508 2401
Email: register@ibcasia.com.sg

Event: Cell Line Development & Engineering Asia
Dates: February 21 - 23, 2012
Venue: Grand Hyatt Shanghai, China
Weblink: www.celllineasia.com
Tel: +65 6508 2401
Email: register@ibcasia.com.sg

Event: 9TH Annual BIO Asia International Conference
Dates: January 31 - February 1, 2012
Venue: TBD, Osaka, Japan
Weblink: www.bio.org/bioasia
Tel: +1 202 962 6666
Email: bioasia@bio.org

Event: Pharma Product & Brand Marketing in Asia 2012
Dates: February 20 - 21, 2012
Venue: Sheraton Towers, Singapore

Weblink: http://conferences.com.sg/conf-pharma2.htm
Contact: Ms Karen Soh
Tel: +65 6592 7362
Email: karen@conferences.com.sg

Event: 2nd Annual Biopharma & VacTech China 2012
Dates: April 24 - 25, 2012
Venue: TBD, Shanghai, China
Weblink: www.biopharma-china.com
Contact: Cady Sun
Tel: +86 21 5172 0126
Email: cady.sun@jfpsgroup.com.cn

Event: Next Generation Sequencing Applications Asia
Dates: March 28 - 29, 2012
Venue: Amara Hotel, Singapore
Weblink: www.ngs-asia.com/Event.aspx?id=636768&MAC=PChina
Tel: +65 6722 9388
Email: enquiry@iqpc.com.sg

Event: World Pharmaceutical Manufacturing Congress 2012
Dates: April 24 - 25, 2012
Venue: TBD, Shanghai, China
Weblink: www.wpmcongress.com
Contact: Ben Ye
Tel: +86 21 6052 0431
Email: ben.ye@s-isc.com

Chinese Physicians Are More Digitally Savvy Than You Think

... continued from page 32

key customers - physicians? This question needs to be answered by the marketers who target physicians for concept shaping, branding, or direct selling. Despite large online customer exposure, active users and bloggers, and established online platforms, we are still missing a willingness to experiment and be creative online. As a consumer, a doctor has already experienced so much fun and efficiency in the "un-professional" side of his/her digital life (think of Taobao - Chinese equivalence of EBay, or Apple Apps, etc.). Therefore, the doctor has high expectations for the experiences professional marketers could provide with their "digital campaigns" (fun, engaging, interactive, rich in multimedia, easily searchable, etc.). An ordinary effort is just a recipe to fail - to a scientific/academic-driven marketer, engaging these physicians will become a real hurdle to jump.

About the Author

Simon Li, is General Manager for China. He can be reached at simon.li@kantarhealth.com. Kantar Health (<http://www.kantarhealth.com>) is a global, evidenced-based decision support partner to the world's leading pharmaceutical, biotech, device and diagnostic companies. With 700+ staff act as catalysts and working closely with customers, Kantar Health is unique in bringing together clinical, medical and methodological expertise, commercial/marketing know-how and proprietary data.



Feature Articles

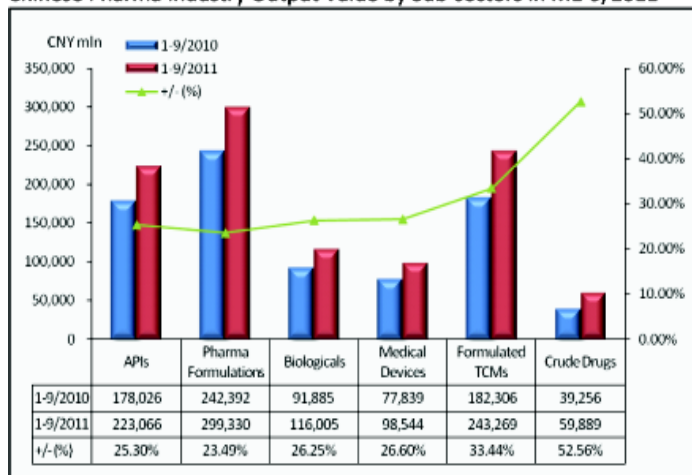
Review of Chinese Pharma Industry Performance in the First Three Quarters

According to official statistics released by the Southern Medicine Economic Institute (SMEI) under the SFDA, the output value and sales of the Chinese pharmaceutical industry surged 28.53% and 29.45% respectively in the first three quarters of 2011, reaching CNY 1,111,261 million and CNY 1,073,938 million respectively.

The following charts illustrate the rising performance of the six Chinese pharmaceutical industry sub-sectors.

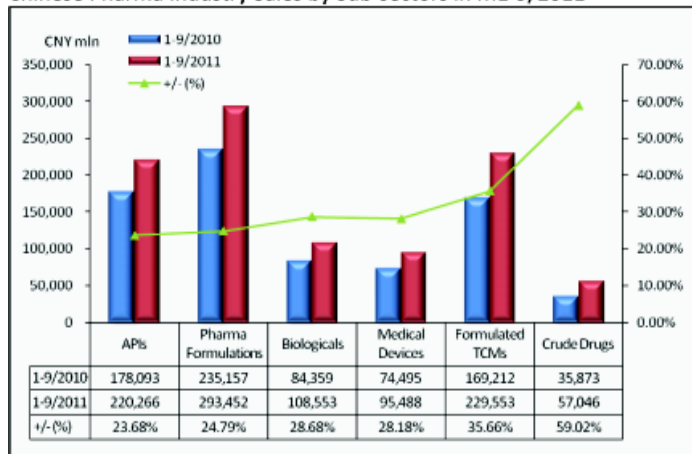
The output value and sales growth of the API, pharma formulation, biological product and medical device sub-sectors were held steady in the period at above 23%, while those were higher for formulated traditional Chinese medicines (TCMs) at 33% and 36%. Meanwhile, herbal crude drugs experienced the sharpest growth of all at 53%.

Chinese Pharma Industry Output Value by Sub-sectors in M1-9/2011



Source: SMEI

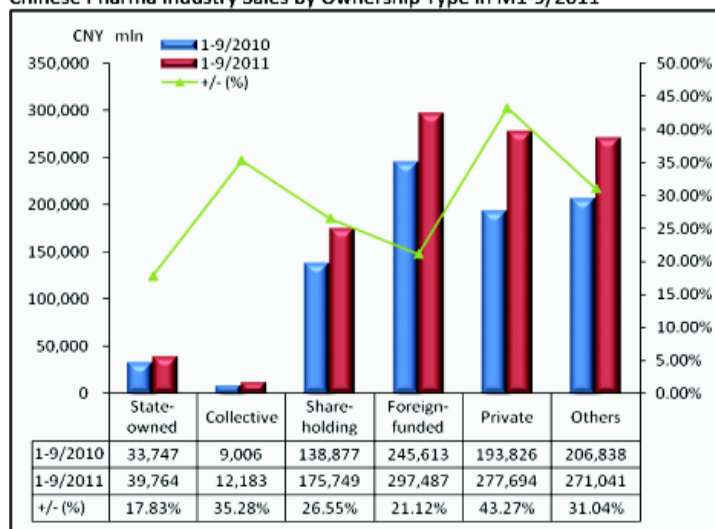
Chinese Pharma Industry Sales by Sub-sectors in M1-9/2011



Source: SMEI

State-owned pharmaceutical companies and foreign-invested enterprises had the lowest sales growth in the first three quarters at 18% and 21%, while shareholding and other enterprises fared slightly better at 27% and 31%. However, private and collectively-owned companies did much better with 43% and 35% revenue growth.

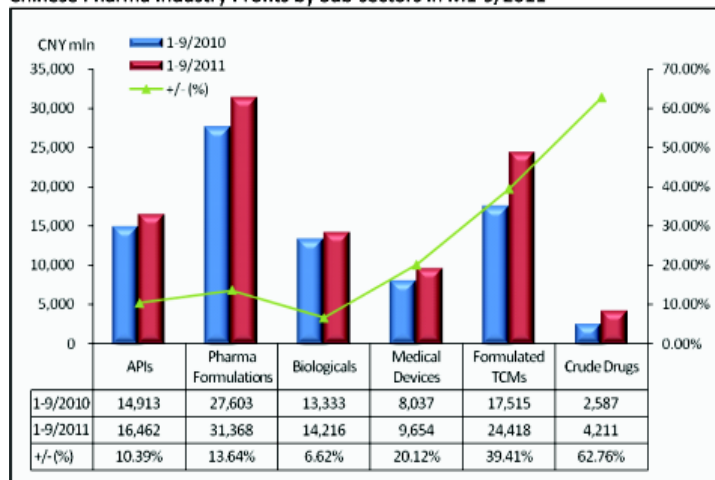
Chinese Pharma Industry Sales by Ownership Type in M1-9/2011



Source: SMEI

In terms of profitability, the API, pharma formulation and biological product sub-sectors had the lowest growth at only around 10% in the first three quarters, while such rates were much higher for formulated TCMs and herbal crude drugs at 39% and 63% respectively.

Chinese Pharma Industry Profits by Sub-sectors in M1-9/2011

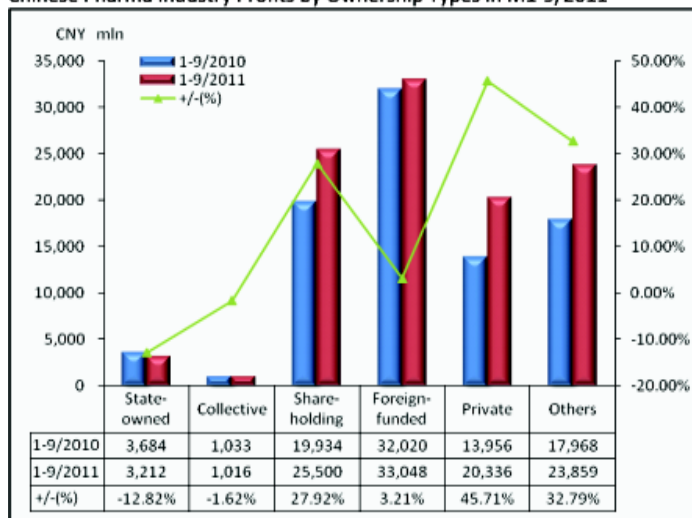


Source: SMEI

On the other hand, the profit of state-owned pharmaceutical companies was the lowest and actually fell 13% in the period, followed by collectively-owned companies (-2%) and Sino-foreign joint ventures (+3%). The profit of private (+46%), shareholding (+28%) and other companies (+33%), however, showed sharp profit growth in the first three quarters.



Chinese Pharma Industry Profits by Ownership Types in M1-9/2011



Source: SMEI

Export of medicines and health products grew 35.74% in the first three quarters, reaching US\$32,781 million. In the meantime, import rose faster at 46.41% to US\$20,948 million.

Import of APIs, pharma formulations and biological products grew 25%, 29% and 7% respectively, while their export surged 50%, 5% and 5% in the same period.

Foreign Trade of Medicines and Health Products in M1-9/2011 (US\$ mln)

Category	Import & Export		Import		Export	
	Total Value	Share (%)	Import Value	Share (%)	Export Value	Share (%)
APIs	21,682	40.35	5,139	24.53	16,543	50.47
Pharma Formulations	7,502	13.96	5,977	28.53	1,525	4.65
Biologicals	3,173	5.91	1,499	7.16	1,674	5.11
Medical Devices	19,171	35.68	7,813	37.30	11,358	34.65
Formulated TCMs	330	0.61	161	0.77	169	0.52
Crude Drugs	647	1.20	95	0.45	552	1.68
Others	1,224	2.28	264	1.26	960	2.93
Total	53,729	100.00	20,948	100.00	32,781	100.00

Source: SMEI

Chinese API Import and Export by Category in M1-9/2011 (US\$ mln)

Category	Export Value	+/- (%)	Share (%)	Import Value	+/- (%)	Share (%)	Trade Surplus	+/- (%)
Amino acids and their derivatives	875	+20.64	5.29	469	+12.39	9.13	406	+17.63
Aminoglycoside	89	+19.78	0.54	0	+598.72	0.00	89	+19.79
Macrolides	299	+55.68	1.81	26	+40.97	0.51	273	+54.38
Respiratory system	21	+38.58	0.13	0	-60.88	0.00	21	+38.57
Sulfonamides	40	-79.43	0.24	5	-93.48	0.10	35	-83.31
Hormones	451	+17.23	2.73	13	+3.33	0.25	439	+16.80
Antipyretic and analgesic	344	-45.92	2.08	4	-98.38	0.08	340	-60.46
Lincomycins	104	+35.23	0.63	0	-91.37	0.00	104	+34.07
Chloramphenicols	97	+51.62	0.59	0	+68.48	0.00	96	+51.64
Anaesthetics	15	+36.20	0.09	10	-33.65	0.19	5	-3.92
Other anti-infectives	924	+136.39	5.59	185	-16.34	3.60	739	+81.15
Other APIs	10,763	+70.82	65.06	4,014	+67.79	78.11	6,749	+69.99
Penicillins	445	+0.58	2.69	27	+23.43	0.53	418	+1.64
Tetracyclines	252	+66.72	1.52	5	+51.32	0.10	247	+66.39
Cephalosporins	330	-4.51	1.99	152	+3.67	2.96	178	-2.07
Vitamins	1,385	-23.08	8.37	207	+2.88	4.03	1,179	-20.48
Digestive system	31	-91.16	0.19	14	-52.80	0.27	17	-88.25
Cardiovascular system	0	-74.69	0.00	5	-24.44	0.10	-5	-30.37
Central nervous system	79	-89.68	0.48	5	-98.69	0.10	74	-92.65
Total APIs	16,543	+28.07	100.00	5,139	+23.04	100.00	11,404	+26.84

Source: SMEI

Stop Press

SFDA to continue crackdown of fake drugs in 2012

At the recent national food and drug regulatory conference held in Beijing, SFDA Commissioner Shao Mingli stated that the Chinese drug regulatory agencies will continue to crackdown on fake drugs with full force.

He confirmed that all pharmaceutical manufacturers involved with the production of fake drugs will have their relevant drug approvals withdrawn and those deliberately manufacturing fake drugs will have their pharmaceutical manufacturer licenses evoked. Besides, pharmaceutical distributors which lease out their licenses and invoices for fake drug distribution and which procure and supply fake drugs with knowledge of suspicious channels and certifications will have their pharmaceutical distribution licenses evoked.

Shao said that in the two-year drug safety correction campaign of the Chinese government between July 2009 and July 2011, all levels of food and drug administrative departments and other governments penalized 42,000 fake drug cases, prosecuted 537 of them and withdrew 70 GMP certifications.

Hengrui Medicine gains USFDA approval for its Irinotecan injection

Jiangsu Hengrui Medicine, a leading Chinese oncology drug company, announced on December 17 that it has received the USFDA approval for marketing of its generic oncology drug, Irinotecan injection, in the United States.

It is reportedly the first time for a Chinese pharmaceutical manufacturer to receive the USFDA approval for an injectable drug. Hengrui is believed have two other drugs for mental disorders, Cabepentin capsules and Risperidone tablets, under ANDA filing with the USFDA.

In addition, the company is expected to file ANDA applications for oncology drugs Docetaxel and Oxaliplatin with the USFDA and the European Medicines Agency soon.

Hengrui Medicine is reported to be developing two class one new oncology drugs which are under clinical studies. In May 2011, the company won SFDA approval of a class one new anti-inflammatory drug, Imrecoxib, which is a COX-II inhibitor.

Chinese pharmaceutical companies have geared up their efforts to penetrate the generic drug markets of developed nations in recent years through upgraded manufacturing facilities and improved regulatory capabilities.

Besides the latest USFDA gain by Hengrui, Huahai Pharma currently possesses eight ANDA approvals and Beijing Double Crane Pharma owns two such approvals for generic drugs in solid dosage forms.

China's Healthcare Outlook in 2012

By Yu Jingyi, *InterChina Consulting*, and Herman Schwieter, *VDS Healthcare*

China's healthcare industry is one of the most dynamic in the world. While the global healthcare market has stagnated recently, China's healthcare marketⁱ grew 25% in 2010 to US\$186 billionⁱⁱ.

Since China's healthcare reforms were fully implemented in 2011, China's basic medical care system for urban and rural residents now covers over 1.28 billion people, or more than 90% of its population. The market has created unprecedented opportunities for international companies with growth rates of 45% for imported pharmaceutical products and 59% for medical devices in the first six months of 2011ⁱⁱⁱ.

We looked at four sectors in this market, Prescription drugs, OTC, Medical Device and Health Food and, in anticipation of the year to come, gave a forecast of how these sectors will develop.

Prescription and OTC

In 2010, China's pharmaceutical market reached US\$112 billion with 22% growth as compared with the previous year, once again outperforming the global market, which grew at 4% - 5%^{iv}.

The impact of healthcare reform has been demonstrated by the shifts in market share among the big hospitals, pharmacies, community healthcare centers (CHC) and rural healthcare centers (RHC).

From 2007 - 2009, hospital sales grew by 27% per year, whereas OTC sales grew at only 7% per year. In 2010, while the overall growth rate for hospital sales slowed to 22%, OTC sales expanded dramatically. This was caused by the inclusion of OTC drugs on the reimbursement list under the new healthcare reform. This change will result in potential new sales to OTC pharmaceutical producers of at least US\$30 billion over the next 5 years.

As is the case for prescription drugs, high end OTC drugs are dominated by imported products due to the perception of their higher quality. Healthcare reform in China aims to expand health insurance coverage to reach the entire population in both urban and rural areas.

As part of this reform, The National Essential Drug List (NEDL) was introduced in 2009 to centralize drug purchasing for CHC and RHC in order to lower overall drug costs to the consumer. Implementation of the NEDL has resulted in the cost of listed drugs being reduced by 25%. The pharmaceutical market in China is on track to keep growing at 24% to US\$147 billion in 2011, and imported pharmaceuticals are expected to hold on to competitive advantages in pricing and drug bidding under current healthcare policy^v.

By the end of 2010, there were 27 websites approved to sell OTC products online. According to the SFDA regulation^{vi}, a website should be independent of hospital, pharmaceutical company, or government agency to be eligible to apply for the online drug store license. However, there are thousands of online

drug stores that are operating illegally, which will undoubtedly lead to even more regulation and control before this channel will become mature.

Although China's pharmaceuticals market is expected to grow at a rate of over 20% annually in the next few years, many US and European MNCs are having difficulty establishing market predominance in China. Despite the fact that half of the top 10 pharmaceutical companies in China are multinational companies, none of them holds more than 2.5% of the total market share^{vii}.

Because of this, many are contemplating a change of strategy which is expected to result in substantial staff reductions in 2012 and 2013.

Since 2006, many pharmaceutical MNCs have restructured their China businesses by establishing specialized sales teams for each business unit. MNCs believed such a structure would increase sales and profits; however, they have since discovered that adding staff does not automatically translate into increased sales. Instead, this increased focus on short-term

performance, along with high staff turnover, was found to damage corporate culture and raise training and recruiting costs. Over the same period, the output of each medical representative declined, and productivity also dropped off, leading to huge overhead costs. Many MNCs are now preparing to abandon this structure due to the high costs and its potential effects on profits.

Medical Devices

China's medical device market grew by 14% to US\$15 billion in 2010, accounting for 5% of the global market. While no more than 30% of pharmaceuticals are imported, 75% of the medical devices are imported or locally produced by the factories of

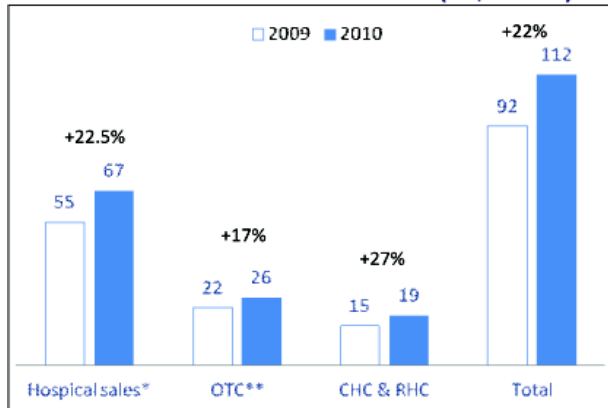
international companies. The huge market base and high overall growth rate have made China the most attractive medical device market in the world.

China has more than 6,000 medical device manufacturers, but since 90% of them are small companies which barely invest in R&D, it is rare for Chinese medical device companies to make real technological breakthroughs^{viii}.

Driven by increasing household income and growing health concerns, patients in China are willing to pay higher fees for access to better quality imported devices. Furthermore, the tendering policy which favors low priced products has not been fully implemented for medical devices. Under current policy, only medical devices with a price tag greater than US\$0.78 million are required to go through a tendering process. Therefore, from high end implants to commonly used consumables, all segments are dominated by imported products.

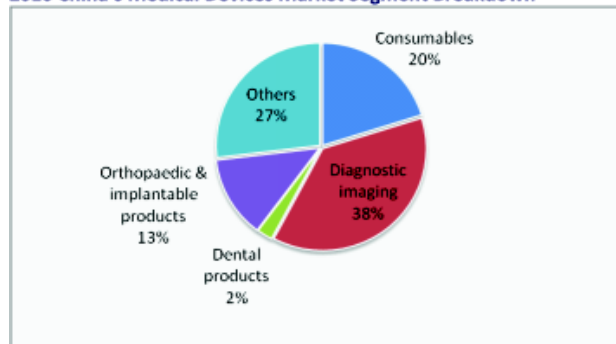
When we breakdown China's medical devices industry into

2009 - 2010 China Pharmaceutical Market (US\$ billions)



Source: Blue Book of 2010 China Pharmaceutical Industry

2010 China's Medical Devices Market Segment Breakdown



Source: Espicom estimates

product segments, the biggest segment is still diagnostic imaging equipment, which includes electro diagnostic apparatus and X-ray apparatus, followed by consumables. The performance of these two segments indicates that both hospital demand and hospital consumption have increased in China.

Currently the authorities are planning to revise the medical devices reimbursement policy in 2012. The current policy is based on procedures rather than the products. The procedure based reimbursement is restricting the hospitals to use expensive products when they want to maintain their income. In the next 2-3 years, China will have a reimbursement coding system that will include both procedure and products; this will create opportunities for more imported medical devices to be reimbursed.

Health food Market

In August of 2011, China issued new regulations on the health food market reducing the total acceptable health claims from 27 to 18, making it more difficult to make undocumented health claims in the sale of health food products. It is expected that these regulations will be revised further before the end of 2011.

Although this will raise the barrier of registration for health foods overall, the new regulations will have a much greater impact on locally produced health food products than on imported products.

From 2008 to 2010, the health food market experienced high growth rates of more than 35% each year, leading to a total market of US\$2 billion in 2010. This trend will likely continue for at least the next 5 years. Currently, no more than 6% of health foods in China are imported whereas the retail prices of all health foods are almost as expensive as those sold in Europe and the U.S.

The health food market was previously not as strictly regulated as the market for pharmaceuticals, however current trends largely driven by huge returns and unscrupulous local practices are forcing stricter regulations on the marketplace.

Although the value of the health food market has grown rapidly over the past few years, that growth mainly comes from retailers such as supermarkets and convenience stores rather than from pharmacies. Consumers also appear to trust the quality of imported health food over that of domestic. The market's need for high-end imported health food and the consumers' willingness to pay for such products will improve once the products have been proven safe and functional.

Synopsis

In summary, we anticipate another 25% growth in China's healthcare industry in 2012. Healthcare reforms will continue to drive the development of the pharmaceutical market, especially the OTC market and hospital sales of prescription drugs and medical devices will grow dramatically as more hospitals are constructed across China.

Also, a more regulated health food market bodes well for imported and domestically manufactured foreign health food products as they will be in a better competitive position relative to their local competitors due to perceived quality superiority. Given the huge base and rapid growth of China's healthcare market, it is quickly becoming the most dynamic in the world.

Although China's market is still difficult to penetrate, early entry is the best strategy to gain market share and competitive advantages.

Outlook of Healthcare Opportunities in China

Opportunities	Forecasted Growth/Growth Drivers
Patented pharmaceutical will keep being advocated by both government and hospitals.	Rapid aging population: in 2011 about 11% of population is over 60 years old, and will exceed 13% in 2015.
Branded Generics will have gain high volume contract from government if it falls into NEDL.	Healthcare reform extended the basic health insurance coverage to 93% of the population (1.25 billion people) by September 2011.
Imported high quality medical devices, from consumable to high value implants and diagnostic imaging equipment, will keep growing at about 15%.	Increasing healthcare concerns and distrust to local products drive the consumers choose more expensive imported pharmaceuticals and medical devices.
Hospital design and hospital engineering companies will have unprecedented opportunities to work with hospitals in China in next 5 years.	With the more strict regulations are implemented in 2012, the fast growing health food market will experience restructure in near future which will bring great opportunities to foreign player.
	There are more than 1300 Level III hospitals (500 beds or more) in China, and almost all of them have plan to renovate existing buildings or construct new hospital.
	China government invested US\$2 billion in healthcare IT in 2010, and much bigger investment will be seen in 2011 and 2012.

ⁱ Healthcare industry includes APIs, chemical drug, biological products, medical devices, traditional Chinese medicine, and Chinese drug preparation.
ⁱⁱ "2010 China Healthcare Industry Analysis and 2011 Perspective", CIconSulting.
ⁱⁱⁱ NDRC Analysis of Pharmaceutical Industry of First Half 2011.
^{iv} IMS Market Prognosis 2010
^v Affected by the fluctuation of currency.
^{vi} "27 Online Drug Stores Are Approved To Sell OTC Products To Consumers", SFDA
^{vii} Fortune: Big Pharma's Challenge: Figuring out China
^{viii} SFDA medical devices manufactures

Stop Press

China Resources bids for leading topical derma drug producer

China Resources Sanjiu Pharmaceuticals, a subsidiary of China Resources Group, is speculated to be close to a deal to acquire Guangdong Shunfeng Pharmaceutical, a leading Chinese producer of topical dermatology drugs. Two other domestic firms are also rumored to be bidding for the company, but insiders suggest that China Resources Sanjiu Pharma is likely to emerge as the winner.

The lowest price tag of the deal is CNY 600 million, according to a source from Guangdong Shunfeng Pharma. The final decision for the deal is expected in January 2012.

Guangdong Shunfeng Pharma owns the leading brand on the Chinese dermatological market, Kang Wang (Ketoconazole and Clobetasol Propionate cream), which accounts for about 4% of the entire market segment.

The company's 2010 sales was CNY 240 million with net profits of CNY 42 million.

Chinese Physicians Are More Digitally Savvy Than You Think

By Simon Li, General Manager, Kantar Health China

Chinese physicians are just as Internet-savvy as their Western counterparts, with 98% of Chinese doctors accessing the Internet, more than half having Internet access in their offices, and spending an average of 11 hours online per week, according to the 2011 Digital Life Physician study of around 7,000 Chinese physicians in 300 cities (2,175 answered offline; 4,857 answered online). This landmark study was conducted jointly by Kantar Health (kantarhealth.com), a leading healthcare-focused global consultancy and marketing insights company, and DXY (DXY.com), the largest online physician portal and community in China.

The study shows that Chinese physicians access the Internet more than ordinary consumers do. Interestingly, physicians in smaller cities are more active online than their larger city counterparts. Physicians in Tier 3 cities spend an average of 6.5 hours per week online, compared with only 3.7 hours per week in Tier 1 cities. This finding might seem surprising initially; however, it becomes more logical after considering that doctors in county-level cities often do not have long lines of patients waiting and that the Internet is vital for these physicians to keep in touch with their colleagues in other regions. This poses an interesting question for the Western pharmaceutical companies contemplating a marketing sales/model to reach the low-tier markets to shape and influence the doctors who were previously not in their target territories: what are the good opportunities to take advantage of a changing technological environment and to engage customers in the boarder market using an Internet-based communication/commercial model?

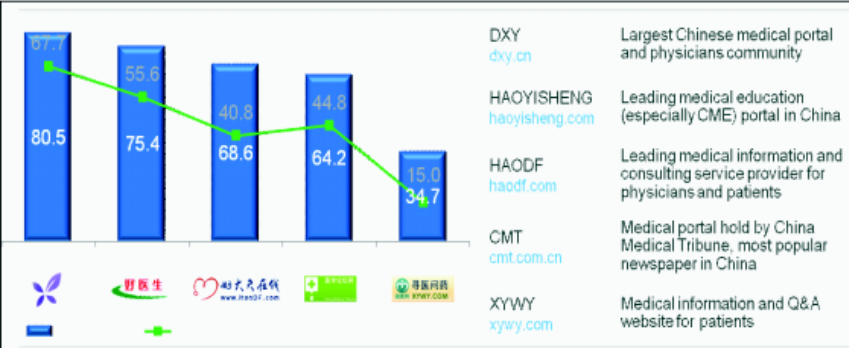
Not only are doctors using the Internet for entertainment, email, and scheduling, the study shows that they spend a significant part of their 11 hours online weekly on activities related to their medical profession. The digital activity profile shows Chinese doctors are spending a good amount of time looking for medical news, educating themselves, and sharing medical knowledge in forum discussions and tweets. The Chinese sites they most often visit include DXY (dxy.com), Good Doctor (haoyisheng.com), and Good Physician (haodaifu.com). (See figure 1 for the top destinations Chinese physicians visit online.)

64% of doctors check news daily, 42% search medical content daily, and one-third use domestic social networks daily (both Twitter and Facebook are blocked in China, but the domestic

social media scene is thriving). The frequency and variability of physicians' online activities contradict the stereotypical image of Chinese doctors being rather Internet laggard and that the only people who use the Internet are young physicians just out of the medical schools (and who are therefore not important as prescribers).

Drawing from the market research technique to profile ordinary consumers online, the report also segments doctors by "digital lifestyles", including:

Figure 1 – Top Destinations Chinese Doctors Visit Online

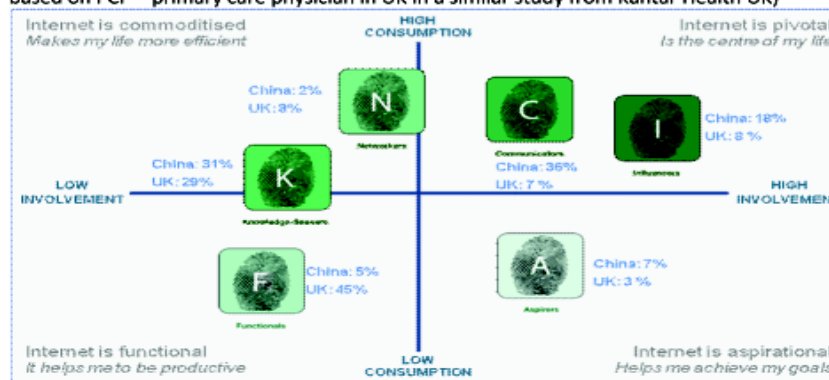


Source: Kantar Health/DXY.com

- Influencers (I): The Internet is an integral part of their lives; they are heavy mobile Internet users; and they are online almost anywhere, anytime.
- Networkers (N): Establishing and maintaining relationships is an important facet of their busy domestic and working lives. They use social networking to save time when keeping in contact with people, use it often at home, and are open to engaging directly with brands and looking for promotions. However, they are not the kind of people to voice opinions online.
- Aspirers (A): Although they don't do much online, they want to, especially when it comes to mobile and creating their own personal online spaces.
- Communicators (C): They are online talkers, the ones who lead with their posts and connect everyone on social media.
- Knowledge Seekers (K): They are not as active in social media but want to share with likeminded people on professional topics.
- Functionals (F): They don't set out to express themselves online; they tend to like emailing, news reading, checking up on sports and weather, and shopping online. They are not that interested in social networking and are worried about data privacy and security. They have generally been using the Internet for a long time.

Again, the interesting finding emerges from the segmentation:

Figure 2 – Online Lifestyle Segmentation – Chinese Physician and UK Physicians (UK physician based on PCP – primary care physician in UK in a similar study from Kantar Health UK)



Source: Kantar Health/DXY.com

Chinese physicians are more likely to have high involvement levels when they are online. Compared with their Western counterparts (see figure 2), they are more likely to be Communicators or Influencers than merely Functionals, who go online just to get specific activities (e.g. email) done. Given an active online physician population, a thriving social media scene and increasingly

digitally-minded physicians, are we missing a good opportunity in China to use the Internet to engage, inform, and influence our

continues on page 27 ...