WiCON

PHARMA CHINA™

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Published monthly On the web continuously www.pharmachinaonline.com

113

Issue

January

2016

In This Issue

Simcere to Co-market Daiichi Sankyo's Hypertension Drug

Simcere announced on December 5 a Strategic Partnership with Daiichi Sankyo to co-market latter's hypertension drug Benicar in China. *P14*

Akeso Biopharma Out-licenses Novel Anticancer mAb to MSD

Akeso Biopharma has entered into a collaboration with MSD to research, develop and commercialize immuno-oncology therapeutics. *P14*

MSD China to Focus on Biopharma Opportunities in China

MSD China is raising efforts and collaborations with partners to tap into huge growth potential in biopharma, President Christopher Round said. *P16*

AstraZeneca Steps Up China Investment thru Alliance with Wuxi PharmaTech

AstraZeneca unveiled plans to spend US$800 million on its Chinese operations over the next 10 years. *P17*

Eisai to Further Expand in China thru Acquisition

Eisai will acquire 100% of Liaoning Tianyi Pharma in a deal worth CNY 500 million. *P18*

Bayer Pulls Ventavis from the Chinese Market

Bayer Healthcare is in the middle of pulling its primary pulmonary hypertension drug Ventavis (inhaled iloprost) from China. *P19*

CONTENTS

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Subscriptions (2016):
Subscription Rate for Journal Edition: US$1,800 for Print or PDF inclusive of S&H (additional print copy in the same envelop is US$1,080).

Gold Package: US$2,950 (includes single subscriptions to both Pharma China Journal Edition and Web Edition, Weekly Alert, Breaking News Alert, Pharma China Archive and Online Databases).

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Editorial

China Gets Serious with Drug Registration Reform, as Pharma Industry Face Mounting Price Pressure

James J. Shen

I was lucky to arrive in Beijing on a December day with clear and sunny sky, narrowly missing the capital's worst smoggy days in years, when air was almost poisoning and visibility was down to a few meters. Pictures posted by friends on WeChat showed that most of the city's great buildings, including the "Giant Underpant", all disappeared from sight at even short distance. Obviously going anywhere was difficult in those days with so little vision forward.

Though Beijing's smog could be cleared completely overnight by a randomly passing winter breeze, it is not as easy to clean up the clouds over the flawed Chinese healthcare system and marketplace. Forward vision has also been blurred.

More storms and dark clouds have been gathering over China healthcare this year as the government stepped up efforts to expand drug cost containment to balance BMI and fiscal budget books, introduce new reform measures to rationalize the healthcare system and streamline drug regulation to ensure quality. The trend is anticipated to further intensify in 2016.

Before we delve into more details of latest healthcare sector developments, let's take a look at the broad Chinese economy in the past month.

Chinese economy to slow further in 2016 but remain steady?

The Chinese economy was reported to be stronger than expected in November, with factory output growth picking up to a five-month high at an annual 6.2% in November, data from the National Bureau of Statistics (NBS) showed, quickening from October's 5.6%. Growth in China's fixed-asset investment, one of the main drivers of the economy, rose 10.2% in the first 11 months, higher than an expected 10.1% rise. Retail sales grew an annual 11.2% in November – the strongest expansion this year – compared with 11.0 percent in October.

Retail sales may expand around 10.7% in 2015, compared with 12% last year, according to SHEN Danyang, spokesman at the Ministry of Commerce, who did not elaborate further on the data on December 17.

A day earlier, China's central bank projected its baseline forecast for 2016 growth at 6.8%, expecting the number of positive factors to gradually increase despite downward pressure on the economy. The rate is slightly lower than the central bank's forecast of 6.9% expansion for 2015, according to a working paper by the People's Bank of China.

Citing overcapacity, profit deceleration, and rising non-performing loans as major drags on the economy, the paper said supportive factors such as the recovery of real estate sales, lagging effects of macro and structural policies and some modest improvement in external demand would help underpin broader growth.

China's economy expanded 6.9% in the first three quarters. To combat the slowdown, the central bank has cut benchmark interest rates six times since November last year and lowered banks' reserve requirement ratio several times.

For next year, the central bank predicted consumer price index inflation at 1.7% and the current account surplus at 2.8% of GDP. Nominal fixed asset investment growth will reach 10.8% in 2016, higher than the 10.3% prediction for this year, while retail sales are expected to expand by 11.1%, according to the paper.

Seeing possible recovery of external demand, the central bank expects export growth at 3.1% in 2016, in contrast to the predicted 2.9% fall for 2015. Meanwhile, imports are expected to rise 2.3% as global commodity prices gradually stabilize.

On the risk side, the paper pointed out uncertainties in the domestic and global financial market as a major threat to stability, including the pace of the U.S. Federal Reserve's interest rate hike.

Meanwhile, results from a private survey of Chinese firms showed that China's economy was plagued by pervasive weakness in the fourth quarter, raising questions about the veracity of stronger than expected official activity data released this month.

"The government may not be in the mood to acknowledge officially that the slowdown has worsened, but self-reporting from the nation's powerhouses will be hard to hide," report authors Leland Miller and Craig Charney wrote.

The quarterly survey of over 2,100 businesses by China Beige Book International (CBB) showed national sales revenue, volumes, output, prices, profits, hiring, borrowing and capital expenditure were all weaker on-quarter, creating more uncertainties for China's economy.

The world's second-biggest economy has been hit by weak demand at home and abroad, factory overcapacity and challenges posed by its transition to a consumption-led growth model from one reliant on investments.

In response, Premier LI Keqiang has recently pledged to step up "supply-side" reform to generate new growth engines in the economy while tackling factory overcapacity and so-called zombie firms.

CFDA Plays Hardball with Drug Evaluation and Registration Reform

Let's turn back to the healthcare sector. The past month has seen a flurry of new drug regulatory introductions and development as the CFDA gets serious with pushing forward drug evaluation and registration system reform.

The CFDA issued another official notice on December 17 to require further strengthened inspection of drug clinical trial data by all provincial level food and drug agencies. The latest notice requires all provincial food and drug agencies to organize and conduct renewed inspections of those drug applications covered by the CFDA No.117 announcement which are still under registration at the moment, as well as to report outcomes of such inspections to the CFDA before the end of December. Provincial level food and drug agencies are also required to order local clinical research institutions to complete self-inspections of clinical trials relating to applications listed in the CFDA No.117 announcement and applications submitted thereafter before January 10, 2016.

The agency also issued three announcements in late November and December 4 reporting a total of 382 drug application withdrawals by 248 pharmaceutical companies. Plus those unannounced withdrawals, the total number of withdrawals reached 727 by December 15, according to Xianda Data.

Besides, the CFDA came out with an official announcement on December 7 over rejection of registration applications for 13 new drugs from 14 applicants, citing false or incomplete trial data. It also rejected 11 registration applications by eight companies last month for inadequate trial data related to generic drugs for heart problems, schizophrenia, pain, infections and other diseases. The CFDA said it will conduct further investigation and determine responsibilities of applicants, designated clinical research institutions and CROs involved in flawed cases.

Tens of leading domestic players, many of them publicly-listed, and a couple of smaller foreign firms, as well as numerous well-known hospitals and CROs, were involved in both rejected and voluntarily withdrawn applications.

In the meantime, a draft document, *Announcement for Determination and Punishment of Drug Clinical Trial Data Fraud*, has been leaked to the Chinese press. It is reportedly under review by the CFDA which is believed to be hearing comments internally and among selected organizations. It provides that, when inspections uncover fraudulent clinical data, related drug registration applications will be rejected and relevant applicants, clinical research facilities, CROs and persons of direct responsibility involved in clinical data frauds will be investigated and punished. Such applicants will banned from applications for the same drugs for three years and from all drug registration applications for one year, while existing registration applications of such applicants will be rejected. If a given applicant is found to be involved in clinical data fraud of three or more drug products under registration applications, all products under registration by the applicant will be deemed to be involved with "suspected clinical data frauds" and handled accordingly.

In other developments of drug registration system reform, the CFDA released an official announcement (2015 Announcement #257) on December 1 to change the regulatory approach of chemical drug bioequivalence studies (BE studies) from mandatory approval to filing requirement from the date of announcement. When BE studies are required, registration applicants should submit relevant information on and obtain filing numbers from the Chemical Drug BE Study Filing Information Platform (*化学药BE试验备案信息平台*, www.chinadrugtrials.org.cn).

The Center for Drug Evaluation (CDE) under the CFDA issued a new draft document, *Technical Guideline for Bioequivalence Studies of Chemical Drugs with Pharmacokinetic Parameters as End Points*, for public comments before December 31, 2015. It also publicized a new draft regulation, *Rules for Drug Technical Evaluation Communications*, and is now soliciting public comments. Comments need to be submitted before December 28, 2015.

There were a few major developments on other regulatory aspects too. The 2015 or 10th Edition of Chinese Pharmacopoeia (ChP) took effect on December 1, 2015, which has comprehensively elevated the drug quality control standards in terms of product coverage, testing methods, control parameters and system streamline. Besides, the new ChP edition further enhances the platform of drug and excipient standards.

The CFDA will formally decentralize GMP certification of sterile drug products to provincial level food and drug agencies (provincial level FDAs) at the end of this year, according to Chinese press reports. The agency has reportedly issued notices recently to provincial level FDAs over capacity building and other preparations. The CFDA also issued a number of inspection guidelines for GMP certification of sterile drug formulations, GMP drug certification application dossier review, drug inspection handbook, as well as onsite inspection procedures, risk evaluation and deficiency correction in order to maintain quality of GMP certification after decentralization. The move was provided in the central government document defining responsibilities of the CFDA when it was established in 2013. Under the document, all GMP certifications for drugs and medical devices should be decentralized to provincial level FDAs.

In an effort to safeguard quality of biological products, the CFDA has drafted the *Rules for Batch Release of Biological Products* and is now seeking public comments. Feedbacks should be sent before January 15, 2016 to the Drug and Cosmetic Registration Department of CFDA.

The NHFPC and the CFDA issued a notice on December 1 to require filing of stem cell clinical research institutions before December 10, in an attempt to push forward implementation of the *Provisions for Stem Cell Clinical Research (Interim)* and the *Guidelines for Stem Cell Formulation Quality Control and Preclinical Research (Interim)* on August 21. All stem cell research projects are required to be conducted only in such registered facilities.

Lastly, but not the least, China and the United States agreed, at the 26th China-U.S. JCCT meeting held in Guangzhou between

November 21 and 23, to further enhance cooperation in the field of food safety, joint actions against online sales of counterfeit drugs, drug and medical device registration approval and clinical trial, as well as dialogue on cosmetics supervision, in order to protect the health of the public.

China Mulls Future Reform Direction as It Seeks to Consolidate BMI and Initiate National Drug Price Negotiation

The National Health and Family Planning Commission (NHFPC) is currently compiling the "*13th Five Year Plan for Building Health China*", which will become the guiding policy for advancing health China building in the 13th Five Year Plan (FYP) period (2016-2020). The NHFPC is now inviting comments and suggestions from the public for this plan which should be submitted before December 31, 2015.

Earlier in November, the NHFPC hosted the *National Healthcare Reform Planning Symposium* where NHFPC Minister LI Bin delivered a keynote speech calling for deepened healthcare reform and conclusive victory of it in the 13th FYP period. She outlined progresses to be made in the period including: 1) nationwide implementation of urban hospital overall reform which encompasses establishment of public hospital administrative committees, streamlined medical service prices, building of a human resource and remuneration system meeting characteristics of healthcare sector and support of social capital in medical service provision; 2) integration of different medical insurance programs, deepening BMI payment system reform and promoting merger of urban and rural basic medical insurance programs; 3) raising consumption of essential drugs, advancing reform of pharmaceutical distribution sector, promoting quality equivalence study of generic drugs, and securing shortage and pediatric drugs; 4) perfecting legal framework, transforming government roles and boosting infrastructural building of regulatory regimes; and 5) further defining government responsibilities.

Later on December 9, a meeting of the Central Leading Group for Deepening Overall Reform chaired by President XI Jinping approved plans to merge China's two medical insurance schemes for urban and rural residents, which are currently separate as the urban resident basic medical insurance (URBMI) and the new rural cooperative medical scheme (NRCMS), a bid to equalize access to health care. The government-run URBMI and NRCMS will be consolidated in terms of enrollment scope, fundraising, fund management, medical service provider management, breadth of coverage and drug reimbursement.

Conversely, the NHFPC issued a new policy document, *Guiding Opinions for Further Streamlining Management of Community Healthcare Services and Promoting Service Quality*, on November 25.

On a positive development for the pharmaceutical industry, the national drug price negotiation trial for patented and exclusively-produced drugs recently began as a part of the new mechanism for public hospital drug purchase, according to the *Health News*, the official newspaper of NHFPC. Five drugs indicated for three diseases are included in the first batch of products under the trial. They include 1) Celgene's Lenalidomide for multiple myeloma; 2) Gilead's Tenofovir for hepatitis B; and 3) AstraZeneca's Gefitinib, Roche's Erlotinib and Zhejiang Beta Pharma's Icotinib for advanced stage non-small-cell lung cancer. The agreements for this negotiation will reportedly be implemented from 2016.

Industry revenue growth down, MNCs remain committed and Local Players Focus on Partnerships

For the first time in the past decade, sales revenues of the Chinese pharmaceutical manufacturing sector rose single digit at 9.6% in the first three quarters of 2015 totaling CNY 1,810 billion, compared with 13.2% growth in the same period of 2014, according to latest data reported by SMEI. By comparison, the sector's net profits grew 14.7% in the first three quarters this year, up from 12.5% in the corresponding period last year. Sales margin of the sector was 10.02% in the period. Among the seven subsectors, SMEI suggests that biological products, TCM crude drugs, medical devices and health materials saw above average revenue growth in the period, while pharmaceutical formulations, APIs and formulated TCMs experienced below average revenue growth at 9.7%, 7.8% and 6.8%.

More MNCs renewed their investment plans in China recently. AstraZeneca unveiled plans on December 16 to spend US$800 million on its Chinese operations over the next 10 years. The company aims to build up its already strong position in China by making and developing more medicines locally. Its latest investments in China are part of a broader push to create an "end-to-end research and development" organization in the country, a company spokeswoman said. Its decision to step up investment in China, notably through a strategic alliance between its subsidiary MedImmune with local firm WuXi PharmaTech, chimes with Beijing's desire to see more treatments made in China.

GlaxoSmithKline has cut 40% of its sales reps and axed some units in China as it eyes a return to growth in 2016, according to GSK China GM Herve Gisserot. The British firm is gambling on a new, cleaner image to reboot its performance and reputation with doctors and consumers, Gisserot told Reuters during a wide-ranging interview. GSK has previously said it would overhaul its business in China to avoid some of the issues that led to the probe, including stopping all sales-based incentives for drug reps and reducing paid junkets for doctors. The problem is, many of GSK's rivals are not following in step, and adapting to a new model means taking a business hit. Gisserot warned that other drugmakers risked punishment by Chinese authorities if they failed to follow GSK's reforms. GlaxoSmithKline's sales dropped from US$1.1 billion in 2012 to US$882 million in 2013 and were flat last year. Gisserot suggested that after a modest increase in sales next year, revenue growth is predicted to be more "dynamic" from 2017, helped by the rollout of new products, including HPV vaccine Cervarix.

Japanese drugmaker Eisai will acquire 100% of Liaoning Tianyi Biopharmaceutical, which manufactures and sells 20 types of generics and has approvals to make around 90 drugs, in a deal worth CNY 500 million in an effort to gain a bigger foothold in China. Eisai will finalize the acquisition this fiscal year at the earliest. Eisai's Chinese pharmaceutical business is projected to reach JPY 50 billion for fiscal 2015, a roughly 20% surge on the year and representing 9.2% of the firm's worldwide sales.

Bayer Healthcare and the Shanghai Institute of Organic Chemistry under the Chinese Academy of Sciences renewed their strategic research partnership agreement on November 25 to continue the cooperative project for discovery of novel organic chemical drug compounds. The cooperation between Bayer and SIOC began in 1996 and the partnership agreement was renewed for the first time in 2010. In a separate development, however, Bayer Healthcare is reportedly to be in the middle of pulling its primary pulmonary hypertension drug Ventavis (inhaled iloprost) from the Chinese market. The product was approved by the CFDA in 2006 and has been selling in China since then with patient assistance programs through China Charity Confederation (CCC). However, CCC sent a notice on June 29 this year to announce Bayer's decision to gradually withdraw this

drug from the Chinese market as of 2015 due to "global strategic adjustments". The decision has led to turmoil among Chinese patients who said they cannot find substitute drugs.

Licensing has long been a hotbed of activities with a rising number of Sino-foreign deals oriented both ways. There is also a tendency that MNCs are becoming more interested in lining up with local companies for in- and out-licensing as well as co-marketing opportunities.

The Deals Monitor of *Pharma China*, which routinely collects information on various types of transactions between Chinese and foreign pharma companies (as well as major domestic events) including M&A, joint venture/strategic alliance, licensing, contract research/collaborative R&D, IPO, OEM and lawsuits/legal disputes, recorded a total of 71 events in the third quarter and 172 events in the first three quarters of 2015.

Most recently, Simcere Pharma announced on December 5 a Strategic Partnership with Daiichi Sankyo under which the two companies will co-market latter's high blood pressure drug Benicar (Olmesartan Medoxomil tablet) in China. Under the agreement, Simcere Pharma will exclusively promote and distribute Benicar in mainland China, while Daiichi Sankyo will be responsible for branding and market access support.

Oramed Pharmaceuticals Inc., an Israeli clinical-stage company, has signed definitive licensing and investment agreements valued at up to US$50 million with Hefei Tianhui Incubator of Technologies Co., Ltd. for exclusive rights to market Oramed's oral insulin capsule, ORMD-0801, in China, Hong Kong and Macau.

Solasia Pharma K.K. and Lee's Pharmaceutical Holdings recently entered into an exclusive license agreement for the commercialization and promotion of Sancuso (granisetron transdermal delivery system) for patients suffering from chemo-therapy-induced nausea vomiting (CINV) caused by chemotherapy in mainland China. Solasia will retain rights to promote Sancuso in three major cities (Beijing, Shanghai and Guangzhou). Solasia obtained an exclusive license to develop and commercialize Sancuso for Asian territories from ProStrakan and is currently waiting for approval from the CFDA.

Akeso Biopharma announced on December 4 that the company has entered into a collaboration with MSD under which the latter will obtain exclusive worldwide rights to develop and commercialize Akeso's compound AK-107, an immune checkpoint blocking antibody.

ZAI Lab and Hanmi Pharma announced on November 23 that they have executed a license agreement under which ZAI Lab will acquire exclusive rights in China (including Hong Kong and Macau) to develop, manufacture and commercialize HM61713, a novel, third-generation EGFR targeted therapy for the treatment of EGFR mutation positive lung cancer.

XL-protein GmbH and Chengdu Easton Pharma announced on December 17 that they have entered into a License, Development and Commercialization Agreement under which XL-protein will apply its proprietary PASylation technology for drug half-life extension to one Easton target. XL-protein will assume responsibility for early preclinical development activities, Easton will be entitled to further development, manufacturing and marketing of the PASylated compound.

Yisheng Biopharma announced on December 14 that its wholly owned U.S. research subsidiary has entered into a collaboration with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) to develop a new vaccine against the Ebola virus using a novel double-stranded RNA-based Toll-Like Receptor 3 (TLR3) agonist adjuvant technology (PIKA). The cooperative research partnership represents a new opportunity for both organizations to develop effective and safe vaccine products against Ebola or other viruses.

There were a few developments on the pharma e-commerce front too. Guangzhou Baiyunshan Pharmaceutical, a listed subsidiary of Guangzhou Pharmaceutical Group, announced on November 30 that it has signed an agreement with a unit of AliHealth for strategic alliance in pharma e-commerce, including O2O business, drug prescription filling, BMI payment and electronic drug regulatory code management.

In a separate development, Guangdong Lifeng Pharma announced in late November that it has received the Internet Drug Transaction License for its B2B pharma e-commerce platform (www.lf99.com.cn) from Guangdong Provincial Food and Drug Administration. The platform, also doing business as the China Promotional Public Service Platform for Overstocked Medicines, is the first Chinese portal specializing in promoting and distributing overstocked medicines.

Those who laugh last, laugh best

A recent *Financial Times* article titled "*China Healthcare: Missing A Beat*" writes that "it (China) looked to be the growth engine for Big Pharma, but bribery and a flawed system have dashed hopes".

It went on to say that "For a while, the big strategic bets placed on China by GSK and other drugmakers looked like paying off as the country's increasingly affluent, urbanized and ageing population clamored for access to modern healthcare. By 2012, the market was growing at an annual rate of 24% and surpassed Japan to become the second-biggest after the US. Then, suddenly, the party stopped. By the middle of this year, growth was down to just 5% bad news for an industry relying on places like China to offset stagnation in Europe and price pressures in the US.

To some extent, the slowdown reflects the adjustment facing multinationals in China as the economy cools, but the change in fortune for big pharma goes beyond a cyclical downturn. It has been triggered not by a drop in demand, on the contrary, China's need for medicines has never been greater, but by deep structural problems in the country's healthcare system.

Pharma companies are being squeezed as China tries to extract greater value from its US$150 billion drugs bill and reform a hospital system whose finances have become unhealthily dependent on pushing pills."

Under increasing financial pressure of the BMI system, local governments have assaulted the pharma industry with wave after wave of cost containment measures, threatening bottomlines of both local and multinational drug companies. The trend is expected to intensify further next year, with the central government upholding the radical healthcare reform experiment in Sanming City of Fujian Province as a model for national reference. The Sanming experiment, which is set in the background of local BMI system in heavy deficits, is known for its ruthless cost containment measures, excessive emphasis on drug prices and harsh hospital reform moves. It is also the first local BMI system paying suppliers of originator drugs and local generics at uniform low prices.

The success of Sanming experiment has been blown out of proportion by the central government and official media. In reality, however, the irrational reform moves led to fallen medical quality, doctors and patients fleeing the city's public hospital system and suppliers of high quality drug products forced to abandon the city market.

Local companies, including leading domestic players, have also

been under the growing heat of tightening drug regulation in terms of both drug registration and quality control. The CFDA, backed by its new leadership who is deeply-rooted with the country's power center (current CFDA commissioner BI Jingquan is also the Deputy Secretary General of the State Council), has shown the pharma industry recently that it actually has plenty of sharp teeth and means to bite for the sake of raising drug quality to align with international standards.

While the CFDA's move to elevate drug quality is contradicted by other government agency's preoccupation to slash drug costs, it nonetheless provides a ray of future hope for MNCs, whose premium quality products are developed and manufactured at higher costs, amid the current stormy weather. With a better policed pharmaceutical industry aligned to rational cost structures, MNCs can expect to compete with domestic companies on a more leveled ground in future. Driving out irregular players will also leave more market vacuum for quality products and suppliers. The real questions are that if the Chinese government is willing to pay for better quality drugs and if the BMI system can afford them. With the world's largest population, what kind of healthcare quality and product mix can and should China get for a merely 5% of GDP? Is the country willing or able to pay more for better products and healthcare?

Well, these answers won't come easy, especially in an authoritarian country like China where it is convenient to hide in the sand of so-called Chinese characteristics. The *Mandarins* are good at claiming fake victories of buying good things cheap and the Chinese public seems naturally inclined to favor such miracles. So the process would be long and painstaking for all stakeholders before China finds its healthcare balance. Only those who survive the process will be able to share the fruits of reform.

An article on the Chinese pharma social media *Saibailan* commented recently on Bayer's planned withdrawal of its pulmonary hypertension drug Ventavis from China like this: "compared with MNCs which do business in global markets and can pull out of a country market in adverse environments, Chinese companies have no choice but to struggle tooth and nail to survive or die here."

Backed by a global business with higher profit margins in developed markets, MNCs have much longer staying power to last until at the end of Chinese healthcare reform process, regardless how uncertain and cloudy it is now. No wonder leading Chinese players have been trying really hard in recent years to expand internationally.

News in Focus

National Drug Price Negotiation Trial Begins with Five Drugs

As a part of the new mechanism for public hospital drug purchase, the national drug price negotiation trial for patented and exclusively-produced drugs began recently, according to the *Health News*, the official newspaper of NHFPC.

Five drugs indicated for three diseases are included in the first batch of products under the trial. They include 1) Celgene's Lenalidomide for multiple myeloma; 2) Gilead's Tenofovir for hepatitis B; and 3) AstraZeneca's Gefitinib, Roche's Erlotinib and Zhejiang Beta Pharma's Icotinib for advanced stage non-small-cell lung cancer.

The agreements for this negotiation will be implemented from 2016, the *Health News* suggests.

An inter-ministerial conference composed of 16 central government agencies has already been established and it held the first meeting in mid-November when the latest trial plan was passed.

Reportedly the following essential principles for the drug price negotiation mechanism trial have been agreed: 1) two tier negotiation mechanism at national and provincial levels will be established; 2) the national level negotiation will decide nationally uniform prices for selected patented and exclusively-produced drugs, while provincial level negotiations will negotiate for prices of other patented and exclusively-produced drugs for their own territories; and 3) inter-provincial drug purchase negotiations are encouraged.

Chinese Government Approves Plan to Merge Health Insurance Programs for Urban and Rural Residents

Senior Chinese officials tabled proposals ranging from healthcare reform to central management of national parks at a major government meeting on December 9.

Chairing the meeting of the Central Leading Group for Deepening Overall Reform, President XI Jinping said China had "gained good momentum in reform this year, and in 2016, the beginning of the 13th Five-Year Plan, efforts need to be focused on the target of building a moderately prosperous society."

The meeting approved plans to merge China's two medical insurance schemes for urban and rural residents, which are currently separate as the urban resident basic medical insurance (URBMI) and the new rural cooperative medical scheme (NRCMS), a bid to equalize access to health care as the incidence of conditions like cancer and diabetes surge. Besides, according to a statement issued after the meeting, the statement called for coordinated reform of medical service provision, basic medical insurance and pharmaceutical sector, as well as the creation of a "multi-layered medical security net" integrating basic medical insurance, insurance for major diseases, medical assistance, commercial medical insurance and charity funds.

The government-run URBMI and NRCMS will be consolidated in terms of enrollment scope, fundraising, fund management, medical service provider management, breadth of coverage and drug reimbursement, the official Xinhua news agency reported on Wednesday, citing decisions made at a meeting chaired by President XI Jinping.

Private health insurance is rare in China and most patients rely on state-run basic medical insurance programs. Many patients struggle to make out-of-pocket payments for diseases like cancer, pushing the government to find new ways to broaden coverage. Growth in pharmaceutical spending in China is set to slow to below 10% through 2020 due to weaker economic growth and the substantial costs borne by patients, IMS Institute for Healthcare Informatics estimates.

China currently has three separate health insurance systems for employed urban residents, other city dwellers and rural residents that are managed by different government ministries, according to Xinhua. Due to different sources of funding and regulations,

the three schemes often have different reimbursement rates and coverage for diseases.

CFDA Issues Announcement for Bioequivalence Study Filing Regulation

The CFDA issued an official announcement (2015 Announcement #257) on December 1 to change the regulatory approach of chemical drug bioequivalence studies (BE studies) from mandatory approval to filing requirement from the date of announcement.

When BE studies are required, registration applicants should submit relevant information on and obtain filing numbers from the Chemical Drug BE Study Filing Information Platform (*化学药BE试验备案信息平台*, www.chinadrugtrials.org.cn).

Provincial level food and drug agencies are responsible for routine supervision and inspection of BE studies conducted by registration applicants and drug clinical institutions in their territories. Relevant inspectors in such agencies should provide and sign comments after satisfactory inspections of BE studies which will be transferred to the CFDA through provincial level agencies.

CFDA will conduct analysis and technical assessments of filed BE study information. For filed information with obvious deficiency and high safety risks, the CFDA will notify relevant applicants to terminate BE studies. The Center for Drug Evaluation under the CFDA may conduct cause-triggered inspections of relevant filed and completed BE study information and random sample inspections during the process of technical review. Those applications found to have issues with truthfulness will not be approved. Such cases will be publicized and investigated when necessary with relevant registration applicants, clinical trial chiefs and local drug officials held responsible.

Relevant chemical drug registration applications accepted before December 1, 2015 may continue with the existing drug registration path which requires approvals of BE studies. Alternatively, such applications can be withdrawn and resubmitted following the new BE study filing path.

After December 1, 2015, CFDA will no longer accept chemical drug registration applications which require BE study approvals.

The following is a through summary of the announcement's attachment, *Scope and Procedures for Chemical Drug Bioequivalence Study Filing*. For full text of the announcement and the attachment in Chinese, please visit the following CFDA weblink: http://www.cfda.gov.cn/WS01/CL0050/136520.html.

Filing Scope

Chemical generic drugs meeting the following situations can apply for BE study filing: 1) drugs copying marketed reference products with the same APIs, delivery routes, dosage forms and specifications. Such reference drugs should be originator drugs; 2) generic drugs already approved for marketing domestically but need to conduct BE studies for relevant changes; and 3) generic drugs already approved for marketing domestically but need to conduct BE studies for evaluation of quality and therapeutic efficacy equivalence, in which case reference products should be originator drugs or internationally-recognized generic drugs.

Chemical drugs belonging to one of the following situations, when BE studies are required, should submit registration applications according to relevant requirements under the *Provisions for Drug Approval*: 1) radioactive drugs, narcotics, class 1 and 2 psychotics and pharmaceutical precursor chemicals; 2) drugs with cytotoxicity; 3) drugs for which BE studies are not suitable to validate quality and therapeutic efficacy equivalence; 4) BE studies not oriented for domestic drug registration or evaluation of quality and therapeutic efficacy equivalence; and 5) drugs for which registration applicants believe may require technical evaluation of potential BE study safety risks.

Filing Procedures

The document provides the following procedures and information requirements for BE studies: 1) registration applicants should apply to authorized drug clinical trial institutions for BE studies, gain approvals of their respective ethical committee approvals and sign BE study contracts; 2) 30 days before their BE studies begin, applicants should file with the chemical drug BE filing information platform designated by the CFDA and submit relevant required information; 3) essential filing information required include applicant information, basic product information, formulation process, quality studies and standards, reference formulation basic information, stabilities studies, APIs, BE study protocols and ethical committee approvals; 4) reference formulations of BE studies as well as essential information of all participating parties should be publicized; 5) applicants should, following obtaining BE study filing numbers, complete all information required on the chemical drug BE filing information platform designated by the CFDA before enrollment of the first test subject and such information will be publicized by the CFDA; those applicants failing to submit testing subject enrollment information within one year must provide explanations; and the filing numbers of those failing to provide such information within two years are forfeited automatically; 6) BE studies should be conducted strictly in accordance with GCP and protocols. Registration applicants should terminate BE studies if there are changes with reference products, APIs, formulation recipes and production during the BE study process and they should submit applications for BE study termination on the CFDA designated BE filing platform. In accordance with the change scenarios, applicants should file information related to changes and obtain new filing numbers before initiating the BE studies again; 7) applicants should submit relevant summary reports or explanations on the CFDA designated BE filing platform within one year of completing or terminating BE studies; 8) when BE studies are completed, registration applicants should submit BE study data dossier, filing information and explanations for changes to the CFDA. On this basis, relevant drug registration applications can be submitted with commitments to truthful, complete and compliant dossier and data; and 9) drug registration applications with BE studies not following requirements of this document will not be accepted by the CFDA.

New Document for Determination and Punishment of Clinical Data Fraud under Discussion by the CFDA

A draft document, *Announcement for Determination and Punishment of Drug Clinical Trial Data Fraud*, has been leaked to the Chinese press. It is reportedly under review by the CFDA which is believed to be hearing comments internally and among selected organizations.

The draft document attempts to define six circumstances of clinical data fraud including 1) making up data such as faking trial subjects and use of fake trial drugs or biospecimens; 2) modifying data without authorizations; 3) misrepresenting or hiding clinical

data; 4) deliberately destroying, transferring or hiding data storage devices; 5) failing to trace and explain data origins; and 6) other circumstances where submitted data is proven to deviate from actual happenings.

It provides that, when inspections uncover fraudulent clinical data, related drug registration applications will be rejected and relevant applicants, clinical research facilities, CROs and persons of direct responsibility involved in clinical data frauds will be investigated and punished in accordance with laws and regulations. Such applicants will banned from applications for the same drugs for three years and from all drug registration applications for one year, while existing registration applications of such applicants will be rejected. If a given applicant is found to be involved in clinical data fraud of three or more drug products under registration applications, all products under registration by the applicant will be deemed to be involved with "suspected clinical data frauds" and handled accordingly.

The draft document reiterates the provision to waive punishments of drug registration applications voluntarily withdrawn by applicants.

Full text of the draft document in Chinese is available from the following weblink: http://www.phirda.com/newsinfo.aspx?id=13684

The Market

Review of Chinese Foreign Trade of Medicines and Health Products M1-10, 2015

The Chinese foreign trade of medicines and health products (MHPs) grew only 4.27% in the first ten months of 2015, reaching a total of US$83,784 million, according to official data published by the *Pharmaceutical Economy*, a pharma industry newspaper under SMEI. Compared with the same period last year, the growth rate dropped 5.6 percentage points.

Among the total, MHP import and export in the period rose 4.75% and 3.89% respectively, as MHP trade surplus grew 0.63% to CNY 9,440 million.

Export sales of leading ten export destinations for Chinese MHPs accounted for 57.34% of total in the first ten months of this year. The top export country market for Chinese MHPs was the U.S., which saw 9.19% growth in the period. It was followed by India, up 7.36%. Chinese MHP exports to South Korea saw the fastest growth in the period at 13.20%.

Chinese Foreign Trade of MHPs in M1-10/2015 (US$ mln)

Category	Export			Import			Surplus/ Deficit
	Export Value	+/- (%)	Share (%)	Import Value	+/- (%)	Share (%)	
WMs	26,260	+1.92	56.34	22,292	+2.30	59.97	+3,968
APIs	21,405	+0.78	45.92	6,968	-1.97	18.75	+14,437
Pharma Formulations	2,629	–	5.64	–	–	–	–
Biochemicals	2,226	–	4.78	–	–	–	–
TCMs	3,083	+6.75	6.61	842	-0.97	2.27	+2,241
Medical Devices	17,269	+6.33	37.05	14,038	+9.28	37.76	+3,231
Total	**46,612**	**+3.89**	**100.00**	**37,172**	**+4.75**	**100.00**	**9,440**

Source: SMEI

Regionally, Asia remained the largest export market for Chinese MHPs with 41.41% market share by value and 3.05% growth in the period. It was followed by Europe and North America.

Regional Export Markets for Chinese MHPs in M1-10/2015

Region	Export Value (US$ mln)	+/- (%)	Share (%)
Asia	19,304	+3.05	41.41
Europe	11,862	-0.52	25.45
North America	8,941	+9.33	19.18
Latin America	6,505	+11.06	13.96
ASEAN		+9.48	
Oceania		+7.03	
Global Total	**46,612**	**+3.89**	**100.00**

Source: SMEI

Private companies led the Chinese export of MHPs in the first ten months of 2015 with 51.62% market share by value, followed by foreign-funded companies with 36.44% share. The top Chinese MHP exporter in the period was Shanghai Joywing, followed by GE Healthcare and Zhejiang Meheco.

The leading ten Chinese MHP import origin countries accounted for 72.84% of total such import in the first ten months of this year. The top Chinese MHP import country origin was the U.S., followed by Germany and Japan.

Foreign companies led the Chinese import of MHPs with 58% market share by value, followed by private companies with 24% share.

Leading Exporters for Chinese MHPs by Ownership Type in M1-10/2015

Property	Export Value (US$ bln)	Share (%)	# of Companies	# of Companies Share (%)	Export Volume Share (%)
Private	24.1	51.62	22,333	76.2	66.22
Foreign-funded	17.0	36.44	5,243	17.9	27.19
State-owned	5.6	11.94	1,717	5.9	6.59
Total	**46.6**	**100.00**	**29,293**	**100.0**	**100.00**

Source: SMEI

Leading Importers for Chinese MHPs by Ownership Type in M1-10/2015

Property	Import Value (US$ bln)	Value Share (%)	Volume Share (%)
Foreign-funded	21.6	58.00	61.53
Private	9.0	24.26	28.82
State-owned	6.6	17.74	9.65
Total	**37.2**	**100.00**	**100.00**

Source: SMEI

Top 10 Chinese MHPs Exporters in M1-10/2015

Rank	Company
1	Shanghai Joywing Logistics
2	GE Healthcare (Shanghai)
3	Zhejiang Medicines & Health Products I/E Co.
4	Shenzhen Mindray Medical International
5	Tongliao Meihua Biotech
6	Zhejiang Huahai Pharma
7	GE Healthcare (Beijing)
8	Zhejiang Chemicals Import & Export
9	ZheJiang Hengdian Apeloa I/E Co.
10	Shanghai Desano Pharma

Source: SMEI

China's Western Medicine Foreign Trade Growth Slowed Further in 3Qs/2015

The Chinese foreign trade of western medicines (WMs) grew only 2.19% in the first three quarters of 2015 to US$43,969 million, down from 12.73% growth in the same period last year, according to data from the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCIEMHP). The growth rate is the slowest in the past ten years.

WM export sales rose 2.05% to US$23,840 million, down from 7.88% in the corresponding period of 2014. Export volume in the period was up 3.44%, but average export price dropped 1.34%.

WM import sales surged 2.36% to US$20,128 million in the first three quarters of this year, down from 19.09% in the same period last year. Export volume in the period was up 6.98%, while average import price dropped 4.32%.

Chinese Foreign Trade of WMs in 3Qs/2015 (US$ mln)

Category	Export			Import			Surplus/ Deficit
	Export Value	+/- (%)	Share (%)	Import Value	+/- (%)	Share (%)	
WMs	**23,840**	**+2.05**	**100.00**	**20,128**	**+2.36**	**100.00**	**+3,712**
APIs	19,453	+0.88	81.60	6,347	-0.88	31.53	+13,106
Pharma Formulations	2,367	+10.01	9.93	9,553	-0.60	47.46	-7,186
Biochemicals	2,019	+4.84	8.47	4,228	+15.81	21.01	-2,209

Source: CCCIEMHP

The top WM export country market in the period was India, followed by the U.S. and Japan. WM export to Thailand saw the highest growth at 22.64%, followed by the U.S. at 6.19% and Spain at 6.15%.

Top 10 Exported Markets of WMs in 3Qs/2015

Region	Export Value (US$ 100 mln)	+/- (%)	Share (%)
India	3,361	+1.38	14.10
United States	3,066	+6.19	12.86
Japan	1,425	–	5.98
South Korea	1,243	–	5.21
Germany	1,083	-7.53	4.54
Netherlands	996	-4.55	4.18
Spain	671	+6.15	2.81
Brazil	655	–	2.75
Thailand	642	+22.64	2.69
Italy	600	+3.21	2.52
Top 10 Total	13,742	–	57.64
Global Total	**23,840**	**+2.05**	**100.00**

Source: CCCIEMHP

Regional Export Markets for Chinese WMs in 3Qs/2015

Region	Export Value (US$ mln)	+/- (%)	Share (%)
Asia	10,714	+1.92	44.94
Europe	6,461	+0.62	27.10
North America	3,273	+6.46	13.73
Latin America	1,843	+2.77	7.73
Africa	942	-1.37	3.95
Oceania	608	+0.44	2.55
Global Total	**23,840**	**+2.05**	**100.00**

Source: CCCIEMHP

Chinese Exporters of WMs by Ownership Type in 3Qs/2015

Property	Export Value (US$bln)	Share (%) by Value	# of Companies	Share (%) by # of Companies
State-owned	3.6	15	761	7.5
Foreign-invested	7.2	30	1,506	14.8
Private	13.1	55	7,885	77.7
Total	**23.8**	**100**	**10,152**	**100.0**

Source: CCCIEMHP

Top 10 Chinese WMs Exporters in 3Qs/2015

Rank	Company
1	Shanghai Joywing Logistics
2	Zhejiang Medicines & Health Products I/E Co.
3	Tongliao Meihua Biotech
4	Zhejiang Huahai Pharma
5	Zhejiang Chemicals Import & Export
6	ZheJiang Hengdian Apeloa I/E Co.
7	Shanghai Desano Pharma
8	Zhuhai United Laboratories
9	Weifang Ensign Industry
10	Zhejiang NHU

Source: CCCIEMHP

Country Origins for Chinese Import of WMs in 3Qs/2015

Region	Import Value (US$ mln)	Share (%)
Germany	3,467	17.22
United States	2,435	12.10
France	1,627	8.08
Italy	1,227	6.10
Switzerland	1,213	6.03
Japan	1,145	5.69
Ireland	970	4.82
United Kingdom	891	4.43
Denmark	761	3.78
Sweden	754	3.75
Top 10 Total	14,490	71.99
Global Total	**20,128**	**100.00**

Source: CCCIEMHP

The leading WM export regional market in the period was Asia, followed by Europe and North America, which saw the highest growth at 6.46.

Private companies were the biggest WM exporters in the first three quarters of this year with 55% market share by value, followed by foreign-invested companies with 30% share.

Germany was the top country origin for Chinese import of WMs in the period with total import valued at US$3,467 million and a market share of 17.22%, followed by the U.S. and France with market shares of 12.10% and 8.08%.

In terms of regional origins, top spot for Chinese import of WMs was North America in the period with 13% market share and highest growth of 5.84%.

Foreign-invested companies continued to dominate import of WMs in the first three quarters of this year with nearly 66% market share by value.

Regional Origins for Chinese Import of WMs in 3Qs/2015

Region	Export Value (US$ bln)	+/- (%)	Share (%)
North America	2.6	+5.84	13
Europe	13.2	+3.66	66
Asia	3.2	-4.86	16
Others	1.0	–	–
Global Total	**20.1**	**+2.36**	**100**

Source: CCCIEMHP

Chinese Importers of WMs by Ownership Type in 3Qs/2015

Property	Import Value (US$bln)	Share (%) by Value	# of Companies	Share (%) by # of Companies
Foreign-funded	13.2	65.79	3,168	48
Private	3.6	17.82	2,970	45
State-invested	3.3	16.39	462	7
Total	**20.1**	**100.00**	**6,599**	**100**

Source: CCCIEMHP

Top 10 Chinese Importers of WMs in 3Qs/2015

Rank	Company
1	AstraZeneca Pharma
2	Pfizer Pharma
3	CR Beiyao Airport (Beijing) Intl Trading
4	Cardinal Health (Shanghai) Logistics
5	Keyuan Xinhai (Beijing) Medical Products Trade
6	Shanghai Roche Pharma
7	Bayer Healthcare
8	Shanghai Sinopharm Wai Gao Qiao
9	Novo Nordisk (China) Pharma
10	Hangzhou Sanofi-Synthelabo Minsheng Pharma

Source: CCCIEMHP

Chinese CRO Market to Growth 20% CAGR Before 2018

In recent years, China's contract research organization industry has developed rapidly, with the market size rising from CNY 8.5 billion in 2007 to CNY 42.6 billion in 2014, registering a CAGR of 25.9%, according to a new report from Reportbuyer.com, China Contract Research Organization (CRO) Industry Report, 2015-2018. With so many favorable policies, especially when a number of well-known proprietary drugs are about to expire, China's CRO market size is expected to continue to grow by around 20% in the years ahead, to an estimated CNY 83.2 billion by 2018.

At present, some European and American CRO enterprises represented by Quintiles and Covance have penetrated the Chinese market by establishing branches or through acquisition and cooperation. These foreign giants, which occupy the majority of China's CRO market share, are driving the industry to develop toward standardization.

There are more than 500 Chinese CRO enterprises, such as WuXi AppTec, Tigermed Consulting, Boji Medical Biotechnological, and HD Biosciences, which have a relatively large scale and develop very well. In 2014, WuXi AppTec represented a 9.69% market share while Tigermed Consulting and Boji Medical Biotechnological accounted for 1.47% and 0.34%, respectively.

As a leader in China's CRO industry, WuXi AppTec posted revenue of CNY 4.1266 billion (equivalent to USD674.3 million) in 2014, up 16.6% from a year earlier. In recent years, the company has seen rapid expansion by acquiring AppTec, ABGENT, Shanghai Medkey Med-Tech Development Co., and NextCODE Health.

Tigermed Consulting is a CRO company that specializes in the services related to clinical trials and clinical research. In 2014, the company recorded CNY 624.6 million in revenue, up as high as 85.6%. In August 2012, the company completed its IPO, and then continuously strengthened its competitiveness through M&A and investment in subsidiaries. During 2013-2014, Tigermed Consulting founded Fantastic Bioimaging, Shanghai Tigermed Consulting Co., Hangzhou Talent MedCinsultant, and Tigermed-IntelliPV Ltd., and purchased BDM and Frontage Labs. In 2015, the company announced a proposed acquisition of Beiyi Renzhi (Beijing) Medical Technology Development Co. and DreamCIS Inc, a South Korean company.

Boji Medical Biotechnological, a comprehensive CRO company, was publicly traded on GEM of Shenzhen Stock Exchange in April 2015. As of the end of 2014, it had provided an accumulated more than 400 clinical research services and over 200 preclinical research services. In recent years, it has begun to focus on international expansion, successively undertaking the service projects of some overseas companies including Sweden's Astrom Research International and South Korea's Hyundai Pharmaceutical.

Chinese Geriatric Drug Market Exceeded CNY 120 Billion in 2014

The population of Chinese senior citizens aged 60 and above rose 4.94% in 2014 to 212.42 million, according to official statistics. By 2025, Chinese experts estimate this figure to exceed 300 million.

Statistical Summary of Chinese Senior Population

Year	Population >= Age 60 (mln)	+/- (%)
2007	153.40	–
2008	159.89	+4.23
2009	167.14	+4.53
2010	177.65	+6.29
2011	184.99	+4.13
2012	193.90	+4.82
2013	202.43	+4.40
2014	212.42	+4.94

Source: NHFPC

Consumption of Geriatric Drugs in Major Cities Public Hospitals 2011-2014

Rank	Therapeutic Category	+/- (%)			
		2011	2012	2013	2014
1	Alzheimer's Disease	+27.77	+29.63	+15.65	+12.32
2	Anti-osteoporosis	+7.68	+15.59	+3.53	+10.08
3	Elderly Osteoarthritis	+13.87	+30.02	+10.92	+15.31
4	Anti-Parkinson	+22.45	+31.38	+12.97	+12.27
5	Anti-prostatic Hyperplasia	+1.33	+15.87	+1.83	+11.62
6	AMD	+6.78	-5.42	+114.62	+110.36
7	Glaucoma	+27.67	+23.49	+7.77	+31.96
8	Urinary Incontinence	+35.53	+50.61	+2.12	+6.83
9	Senile Cataract	+6.64	+14.25	+35.97	-2.66

Source: NHFPC

The incidence rate of chronic diseases among Chinese senior citizens is 67.3%, NHFPC data suggests. Their average medical expenditure is around three times of that for the young, accounting for 30%-35% of national total medical expenditures annually.

SMEI data shows that the public hospital consumption of geriatric drugs was around CNY 30 billion and estimated total Chinese consumption of such drugs exceeded CNY 120 billion in 2014.

Leading senile degenerative diseases in China include Alzheimer's disease, Parkinson's disease, senile osteoporosis, senior degenerative arthritis, senile benign prostatic hyperplasia, AMD, glaucoma, cataract, presbycusis and degenerative valvular disease.

Chinese Cardiovascular Disease Drug Market to Surpass CNY 150B in 2015

China's morbidity of high blood pressure and diabetes is estimated by the NHFPC to be around 25.2% in 2012. It is estimated the country has as many as 290 million cardiovascular disease (CVD) patients.

The Chinese CVD drug market surged 120.98% between 2011 and 2015 and the market size is expected exceed CNY 150 billion in 2015.

Data from the China Pharmaceutical Industry Information Center (CPIIC) under the Ministry of Industry and Information Technology (MIIT) shows that the CVD drug purchase by representative urban hospitals in 22 major Chinese cities grew 10.14% in 2014, reaching CNY 21,565 million.

The following table provides more details of CVD drug purchases by representative hospitals of 22 major Chinese cities between 2006 and 2015.

Cardiovascular Drugs Consumption in Rep Hospitals of 22 Chinese Cities 2006-2015

Year	Cardiovascular Drugs		Anti-hypertension Drugs		Statins		Sartans		Calcium Channel Blockers	
	Sale Value (CNY bln)	+/- (%)	Sale Value (CNY bln)	+/- (%)	Sale Value (CNY bln)	+/- (%)	Sale Value (CNY bln)	+/- (%)	Sale Value (CNY bln)	+/- (%)
2005	4.59		1.5		0.2		0.3		0.6	
2006	5.39	+17.28	1.7	+17.95	0.3	+36.88	0.4	+40.55	0.7	+13.78
2007	6.58	+22.14	2.2	+24.56	0.4	+35.03	0.6	+43.58	0.9	+21.09
2008	7.62	+15.85	2.6	+21.96	0.5	+33.75	0.8	+26.64	1.1	+21.12
2009	9.18	+20.43	3.2	+21.14	0.7	+34.65	1.0	+30.76	1.3	+16.98
2010	11.11	+21.11	3.7	+15.53	0.9	+28.39	1.2	+21.49	1.4	+14.27
2011	12.90	+16.02	4.1	+11.11	1.1	+24.18	1.4	+16.85	1.5	+7.84
2012	15.37	+19.16	4.6	+12.65	1.6	+38.42	1.7	+18.22	1.7	+8.69
2013	17.21	+12.03	5.1	+10.56	2.0	+29.40	1.9	+12.86	1.8	+6.45
2014	18.96	+10.14	6.5	+26.78	2.5	+24.19	2.2	+16.67	1.6	-9.57
2015E	21.57	+13.74	7.3	+12.90	3.4	+32.29	2.6	+18.28	1.7	+3.88

Source: CPIIC

Review of Chinese Hospital Drug Market for Anti-asthma Drugs

The Chinese hospital drug market of anti-asthma drugs was up 19.6% in 2014, reaching a total of CNY 1,942 million, according to a recent feature article on the *Medicine Economic Information* journal published by SMEI.

With continuously increasing market share in the past eight years, anti-asthmatic drugs accounted for nearly 51% of respiratory system drug hospital sales. However, the annual growth rate of anti-asthmatic drug sales in Chinese hospitals has also fallen persistently from 30%-40% before 2011 to around 20% in the last three years.

Respiratory System Chemical Drugs in Public Hospitals 2006-2014

Year	Respiratory System Market		Anti-asthma Market		
	Sales Value (CNY mln)	+/- (%)	Sales Value (CNY mln)	+/- (%)	Share (%)
2006	849	–	244	–	28.76
2007	1,026	+20.88	318	+30.33	31.00
2008	1,264	+23.20	433	+35.99	34.22
2009	1,460	+15.51	551	+27.29	37.71
2010	2,021	+38.42	813	+47.75	40.25
2011	2,529	+25.14	1,107	+36.09	43.78
2012	2,928	+15.78	1,342	+21.24	45.84
2013	3,264	+11.48	1,624	+21.01	49.76
2014	3,826	+17.22	1,942	+19.57	50.76

Source: SMEI

Top 10 Anti-asthma Chemical Drugs in Chinese Hospitals 2014

Inhaled Drugs	Systemic Drugs
Budesonide	Montelukast
Fluticasone Propionate + Salmeterol	Doxofylline
Budesonide Formoterol Powder	Compound Methoxyphenamine
Tiotropium Aerosol	
Ipratropium Bromide Aerosols and Solutions	
Ipratropium Bromide and Albuterol Aerosol Solutions	
Terbutaline Atomization	

Source: SMEI

There are a total of 50 anti-asthma drugs being used actively in Chinese hospitals. The top ten chemical drugs are shown in the following table.

Budesonide was the top anti-asthma drug in Chinese hospitals with CNY 436 million sales in 2014, up 29.89% year on year. AstraZeneca continued to dominate 99.6% of the Chinese hospital market for Budesonide, despite launches of several domestic generics in recent years.

Chinese patients are found to be resistant to inhaler drugs and they tend to prefer oral and injectable anti-asthma drugs, which have market shares of 34.8% and 33.6% respectively.

While theophylline drugs are the most commonly-used anti-asthmatic drugs in Chinese hospitals, luekotriene receiptor antagonists (LRAs) saw the highest growth in recent years.

LRA and Theophylline Consumption in Chinese Hospitals 2006-2014

Year	LRAs		Theophyllines	
	Sales Value (CNY mln)	+/- (%)	Sales Value (CNY mln)	+/- (%)
2006	32		47	
2007	43	+35.99	63	+32.88
2008	59	+37.51	84	+33.96
2009	75	+25.46	117	+38.78
2010	111	+48.40	168	+43.80
2011	137	+23.54	217	+29.06
2012	175	+28.20	240	+10.93
2013	206	+17.26	242	+0.77
2014	251	+22.12	274	+13.06

Source: SMEI

Representative drugs in the above two therapeutic subclasses are as follows:

Representative LRA and Theophylline Drugs in Chinese Hospitals

LRAs	Theophyllines
Montelukast	Doxofylline
Zafirlukast	Compound Methoxyphenamine
Seratrodast	Dyphylline
Ibudilast	Aminophylline
Pranlukast	Theophylline and Ephedrine HCl compound preparation
Pemirolast	Aminophylline Bromhexine and Chlorphenamine
Zileuton	Theophylline Sodium Glycinate
Tranilast	
Suplatast Tosilate	

Source: SMEI

Industry News

CPIIC Releases Latest Chinese Pharma Data and Forecasts

The China Pharmaceutical Industry Information Center (CPIIC) released on December 1 a range of latest Chinese pharmaceutical industry and market data along with its forecasts for 2015 and 2016.

The Chinese pharmaceutical market growth slowed further to 12.99% in 2014, down from 14.97% in the previous year and nearly 20% in 2011, according to the CPIIC.

China Pharma Market Size and Growth 2010-2014

Year	Terminal Market (CNY bln)	+/- (%)
2010	675.0	–
2011	809.7	+19.96
2012	955.5	+18.01
2013	1,098.5	+14.97
2014	1,241.3	+12.99

Source: CPIIC

Structure of Chinese Pharma Market in 2014

Sector	Terminal Market (CNY bln)	Share (%)
Pharma Formulations	769.6	62
TCMs	384.8	31
Biologicals	86.9	7
Total	**1,241.3**	**100**

Source: CPIIC

CPIIC forecasts that the revenues and net profits of Chinese pharmaceutical manufacturing sector will grow at 10.69% and 12.03% respectively in 2015 and rise again by 9.57% and 7.51% in 2016, maintaining a trend of slowing growth. The net profit margin of the Chinese pharmaceutical industry has been 9.5% to 10.4% between 2011 and 2015, which has been consistently higher than the average margin for all Chinese industries in the period at less than 6%.

Revenues and Profits of Chinese Pharma 2014-2016E

Year	Revenues (CNY bln)	Net Profits (CNY bln)
2010	1,193.9	130.9
2014	2,455.3	246.0
2015E	2,717.8	275.6
2016E	2,978.0	296.3

Source: CPIIC

Forecasts of Chinese Pharma Revenues and Profits by Subsectors 2016

Sector	Sales Revenue (CNY bln)	Share (%)	Net Profits (CNY bln)	Share (%)
Pharma Formulations	768.15	25.79	87.50	29.53
TCMs	701.55	23.56	71.12	24.00
APIs	506.91	17.02	40.77	13.76
Biologicals	334.32	11.23	36.35	12.27
Others	667.07	22.40	60.56	20.44
Total	**2,978.0**	**100.00**	**296.3**	**100.00**

Source: CPIIC

Despite falling growth rates, the industrial value added growth of Chinese pharma has consistently outpaced that of GDP in the past five years.

Growth of Chinese Pharma Industrial Value Added vs. GDP

Year	Industrial Added Value Growth (%)	GDP Growth (%)
2010	13.7	10.6
2011	17.7	9.5
2012	15.2	7.7
2013	13.3	7.7
2014	12.1	7.3

Source: National Bureau of Statistics

Total Chinese Healthcare Expenditures 2010-2014

Year	Total Health Expenditure (CNY bln)	+/- (%)	As % of GDP
2010	1,998.04		4.98
2011	2,434.59	+21.85	5.15
2012	2,784.68	+14.38	5.41
2013	3,186.90	+14.44	5.57
2014	3,699.99	+16.10	5.82

Source: CPIIC

Meanwhile, growth of overall Chinese healthcare expenditures continued to rebound in 2014 at 16.10%, up from 14.44% in 2013. This figure as a percentage of GDP also kept rising in the past five years to 5.82 last year.

CPIIC also estimates the Chinese broad healthcare market in 2014 to be CNY 4,453.2 billion, encompassing medical services, pharmaceuticals, medical devices and other health products.

Chinese Broad Healthcare Market in 2014

Sector	Value (CNY bln)	Share (%)
Medical Service	2,140.0	48
Drugs	1,781.3	40
Medical Devices	133.6	3
Others	400.8	9
Total	**4,453.2**	**100**

Source: CPIIC

Chinese Pharma Sales Grew 9.6% in the First Three Quarters of 2015

For the first time in the past decade, sales revenues of the Chinese pharmaceutical manufacturing sector rose 9.6% in the first three quarters of 2015 totaling CNY 1,810 billion, compared with 13.2% growth in the same period of 2014, according to latest data reported by SMEI.

By comparison, the sector's net profits grew 14.7% in the first three quarters this year, up from 12.5% in the corresponding period last year. Sales margin of the sector was 10.02% in the period.

Among the seven subsectors, SMEI suggests that biological products, TCM crude drugs, medical devices and health materials saw above average revenue growth in the period, while pharmaceutical formulations, APIs and formulated TCMs experienced below average revenue growth at 9.7%, 7.8% and 6.8% with total revenues of CNY 320 billion, CNY 500 billion and CNY 430 billion.

The net profits of pharmaceutical formulation, API and formulated TCM subsectors surged 12.9%, 10.6% and 14.0% respectively in the first three quarters of this year to reach CNY 58 billion, CNY 23 billion and CNY 45 billion. Sales margins of the subsectors were 11.59%, 19.2% and 10.44%.

Regulatory Changes in China to Impact Development & Manufacturing Strategies

The China Food and Drug Administration (CFDA) has recently published long-anticipated reforms designed to accelerate the regulatory review of new drugs and expand options for manufacturing those approved. According to PaizaBio, the new policies, which went into effect December 1 and are posted on CFDA's website, will impact both Chinese and Western pharmaceutical companies.

The reforms represent major changes in China's drug development and commercialization policies, addressing critical areas: accelerating the high-volume backlog of drugs awaiting review and approval by the CFDA and fostering domestic clinical drug development and manufacturing to international technical and quality standards.

Streamlining Drug Review

Streamlining the review of innovative new drugs is a top priority of the CFDA given growing public health issues that stand to benefit from effective pharmacological treatments. The new regulatory policy significantly expands the types of drugs that may qualify for a streamlined review process via the Fast Track or green approval pathway and redefines what qualifies as a new drug. Prior to the policy change, the Fast Track regulatory approval pathway was limited to novel drugs not approved for use anywhere in the world or drugs addressing areas of critical and high unmet medical need.

The following drug categories stand to benefit from China's redefined Fast Track regulatory approval pathway:

- Pediatric/geriatric drugs;
- Drugs sponsored by national science and technology related grants;
- Drugs to treat diseases or conditions prevalent in China;
- Foreign innovative drugs manufactured locally in China;
- Foreign drugs manufactured at an US-FDA or EU-EMA qualified plant under review by the respective regulatory authorities (FDA/EMEA) for concurrent marketing authorizations; and
- Innovative drugs using advanced technology, using innovative treatment protocols or having significant clinical benefit.

Fast Track approval will be permitted if a drug falls in one of these categories, and a clinical trial application is submitted three years prior to the date of patent expiration or the marketing authorization application is submitted one year prior to the date of patent expiration.

Redefining "New"

The new policies also seek to clarify what constitutes a "new" drug. The CFDA now defines new drugs as only those pharmaceutical products that have never been marketed anywhere in the world or those that represent an improved form of the new drug. Generic drugs are defined as pharmaceutical products that are consistent with the reference or originator drug in terms of quality or efficacy. The CFDA plans to introduce a classification system, which address these new definitional categories.

To facilitate clinical development of new drugs in China, the CFDA clinical trial application process will be streamlined; a single umbrella approval will replace the current system requiring approval at each phase of a trial.

Expanding Manufacturing Options

Historically, only China-based drug manufacturers could apply for approval to market new drugs in China. Drug research organizations without large scale manufacturing capabilities were required to transfer new drug innovations to a manufacturer that would then become the Marketing Authorization Holder (MAH).

This mandatory transferal of marketing rights created a disincentive for innovation and commercialization by research-based organizations at a time when China is focusing on building a more innovation-driven economy. The new policy now enables research-based organizations to commercialize their innovations while retaining marketing rights. As part of this development, China is launching a pilot MAH program in ten Chinese provinces allowing research-based organizations and individuals to outsource drug manufacturing to a contract manufacturing organization (CMO), while retaining marketing authorization status on approved drugs.

Impact on Multinational Pharma

China's policy changes have the potential to significantly impact

the global clinical development and manufacturing strategies of multinational pharmaceutical companies operating in China, said Stuart Rose, founder and CEO of PaizaBio, a company focused on helping western-based pharmaceutical companies manufacture drugs in China for the Chinese market. Rose is currently in China as a featured speaker at the 2015 China National Science and Technology Cooperation Week in Dongguan City, as a guest of Tsinghua University's Donguan Innovation Center.

"With 1.4 billion people, China represents the largest drug market in the world. Yet western pharmaceutical companies have only a small foothold," Rose said. "This is largely because China is a complicated environment for western companies in which to operate. These new policies reflect China's growing willingness to engage multinationals in their drug development initiatives and allow contract manufacturing of new drugs in China for the Chinese market."

Rose added, "Entering China is not easy; the new policies reflect China's intent to be an active participant in global drug development and commercialization. That will make manu-facturing in China for the Chinese market through a CMO like PaizaBio an attractive way to comply with CFDA policies and gain immediate access to China's 1.4 billion citizens."

First Pharma B2B Platform for Over-stocked Medicines Approved in Guangdong

Guangdong Lifeng Pharma announced on November 24 that it has received the Internet Drug Transaction License for its B2B pharma e-commerce platform (www.lf99.com.cn) from Guangdong Provincial Food and Drug Administration.

The platform, also doing business as the China Promotional Public Service Platform for Overstocked Medicines, is the first Chinese portal specializing in promoting and distributing overstocked medicines.

The portal will offer best discounts to help manufacturers sell their overstocked medicines, which are usually products with less than nine months of validity periods, according to Xuefeng HUANG, Chairman of Lifeng Pharma.

He said that such products are estimated to account for 3% of China's pharmaceutical output, valuing at around CNY 80 billion. Currently at least CNY 30 billion worth of such medicines become expired and have to be destroyed annually.

Huang said his company plans to hire 3,500 sales people within five years to help promote and sell such medicines.

He also revealed that Lifeng Pharma has entered into strategic alliances with leading Chinese pharmaceutical companies including Guangzhou Pharma, Shandong Luoxin, Shandong Xinhua and North China Pharma.

Local Company News

Simcere Pharma to Co-market Daiichi Sankyo's High Blood Pressure Drug in China

Simcere Pharma announced on December 5 a Strategic Partnership with Daiichi Sankyo under which the two companies will co-market latter's high blood pressure drug Benicar (Olmesartan Medoxomil tablet) in China.

Under the agreement, Simcere Pharma will exclusively promote and distribute Benicar in mainland China, while Daiichi Sankyo will be responsible for branding and market access support. Both parties will share proceeds from sales. Specifics of the financial arrangement were not disclosed.

Olmesartan medoxomil is an angiotensin receptor blocker (ARB), used alone or in combination with other medications to treat high blood pressure. It was developed by Sankyo in 1995. Benicar was approved in China in 2012.

The deal is the first Chinese exclusive sales agreement of Daiichi Sankyo in high blood pressure therapeutic area and also its first national sales partnership with a local Chinese pharmaceutical company. For Simcere, it is the first commercialization agreement for an originator drug which is already on the Chinese market.

Akeso Biopharma Out-licenses Novel Anticancer mAb to MSD

Akeso Biopharma Inc. (Akeso) announced on December 4 that the company has entered into a collaboration with MSD, known as Merck (NYSE:MRK) in the United States and Canada, to research, develop and commercialize immuno-oncology therapeutics.

According to this agreement, MSD will obtain exclusive worldwide rights to develop and commercialize Akeso's compound AK-107, an immune checkpoint blocking antibody discovered by Akeso in China. Under the terms of the agreement, Akeso will receive an upfront payment from MSD and up to US$200 million in development and commercialization milestone payments. Additional details were not disclosed.

Uni-Bio Buys Global Rights of Diabetes Drug from Jiangsu Hansoh

Uni-Bio Science Group Limited (HKEx code: 690) announced on November 26 that it will acquire exclusive global rights to manufacture and commercialize mitiglinide, a new oral antidiabetic agent, from Jiangsu Hansoh Pharmaceutical Co. Ltd.

Mitiglinide is a new, oral antidiabetic agent in China which belongs to the glinides class of blood glucose lowering compounds. It is known to improve postprandial hyperglycemia in patients with Type 2 diabetes and has received New Drug Approval as a first and/or second line of treatment for the disease from the CFDA.

Hansoh has developed its own version of mitiglinide; it is currently being marketed and sold in China and Hansoh has successfully won a number of provincial tenders to date. Under the terms of agreement, Uni-Bio will acquire exclusive rights to distribute and commercialize Hansoh's mitiglinide globally and will manufacture the drug in its CGMP-certified plant in Beijing. Hansoh will continue to provide the active pharmaceutical ingredient to Uni-Bio.

ZAI Lab, Hanmi Execute License Agreement for Novel Lung Cancer Drug in China

ZAI Lab and Hanmi Pharma announced on November 23 that they have executed a collaboration and license agreement under which ZAI Lab will acquire exclusive rights in China (including Hong Kong and Macau) to develop, manufacture and commercialize HM61713, a novel, third-generation EGFR targeted therapy for the treatment of EGFR mutation positive lung cancer.

HM61713 is a novel, third-generation, irreversible EGFR mutant-

selective tyrosine kinase inhibitor (TKI) developed to specifically target tumors with T790M mutations. At the ASCO Annual Meeting 2015, interim results of the Phase I/II clinical trial were presented and showed strong efficacy signals, combined with a favorable safety profile. In July this year, Hanmi and Boehringer Ingelheim entered into an exclusive license and collaboration agreement for the development and global commercialization rights, except South Korea, China and Hong Kong, of HM61713 (BI1482694).

Luqa Signs Agreement with Lab Genevrier for Novel Skin Product

Luqa Pharma, a China focused specialty pharmaceutical company, announced on December 7 the signing of a licensing agreement with Laboratoires Genevrier for Viticell, an innovative single-use kit for the treatment of Vitiligo to be commercialized in the People's Republic of China, Hong Kong and Macau.

Vitiligo is a continual and long term skin problem that produces white depigmentation patches that develop and enlarge only in certain sections of the skin. The disease is not contagious, nor life threatening, but can be life altering, affecting the self-esteem of patients suffering from it.

With this product, Luqa reinforces its commitment towards innovation, and its leading position as provider of advanced treatments for skin diseases. Robert Braithwaite, Luqa's CEO stated: "This collaboration is aligned with our strategy to introduce the most innovative medical solutions for unmet dermatological medical needs. We are proud to collaborate with Laboratoires Genevrier in providing an innovative and effective treatment to Vitiligo patients China. We continue in our quest to improve the quality of life of patients by providing innovative solutions."

Aoxing Pharma Inaugurates Narcotic Drug R&D Center

Aoxing Pharma, a specialty pharmaceutical company operating in China, announced the inauguration of its new Narcotic and Psychotropic Drug Research Center on December 5.

Construction of the Center was funded by the Reform and Development Commission of Hebei Province in China along with Aoxing Pharma's Chinese subsidiary, with a total investment of US$2.15 million, the company said.

This state-of-the art research center occupies 2,200 square meters. The center will provide facilities for narcotic and psychotropic drug research and development, including chemical synthesis, transdermal patch formulation, pilot manufacturing, quality review and analytical labs.

The center is outfitted with the latest technology, to offer an optimal research environment to the research scientists at Aoxing Pharma.

Separately, Aoxing said Wilfred Chow resigned from his position as the company's chief financial officer. ZHANG Guoan, Aoxing Pharma's senior vice president for finance, will assume the position of CFO.

Guangzhou Baiyunshan Pharma, AliHealth Enter Partnership for O2O Business

Guangzhou Baiyunshan Pharmaceutical, a listed subsidiary of Guangzhou Pharmaceutical Group, announced on November 30 that it has signed an agreement with Alibaba Health Information Technology (Beijing) Co. Ltd., a fully-owned subsidiary of AliHealth for strategic alliance in pharma e-commerce, including O2O business, drug prescription filling, BMI payment and electronic drug regulatory code management.

Guangzhou Baiyunshan stated that the deal will be beneficial to the company's business positioning for pharma e-commerce, although the Chinese pharmaceutical regulatory regime for online drug sales remains tight-gripped and expected liberalization is nowhere near sight.

Guangzhou Baiyunshan currently owns and operates Guangzhou Jianmin retail pharmacy chain as well as its B2C operations.

Earlier in May this year, Shanghai Pharma also entered an exclusive strategic cooperation framework agreement with China's leading e-commerce firm Beijing Jingdong Century Trading Co., Ltd., which owns and operates JD.com, in developing pharmaceutical e-commerce business.

Ascletis Secures US$20M Investment from Goldman Sachs

Ascletis, a China-based biotechnology company focused on innovative drug development, announced on December 2 that Goldman Sachs completed a US$20 million investment in the company. So far, Ascletis has completed two rounds of financing within the past two months. The first round of US$35 million investment was led by C-Bridge Capital, Tasly Pharmaceutical and Pavilion Capital.

Proceeds from this round of financing will be used to strengthen Ascletis' R&D capacity, and broaden the scope of its R&D pipeline.

Ascletis is dedicated to discovering and developing new treatments for infectious diseases and cancer. The company is currently focused on HCV treatment regimens.

Financial-related Local Company News in Brief

A number of recent financial-related news events of the Chinese pharma industry were recorded by *Pharma China* in November and December and they are shown in the following table:

Company Financial News Brief November/December 2015

Announcement Date	Main Parties	Deal Size	Subject	Description
11/21/2015	Hainan Poly Pharm	CNY 538.8M	IPO	It has filed an IPO application with CSRC to raise CNY 538.8 mln to fund two manufacturing projects.
11/22/2015	North China Pharma (NCPC)	CNY 258.4M	M&A	Guoke Rongan Biotech will acquire 47% of its subsidiary NCPC Gene Tech for CNY 258.4 mln.
11/23/2015	Akesobio (Zhongshan)	CNY 130M	Fund raising	It completed round A financing of CNY 130 mln to fund clinical trials of mAbs, expand pipeline and building GMP manufacturing facilities.
11/23/2015	BSK BioPharma	CNY 150 mln	Fund raising	It is seeking to raise CNY 150 mln by offering a 20% stake in its Series A funding round. Proceeds would be used to enhance pipeline.
11/25/2015	Harbin Gloria Pharma	CNY 2.4B	M&A	It has agreed to acquire an 85% stake in Shanxi Pude Pharma for CNY 2.4 bln.
11/25/2015	Tianjin Ringpu Biotech	CNY 124M	M&A	It has agreed to acquire a 38.3% stake in South China Biopharma for CNY 124 mln in cash.
11/28/2015	China Grand Pharma and Healthcare Holdings	CNY 210M	M&A	It is to acquire a 30% stake in Beijing Jiu He Pharma from Ningbo CDH for CNY 210 mln.
11/30/2015	Zhangjiang S&T Venture Capital	CNY 58.3M	Divestment	It is seeking divestiture of a 12% stake in Shanghai Haitai Pharma for a minimum of CNY 58.3 mln.
11/30/2015	Shijiazhuang Yiling Pharma	CNY 1.3B	Fund raising	It is to raise up to CNY 1.3 bln in private placement of shares to fund projects and boost capital.
11/30/2015	Guangdong Taicheng Pharma	CNY 297M	M&A	It has reached an agreement to acquire a 100% stake in Taishan Xinning Pharma for CNY 297 mln.
12/1/2015	3SBio	n/a	M&A	It is expanding its biosimilar business by raising its stake in Shanghai CP Guojian Pharma to 54%.
12/2/2015	Xiangxue Pharma	HK$31M	Investment	Its HK subsidiary signs agreement to invest HK$31 mln in Chuangmei Pharma's stock offering in HK.
12/2/2015	Chuangmei Pharma	n/a	IPO	It is to raise HK$214 mln from an IPO at HKSE and will use ~15% of proceeds for potential acquisition of pharma distributors in southern China.
12/4/2015	Tianyishi Pharma	CNY 30M	Fund raising	It is seeking to raise CNY 30 mln to raise production capacity and may also consider a majority stake divestment to a listed biotech company.
12/5/2015	Renhe Pharma	CNY 277M+ CNY 49M	M&A	Renhe will acquire 56% of online pharmacy player Beijing Jingwei Yuanhua Pharma for CNY 277 mln. It will also inject CNY 49.44 mln into the firm to raise its stake to 60%.
12/10/2015	Kangmei Pharma	CNY 8.1B	Fund raising	It aims to raise up to CNY 8.1 bln in share private placement to replenish capital, repay bank loans.
12/10/2015	Yifan Xinfu Pharma	CNY 374M	M&A	It plans to acquire 100% of Sichuan Tianlian Pharma for CNY 303 mln and 100% of Shenyang Aohua Pharma for CNY 71 mln.
12/11/2015	Jiangsu Hansoh Pharma	$1.5B	IPO	It is planning an IPO worth $1.5 bln in Hong Kong in the first half of 2016.
12/11/2015	Beijing Zhongguancun Sihuan Pharma	CNY 309.2M	M&A	It has signed an agreement to acquire a 78.8% stake in Duoduo Pharma for CNY 309.3 mln.
12/11/2015	Jiangzhong Pharma	CNY 66.7M	M&A	It agreed to divest its 51% stake in Jiangxi Jointown Pharma to Jointown Pharma for CNY 66.7 mln.
12/15/2015	HEC Changjiang Pharma	$ 1.14B – $1.56B	IPO	It launched IPO in HK and will issue 90.132 mln shares. The net proceeds amount to $1.14 bln – $1.56 bln.
12/18/2015	Shandong Xinhua Pharma	CNY 720.7M	Fund raising	It plans to raise up to CNY 720.7 mln in share private placement.

Source: Pharma China

Foreign Company News

MSD China to Focus on Biopharma Opportunities in China

MSD China is strengthening its efforts and collaborations with partners to tap into huge growth potential in biopharmaceuticals, President Christopher Round said. Round was speaking at the China Bio-Pharma Executive Summit, where dozens of biopharmaceutical industry leaders discussed industry trends and topics of interests.

China's biopharmaceutical industry saw an annual revenue growth of 13.95% and profit growth of 11.82% in 2014. Its revenue size is expected to touch US$100 billion this year. In the next 5-10 years, the industry predicts an annual growth pace of 12% to 20%. The government is also making significant long-term investments in research and development and the State Council included the field of life sciences as one of the seven strategic emerging industries.

Round pointed out that China's therapeutic biologics market was still emerging, accounting for only 2% of the value of the global market. The overall Chinese pharmaceutical market accounts for only 7 percent of the global market.

"As the new round of industry revolution unfolds in front of us, China still has a lot of potential to unlock and that is why it is so

important for us to talk about biopharmaceuticals and China, and the biopharmaceutical industry in China," he told the forum. "The biopharmaceutical revolution has made the impossible possible in many fronts of drug development, and I assure you that in the near future, we will be continuously amazed by more and innovative biologics to save and improve people's lives."

Round cited as example how MSD's hepatitis B vaccine helped to prevent an epidemic in the late 1980s. "Biologics are fundamentally changing our society, and this change is relevant to each of us," he added. "In 1989, MSD signed an agreement with the Chinese government to license our technology to produce the world's most advanced genetically engineered recombinant hepatitis B vaccine at that time, and this technology transfer enabled a national hepatitis vaccine program that has virtually halted an epidemic in its tracks."

"MSD is strengthening its focus on biologics as we see a number of opportunities in China, as some very promising early-stage research results and mature biopharmaceutical products surface in this market," Round said.

Currently, China is one of the top markets for MSD in the world, and is soon to surpass France and Germany, becoming the third largest market only after the US and Japan.

"Research and development is the cornerstone of our industry, and innovation is the fundamental driver of our business and I believe only those that are committed to continuous research and development can survive this revolution," he said.

MSD established a clinical data management center in Beijing in 2005, and a comprehensive R&D center in Beijing in 2011. Earlier this year, MSD established a Far East Innovation Center located in Shanghai to search for collaborative and licensing opportunities with local companies and research institutes. This center was designed to cover the Asia Pacific region.

MSD is also actively looking for therapeutic solutions currently under development to meet local medical needs, and perhaps in the not too distant future, it can bring break-through science originating from China to benefit the world.

Round added that MSD's mission was not over after having successfully developed an innovative therapy. "We need to work with related stakeholders to make the product accessible to patients in need ... The biopharmaceutical revolution is also fundamentally changing our industry's ecosystem, in which patients, drug developers and makers, and government agencies face new opportunities and new challenges," he said.

At the same time, MSD is also working with partners to develop biosimilars. Round said, "high-quality biosimilars can improve patient's accessibility to lifesaving biological medicines across the globe, while respecting the intellectual property rights of the originator."

In the evolving environment, doctors will need to continue to improve their capability to properly take on their increased roles, and drug developers and makers should be their trusted partners, Round added. The government, doctors, drug developers, and drug manufacturers need to establish interactive platforms to foster information exchange, and provide one another with their perspectives on the newest healthcare solutions, he said.

AstraZeneca Steps Up China Investment thru Alliance with Wuxi PharmaTech

AstraZeneca was boosted on December 16 by a double dose of Asian news as it unveiled plans to spend US$800 million (GBP 533 million) on its Chinese operations and agreed to buy Takeda Pharmaceutical's lung treatments, including expanded rights to a medicine for chronic obstructive pulmonary diseases (COPD) for US$575million (GBP 383 million).

The company aims to build up its already strong position in China by making and developing more medicines locally, and will invest more than US$800 million (GBP 527.8 million) in the country over the next 10 years. Its latest investments in China are part of a broader push to create an "end-to-end research and development" organization in the country that will involve the investment of hundreds of millions of dollars over the next 10 years, a company spokeswoman said.

The British drugmaker's decision to step up investment in China, notably through a strategic alliance between its subsidiary MedImmune with local firm WuXi PharmaTech, chimes with Beijing's desire to see more treatments made in China.

The upside for AstraZeneca should be that locally produced medicines win faster approval from the China Food and Drug Administration, rather than being delayed for years as often happens with imported products.

Under the agreement, AstraZeneca has the option to acquire WuXi AppTec's biologics manufacturing facility in Wuxi city, one of several manufacturing facilities for WuXi, in the next few years. Prior to that, WuXi Biologics, the biologics division of WuXi AppTec, remains the exclusive partner for R&D manufacturing for MedImmune's innovative biologics in China.

The alliance builds on the existing joint venture between WuXi and MedImmune that was formed in 2012 to develop and commercialize MEDI5117, a novel biologic for autoimmune and inflammatory diseases. It is the first such collaboration in China between a global company and a Chinese company to develop novel biologics. The IND application was subsequently accepted by CFDA for review in March 2015. WuXi will continue manufacturing for the program at its state-of-the-art biologics facilities, the first in China to meet cGMP standards of the United States, the European Union and China. WuXi is committed to its manufacturing capabilities in China and will continue to provide its clients with the highest quality of service.

In April 2015, WuXi announced that it is building the largest state-of-the-art biomanufacturing facility globally, using fourteen 2000L and two 1000L disposable bioreactors, which will support late-phase clinical and commercial manufacturing. The first phase of the facility will be operational in January 2017.

"We don't want to have drugs that are approved in the U.S. and elsewhere and it then takes another five or six years to bring them to patients in China," Bahija Jallal, head of research at AstraZeneca's biotech division MedImmune, told Reuters.

In future foreign firms will be more reliant on new, patented medicines, analysts believe, although the scale of demand for such expensive products is uncertain in a country with only basic health insurance cover. AstraZeneca hopes to position itself better for this new era with its new investments.

One element involves WuXi AppTec producing new biotech medicines locally in China, with AstraZeneca having the option to acquire WuXi's manufacturing capacity through an overall investment of US$100 million.

AstraZeneca is also spending US$50 million on developing traditional "small molecule" drugs in China and is creating a new global hub for pharmaceutical development in and around Shanghai.

The decision to increase local Chinese investment parallels similar moves made by AstraZeneca and other international drugmakers to invest in production in Russia – another country where the government is keen to build up local pharmaceutical capacity.

"In a few larger emerging markets that want to play a bigger role in meeting their healthcare needs locally, having a local capability can make a big difference," said AstraZeneca's head of international operations Mark Mallon. "Russia and China are two markets that are important enough that we are ready to partner with governments and meet their desires."

GSK China Slashed 40% of Its Sales Force To Reboot China Business

GlaxoSmithKline has cut 40% of its sales reps in China and axed some units as it eyes a return to growth in 2016, after sales plunged during a bribery scandal that landed it with a record US$490 million fine in 2014, according to GSK China GM Herve Gisserot.

The British firm is gambling on a new, cleaner image to reboot its performance and reputation with doctors and consumers, Gisserot told Reuters during a wide-ranging interview at the group's Shanghai headquarters. It is the first time Gisserot has spoken at length about the firm's progress since the high-profile scandal.

Gisserot, who took over the position from Mark Reilley two years ago, said "obviously [GlaxoSmithKline] is a very well-known name in China and unfortunately not for the right reasons," adding "we are in the process of rebuilding our reputation, and we have to be very humble."

GSK has previously said it would overhaul its business in China, and more globally, to avoid some of the issues that led to the probe, including stopping all sales-based incentives for drug reps and reducing paid junkets for doctors. GSK sales staff now have to work very differently. Reps have iPads to monitor every interaction with doctors, while fancy meals on expenses have been replaced by a centrally controlled catering system providing "lunch boxes" worth no more than CNY 60 (US$9.40). The move is explicitly designed to take cash out of the system. Bonuses also make up just 25% of salaries, down from 40% pre-scandal, and won't be tied to sales.

The problem is, many of GSK's rivals are not following in step, and adapting to a new model means taking a business hit. Gisserot warned that other drugmakers risked punishment by Chinese authorities if they failed to follow GlaxoSmithKline's reforms.

"Our ability to win under the new model is a question I regularly have to debate with our own employees," Gisserot said. "Can we outperform the market in the short term? Probably not."

GlaxoSmithKline's sales dropped from GBP 759 million (US$1.1 billion) in 2012 to GBP 585 million (US$882 million) in 2013 and were flat last year. Gisserot suggested that after a modest increase in sales next year, revenue growth is predicted to be more "dynamic" from 2017, helped by the rollout of new products, including HPV vaccine Cervarix.

However, the executive cautioned that the days of double-digit growth in China were over as the government tries to drive down prices. "The pharma model in China is not sustainable ... others will have to adjust," Gisserot remarked.

Gisserot noted that GlaxoSmithKline will also not undertake expansion at the rate it did previously. "We added a floor every year without making sure the building had the foundation to be sustainable," Gisserot said, adding "my job now is to make sure the foundations are fit for future growth."

The wider market has seen huge price pressures on drugs as Beijing tries to curb over-prescribing by hospitals, which still make money from dishing out drugs, and rein in an overall healthcare bill set to expand to US$1.3 trillion by 2020.

Gisserot said this would erode sales of expensive branded generics – long a cash cow for Big Pharma in China – and shift the industry's reliance towards more innovative drugs, hopefully helped by faster approvals, although this will take time. "We certainly expect in next couple of years to see a significant price pressure," he said.

Gisserot added GSK, which previously promised to become a "model for reform" in China, was willing to cut prices and promote technology transfer – both demands from a government anxious to secure long-term drug supplies.

With more than 30 staff employed solely to check every single expense claim, GSK is now paying a high price to ensure compliance, but Gisserot warned China's anti-bribery drive could in future snare others.

"I cannot believe [GlaxoSmithKline] is a one off. This anticorruption [drive] will continue. I hope others will learn before it is too late," he remarked.

Eisai to Further Expand in China Through Acquisition of Liaoning Tianyi

Japanese drugmaker Eisai will acquire 100% of a Chinese generics company in a deal worth CNY 500 million (US$78.2 million) in an effort to gain a bigger foothold in the world's second-largest pharmaceutical market.

Liaoning Tianyi Biopharmaceutical manufactures and sells 20 types of generics and has approval to make around 90 drugs. The company employs approximately 250 people and recorded CNY 34 million in sales for the first six months of the year, according to an announcement on November 27. Eisai will finalize the acquisition this fiscal year at the earliest.

Eisai already sells brand-name drugs in China, which is a fast-growing market. Eisai's Chinese pharmaceutical business rose 29% in 2014 to JPY 41 billion, accounting for 7.2% of the company's global sales. The company projects JPY 50 billion (US$404 million) in Chinese sales for fiscal 2015, a roughly 20% surge on the year and representing 9.2% of the firm's worldwide sales.

Generics, however, make up 80% of the Chinese market, and their use will likely increase in rural areas in the near future. Eisai plans to utilize existing sales channels and sell Tianyi's generics to hospitals throughout China. The company will distinguish itself from the competition by putting out high-quality drugs employing technology normally used for name-brand drugs.

Eisai's profitability in Japan and Europe is currently suffering due to expired patents for mainstay drugs. As part of restructuring, the company inked a deal in October to spin off its gastrointestinal drug business and integrate it with Ajinomoto Pharmaceuticals. Eisai also agreed in November to sell off a unit that produces clinical diagnostic reagents to Sekisui Chemical. The drugmaker is pouring funds into its Chinese operation in a bid to bounce back.

Bayer Renews Drug Discovery Partnership with SIOC under CAS

Bayer and the Shanghai Institute of Organic Chemistry (SIOC)

under the Chinese Academy of Sciences renewed their strategic research partnership agreement on November 25 to continue the cooperative project for discovery of novel organic chemical drug compounds.

The cooperation between Bayer and SIOC began in 1996 and the partnership agreement was renewed for the first time in 2010.

The latest agreement renewal calls for further cooperation, on the basis of past successes, in the areas of new synthesis methods, natural product derivatives and metal organic chemistry. The focus of cooperation in the renewed agreement has shifted to explorations of innovative technologies for organic synthesis from previously discovery of new compounds through organic chemistry.

Bayer Pulls Ventavis from the Chinese Market

Bayer Healthcare is reportedly to be in the middle of pulling its primary pulmonary hypertension drug Ventavis (inhaled iloprost) from the Chinese market.

The product was approved by the CFDA in 2006 and has been selling in China since then. The 30 day-cost of the drug was CNY 49,500 when first launched in China, but the cost has been sharply reduced after Bayer and the China Charity Confederation (CCC) launched in 2008 a patient assistance program under which patients will receive four free courses of treatment for each course they pay for. The cost was further reduced in 2013 when Bayer increased the free courses of treatment to eight for each course purchased. The 30 day-cost is therefore now at CNY 5,500 and more patients can now afford to use it.

However, CCC sent a notice on June 29 this year to announce Bayer's decision to gradually withdraw this drug from the Chinese market as of 2015 due to "global strategic adjustments".

The decision has led to turmoil among Chinese patients who said they cannot find replacement drugs. The only possible substitute is imported Remodulin (Treprostinil injection) from United Therapeutics which costs CNY 9,900 per injection with no patient assistance available, but some patients do not respond well to the drug and the cost is prohibitive for the most.

CCC's notice said it has assisted nearly 1,000 patients since 2008 with free drugs valued at around CNY 50 million.

However, it is estimated that there are between 20,000 and 30,000 Chinese patients who need to be treated by the drug, according to Dr. Zhihong LIU of Fuwai Hospital, who said United Therapeutics's Remodulin is far too expensive and few can afford to use it, although the product is now the first line recommendation for serious pulmonary hypertension. She added that there are few medicines available for pulmonary hypertension treatment in China.

Meanwhile, an open petition signed by over 1,400 Chinese patients, patient organizations and NPC delegates was sent on December 10 to Bayer Healthcare headquarters pleading the company to reconsider its decision.

Chinese patients received support from the American Pulmonary Hypertension Association which also sent a letter to Bayer CEO Marijin Dekkers questioning the ethics of Bayer to pull Ventavis out of China.

Chinese reporters contacted the CCC and Bayer Healthcare's Greater China office. They are waiting for further responses from the company about the matter.

Oramed Inks Licensing Deal with Hefei Tianhui Incubator for Oral Insulin

Oramed Pharmaceuticals Inc., an Israeli clinical-stage company, has signed definitive licensing and investment agreements valued at up to US$50 million with Hefei Tianhui Incubator of Technologies Co., Ltd. (HTIT) for exclusive rights to market Oramed's oral insulin capsule, ORMD-0801, in China, Hong Kong and Macau. The agreements were signed at the Israel Knesset (Parliament).

The license agreement payments include a US$3 million due upon execution of the agreement, US$8 million in near-term payments subject to Oramed entering into certain agreements and the balance payable upon achievement of certain milestones.

In addition, if all conditions are met, HTIT will pay a 10% royalty on net sales of the related commercialized products. In addition to the contemplated payments under the license agreement, pursuant to the investment agreement, Oramed will issue to HTIT 1,155,469 restricted shares of Oramed's common stock at a price per share of approximately US$10.39 and US$12 million in total, subject to customary closing conditions.

Solasia, Lee's Enter China License Agreement for Sancuso

Solasia Pharma K.K. and Lee's Pharmaceutical Holdings Limited (SEHK stock code: 0950) jointly announced on November 26 that the two parties have entered into an exclusive license agreement for the commercialization and promotion of Sancuso (granisetron transdermal delivery system) in the People's Republic of China excluding Taiwan, Hong Kong, Macau and the Retained Territory. Solasia will retain rights to promote Sancuso in three major cities (Beijing, Shanghai and Guangzhou; the "Retained Territory") in the PRC.

Under the terms of the Agreement, Solasia granted Lee's Pharma an exclusive license and right for promoting, commercializing, distributing and selling Sancuso in the licensed territory for the patients suffering from chemotherapy-induced nausea vomiting (CINV) caused by chemotherapy.

Solasia obtained an exclusive license to develop and commercialize Sancuso for Asian territories from ProStrakan and is currently waiting for approval from the China Food and Drug Administration.

Sancuso is an extended release transdermal system, delivering the anti-emetic, granisetron, steadily into the patient's bloodstream over several days without the need for injections or swallowing pills. Granisetron is a 5-HT3 receptor antagonist with well-established efficacy against chemotherapy-induced nausea and vomiting (CINV). Sancuso was approved by the U.S. Food & Drug Administration (FDA) in September 2008 for the prevention of CINV in patients receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days.

XL-Protein, Easton Pharma Agree to Develop Biopharmaceuticals Using PASylation Technology

XL-protein GmbH and Chengdu-based Easton Pharmaceutical Co., Ltd. announced on December 17 that they have entered into a License, Development and Commercialization Agreement for novel, long-acting biopharmaceutical products to address a range of unmet needs in ophthalmology and potential further indications. Under this collaboration, XL-protein will apply its

proprietary PASylation technology for drug half-life extension to one Easton target. XL-protein will assume responsibility for early preclinical development activities, Easton will be entitled to further development, manufacturing and marketing of the PASylated compound.

According to the agreement, XL-protein will receive an upfront payment as well as payments for achievement of preclinical, clinical, regulatory and commercial milestones. Furthermore, XL-protein will receive tiered, mid- to mid-high single digit royalties on sales from marketed compounds resulting from the collaboration. Easton will have exclusive marketing rights for the P.R. of China for all PASylated products under the agreement. Easton may choose to executive options to obtain world-wide rights and rights for additional therapeutic indications. Further financial terms have not been disclosed.

Service Provider News

WuXi Pharma Goes Private with Merger Transaction Completed

WuXi PharmaTech (Cayman) Inc. (NYSE: WX) announced on December 10 the completion of its merger with WuXi Merger Limited, a wholly-owned subsidiary of New WuXi Life Science Limited pursuant to the previously announced Agreement and Plan of Merger dated as of August 14, 2015. As a result of the Merger, the latter has acquired WuXi PharmaTech in a cash transaction valued at approximately US$3.3 billion. The merger is a vital step for the company to go private and delist from the NYSE.

Subsequently, WuXi PharmaTech has requested that trading of its ADSs on the New York Stock Exchange be suspended as of the close of trading on December 10, 2015.

A senior executive of WuXi PharmaTech revealed to the Chinese press back in August that the company intents to return to the Chinese A share stock market after delisting from the NYSE through a reverse merger.

Most recently, an insider told the *First Financial Daily* that, as the next step after NYSE delisting, WuXi PharmaTech is likely to split into three companies for separate domestic stock listings.

WuXi PharmaTech and PRA Health Sciences Restructure Relationship in China

WuXi PharmaTech (Cayman) Inc. (NYSE: WX), a leading open-access R&D capability and technology platform company serving the pharmaceutical, biotechnology, and medical device industries, and PRA Health Sciences, Inc. (NASDAQ: PRAH), a leading global clinical contract research organization, announced on December 7 a restructuring of their relationship for the delivery of clinical trial management services in China, Macau and Hong Kong. The two companies formed a joint venture for this purpose in March 2013.

Under the new arrangement, the portion of the joint venture located in mainland China will become a wholly owned subsidiary of WuXi, and the portion of the joint venture located in Hong Kong will become a wholly owned subsidiary of PRA. In addition, PRA will retain its Strategic Solutions business in China and Hong Kong, which offers custom-built clinical development solutions to sponsors. In connection with this restructuring, PRA and WuXi will form a preferred provider relationship under which WuXi will provide full-service clinical trial services for global clinical trials subcontracted by PRA in China.

"WuXi approached us to explore the restructuring of our relationship to better align with their current objectives in China," said PRA's CEO Colin Shannon. "This restructuring allows us to continue our strong relationship with WuXi to support our client needs in China and to leverage the business that we have built together."

Pharmaron Granted GLP Certification for Its Beijing Facility

Pharmaron announced on December 15 that the company has received a Certificate of GLP Compliance, covering genetic toxicology and reproductive toxicology (DART Segments I and II), from the CFDA for its GLP safety assessment facility in Beijing. This is the second GLP compliance certificate granted to this facility by the CFDA since 2013. As such, Pharmaron can offer full IND-enabling safety assessment services to partners in support of their IND filings with the CFDA.

Pharmaron is a private, premier R&D service provider for the life science industry. Founded in 2003, Pharmaron has invested in its people and facilities, and established a broad spectrum of drug R&D service capabilities, ranging from synthetic and medicinal chemistry, biology, DMPK, pharmacology and safety assessment to chemical & pharmaceutical development. Its safety assessment platform has a long-standing track record of performing studies for international IND/NDA filing, particularly with the US FDA.

With the addition of the CFDA-granted GLP compliance certificates since 2013, Pharmaron is in a leading position in providing IND/NDA-enabling services for multiple regulatory filings, including the CFDA, US FDA and OECD regulatory agencies. For more information, please visit www.pharmaron.com.

Regulatory News

Chinese Pharmacopoeia 2015 Became Effective on Dec. 1

The 2015 or 10th Edition of Chinese Pharmacopoeia (ChP) took effect on December 1, 2015.

Issued by the CFDA on June 5 this year, the total No. of monographs in ChP 2015 is 5,608, which is 1,082 more than the 2010 Edition.

The number of excipient monographs in ChP 2015 is 270, up from just 132 in the 2010 Edition.

There are a total of four volumes in the 2015 ChP, including volume 1 (TCMs), volume 2 (Chemical drugs), volume 3 (Pharmaceutical excipients) and volume 4 (Appendices).

The 2015 ChP has comprehensively elevated the drug quality control standards in terms of product coverage, testing methods, control parameters and system streamline, according to CFDA Vice Minister WU Zhen. Besides, the new edition further enhances the platform of drug and excipient standards.

CFDA Issues New Policy for Food and Drug Safety Credit Rating System Building

CFDA published at its website on December 15 a new policy, *Guiding Opinions for Infrastructural Building of Food and Drug Safety Credit Rating System*, which is back-dated November 19.

The goal of the system is to compile credit rating information, define scope of public sharing for all types of information, accelerate building of food and drug safety credit rating information database and exchange platform, strengthen credit information collection, management and publication, as well as implement credit rating appraisal of food and drug manufacturers, distributors and relevant personnel, so that trustworthiness is incentivized and bad credit is punished.

The system is targeted for completion in three phases: 1) *Phase 1 (before 2016)* – Developing top level design of food and drug safety credit rating system, improving relevant schemes, establishing credit rating files for companies and relevant personnel, beginning to building credit rating information databases, exploring classified management standards of credit rating information, and preliminarily establishing the relevant credit rating appraisal mechanism; 2) *Phase 2 (2017-2018)* – Initially establishing the food and drug safety credit rating information databases, improving classified management standards for food and drug manufacturer and distributor credit rating, and fully implementing credit rating infrastructural building; and 3) *Phase 3 (2019-2020)* – Building food and drug safety credit rating information databases connecting food and drug agencies at the national, provincial, municipal and county levels; and initially realizing classified management for credit rating of food and drug manufacturers, distributors and relevant personnel.

Further details and full text of the document in Chinese is available by clicking on the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0852/138006.html.

CFDA to Decentralize GMP Certification of Sterile Drug Formulations

The CFDA will formally decentralize GMP certification of sterile drug products to provincial level food and drug agencies (provincial level FDAs) at the end of this year, according to Chinese press reports. The agency has reportedly issued notices recently to provincial level FDAs over capacity building and other preparations.

The CFDA also issued a number of inspection guidelines for GMP certification of sterile drug formulations, GMP drug certification application dossier review, drug inspection handbook, as well as onsite inspection procedures, risk evaluation and deficiency correction in order to maintain quality of GMP certification after decentralization.

The move was provided in the central government document defining responsibilities of the CFDA when it was established in 2013. Under the document, all GMP certifications for drugs and medical devices should be decentralized to provincial level FDAs. It was speculated at the time that the CFDA would decentralize GMP certification of high risk drug products including injectable and radioactive drugs, blood products and biological products at the beginning of this year.

It is now speculated by industry experts that, following the proposed decentralization of sterile drug GMP certification at the end of this year and in order to relieve their sharply increased workloads, provincial level FDAs are likely to further decentralize GMP certification of TCM crude drugs to municipal level FDAs.

CFDA Rejects 13 New Drug Applications after Inspections Uncovered Flaws

The China Food and Drug Administration (CFDA) issued an official announcement on December 7 to publicize its rejection of registration applications for 13 new drugs from 14 applicants, citing false or incomplete trial data, as the government toughens enforcement of quality standards. The agency's announcement details the flaws in clinical trial data of all these 13 applications.

The CFDA will conduct investigation of Suzhou University No.2 Affiliated Hospital for its fraudulent practices in clinical trial data and extend inspections to related CROs and other clinical trials conducted by the hospital. The agency also ordered Hunan Provincial Food and Drug Administration to conduct investigation of Hunan Tiger Xiangya Pharmaceutical Research Co. Ltd. for its relevant violations. It has also transferred the violation case of the PLA No.458 Hospital in clinical trials to the Health Division under the PLA General Logistics Department for further investigation.

The CFDA said it will, on the basis of investigation outcomes, determine responsibilities of applicants, designated clinical research institutions and CROs. Relevant responsible parties with clinical institutions will be dealt with by the health and family planning agencies, while those who break criminal laws will be transferred to the police. Relevant investigation outcomes and punishments will be announced separately.

The agency last month also rejected registration applications by eight Chinese companies for inadequate trial data related to generic drugs for heart problems, schizophrenia, pain, infections and other diseases.

The quality of locally made drugs is a priority for the government, which is pushing an ambitious program of healthcare reforms to reduce reliance on both generic and innovative imported drugs.

The regulator's crackdown comes after it called on drug registration applicants to carry out their own internal investigations into trial data in July, a move expected to raise the quality of local drugs over the long-run, creating a challenge for global pharmaceutical firms.

The top 10 Chinese drugmakers have seen sales grow around 12% this year, according to data from IMS Consulting, twice the rate of multinationals, which suffered a setback from a bribery scandal at GlaxoSmithKline two years ago.

CFDA Announces More Voluntary Registration Withdrawals from Pharma Cos, Many Leading Players

The CFDA issued its #264 Announcement in 2015 on December 14 reporting voluntary withdrawals of 131 drug registration applications from 82 pharmaceutical companies.

Among the 82 companies, many are leading players such as Beijing Sihuan Pharma, Shenzhen Zhijun Pharma, Zhuhai United, Hunan Hisun (a subsidiary of Zhejiang Hisun), two subsidiaries of Shijiazhuang Pharmaceutical Group, Ruiyang Pharma, Shandong Luoxin, Chengdu Hengrui, Tianjin Pharmaceutical Research Institute, Zhejiang Xianju, Sino-American Huadong, Chongqing

Huapont, Southwest Pharma and Beijing Hanmi Pharma.

Please visit the following CFDA weblink for a complete list of withdrawn applications and their applicants in Chinese: http://www.sda.gov.cn/WS01/CL0050/137900.html

Earlier on November 11, the CFDA rejected 11 drug registration applications from eight Chinese companies making generic drugs for heart problems, schizophrenia, pain, infections and other diseases due to untruthful and incomplete clinical data.

China's leading drug exporter Zhejiang Huahai Pharma is among the eight rejected companies, which also include Hainan Pharma, Hebei Pharma, Qingdao Bai Yang Pharma, Zhejiang Angli Kang Pharma, Hainan Kang Chi Pharma, Guangdong Pharma and Shandong Da Yinhai.

The crackdown followed a call in July for manufacturers to carry out their own internal investigations into trial data, which had already led to a number of voluntary recalls. The CFDA then carried out a series of on-site inspections between Oct. 26 and Oct. 31 and discovered that clinical trial data in applications from eight companies for 11 drug products were incorrect or incomplete.

Subsequently on November 26, the CFDA announced voluntary withdrawals of 164 drug registration applications by 90 pharmaceutical companies. Among the 90 companies, 14 are publicly-listed leading players including Hisun Pharma, Conba Pharma, Huahai Pharma, Shuangcheng Pharma, Lingkang Pharma, Renhe Pharma, Lukang Pharma, Kelun Pharma, Huapont Health, Kangyuan Pharma, Jinling Pharma, Hengrui Medicine and Kangzhi Pharma.

Huahai Pharma is reported to be the company with the largest number of such withdrawals, which pulled back eight drug applications. In fact, most of the affected drugs under application by Huahai Pharma are already approved for marketing in the U.S. But Zhejiang Huahai has denied any links between the CFDA rejection and its subsequent voluntary withdrawals.

Later on December 3, the agency announced another 87 withdrawals by 62 pharmaceutical companies including additional listed leading players as well as India's Dr. Reddy's Laboratories.

By December 15, CFDA announced that a total of 382 drug application withdrawals by 248 pharmaceutical companies. Plus those unannounced, the total number of withdrawals is 727, according to Xianda Data.

CFDA Calls for Reinforced Inspection of Drug Clinical Trial Data

The CFDA issued another official notice on December 17 to require further strengthened inspection of drug clinical trial data by all provincial level food and drug agencies.

The notice named Hainan, Shandong and Guangdong as examples of "most provincial level food and drug agencies" which have organized and carried out serious inspections of drug clinical trial data as required by the CFDA, but it also criticized a few unnamed provincial level food and drug agencies for not paying enough attention to the required inspection with "low quality outcomes".

The CFDA therefore issued the latest notice to require all provincial food and drug agencies to organize and conduct renewed inspections of those drug applications listed in the CFDA No.117 announcement which are still under registration at the moment, as well as to report outcomes of such inspections to the CFDA before the end of December. Provincial level food and drug agencies are also required to order local clinical research institutions to complete self-inspections of clinical trials relating to applications listed in the CFDA No.117 announcement and applications submitted thereafter before January 10, 2016.

(The No. 177 CFDA announcement was issued on July 22 to mandate applicant self-inspection of clinical trial data for 1,622 drug registration applications. By December 15, CFDA announced that a total of 382 drug application withdrawals by 248 pharmaceutical companies. Plus those unannounced, the total number of withdrawals is 727, according to Xianda Data. The CFDA also announced rejection of 24 registration applications from 22 applicants in November and December, citing false or incomplete trial data, as the government toughens enforcement of quality standards.)

The CFDA wants the provincial level food and drug agencies to order applicants withdraw registration applications when false or incomplete trial data are discovered. For those applications with false or incomplete trial data reported by clinical research institutions or CROs, provincial level food and drug agencies should interview drug applicants and order them to withdraw applications. Those refusing to withdraw should be reported to the CFDA. For those applications voluntarily withdrawn, the CFDA notice stated that the applicants can reorganize clinical trials according to new requirements.

The flaws of untruthful data, which are made up intentionally and should be penalized severely, and incomplete data, which are usually technical deficiencies, should be distinguished. Provincial food and drug agencies are reminded by the CFDA notice not to mix these two different types of flaws.

The CFDA will continue to organize its own inspections and will hold incompetent inspectors from provincial level food and drug agencies responsible for flawed cases.

Provincial food and drug agencies are also required to conduct inspections of drug clinical trials undertaken after issuance of the CFDA No.117 announcement. Those faking data will be severely punished with incompetent provincial level inspection held accountable.

Full text of the notice in Chinese can be found at the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0050/138362.html.

CDE Seeks Comments on New Bio-equivalence Technical Guideline

CDE issued a new draft document, *Technical Guideline for Bioequivalence Studies of Chemical Drugs with Pharmacokinetic Parameters as End Points*, for public comments before December 31, 2015.

Comments can be submitted through CDE website's "*Guideline Comment Seeking*" column or by clicking on the following weblink: http://www.cde.org.cn/zdyz.do?method=largePage&id=227.

Feedbacks and questions can also be addressed to the following CDE contact persons:

Contacts: LI Li (李丽) or ZHANG Yuhu (张玉琥)
Email: lil@cde.org.cn or zhangyh@cde.org.cn
Tel: +86 10 68585566 ext. 1532 or 1538

The draft guideline was developed referencing relevant USFDA technical guidelines for human bioequivalence studies of generic drugs, as well as relevant requirements of domestic laws &

regulations and domestic clinical trial regulatory regime.

The core technical requirements of this guideline are mandated to be the same as relevant published USFDA guidelines.

CFDA Solicits Comments on *Rules for Batch Release of Biological Products*

In an effort to safeguard quality of biological products, the CFDA has drafted the *Rules for Batch Release of Biological Products* and is now seeking public comments.

Feedbacks should be sent via the following means before January 15, 2016 to the Drug and Cosmetic Registration Department of CFDA.

Contact: GUO Xiuxia (*郭秀侠*)
Email: yhjgs@cfda.gov.cn
Tel: 010-88330821

Full text of the draft regulation in Chinese is available for download at the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0778/138003.html

CDE Issues Draft *Rules for Drug Technical Evaluation Communications* for Comments

The Center for Drug Evaluation (CDE) under the CFDA publicized a new draft regulation, *Rules for Drug Technical Evaluation Communications*, and is now soliciting public comments.

Comments need to be submitted before December 28, 2015 through the following means:

HUANG Qingzhu (*黄清竹*), huangqzh@cde.org.cn or
PU Jiaqi (*蒲嘉琪*), pujq@cde.org.cn

According to the draft rules, "communications" in the context of this regulation refers to the "communications over key technical issues which are not covered by existing drug R&D and evaluation guidelines during the process of drug R&D or technical evaluation. Such communications, including communication meetings and general communications, should be raised by applicants, consulted by reviewers with relevant evaluation departments and jointly agreed with applicants."

"All communication proposals, agreements, proceedings, meeting organization and execution, and recording should follow the provisions of this regulation," the draft regulation requires.

Besides, the draft document provides that R&D of innovative new drugs and drugs urgently needed clinically are offered precedence in the application of this regulation.

For full text of the draft regulation in Chinese, please visit the following CDE weblink: http://www.cde.org.cn/news.do?method=viewInfoCommon&id=313508.

NHFPC and CFDA Issues Notice About Filing of Stem Cell Clinical Research Facilities

The NHFPC and the CFDA issued a notice on December 1 to require and accelerate filing of stem cell clinical research institutions, in an effort to push forward implementation of the *Provisions for Stem Cell Clinical Research (Interim)* and the *Guidelines for Stem Cell Formulation Quality Control and Preclinical Research (Interim)* on August 21.

Qualified clinical research facilities should meet all the requirements in the Article 7 of the *Provisions for Stem Cell Clinical Research (Interim)*. The notice sets out details of required documentations for filing as well as relevant application procedures which mandates filing to be submitted to the R&D administration departments of the provincial level health and family planning commissions (PHFPCs) for joint review by the PHFPCs and the provincial level food and drug agencies (PFDAs).

Filings passing provincial level reviewed will be submitted to the National Stem Cell Clinical Research Expert Committee (Address: Rm 1013, 10th Floor, Guangqujiayuan No.2 Building, Dongcheng District, Beijing 100022. Tel: +86 10 62115986) before December 10. The committee is responsible for reviewing the submitted filings on behalf of the NHFPC and CFDA. Those passing review will be registered for stem cell clinical research.

All stem cell research projects are required to be conducted only in such registered facilities.

NHFPC Contacts:

YING Xuke and WANG Jinqian (*尹旭珂* and *王锦倩*), Science and Education Department
Tel: +86 10 68792955 Fax: +86 10 68792955

CFDA Contact:

CHANG Weihong (*常卫红*), Department of Chemical Drug and Cosmetic Registration
Tel: +86 10 88330713 Fax: +86 10 68316572

Legal / IPR News

China and the U.S.to Further Strengthen Cooperation in Food and Drug Regulation

At the 26th China-U.S. Joint Commission on Commerce and Trade (JCCT) held in Guangzhou between November 21 and 23, China and the United States agreed to further enhance cooperation in the field of food safety, joint actions against online sales of counterfeit drugs, drug and medical device registration approval and clinical trial, as well as dialogue on cosmetics supervision, in order to protect the health of the public.

The US Trade Representative said that, through sustained engagement during the course of this past year, the United States and China have reached agreement in several areas of key importance, including in the following areas:

Pharmaceutical and Medical Devices: The United States and China achieved concrete outcomes on implementing mutually agreed goals of eliminating drug and medical device application backlogs and improving the time it takes to make these products available to Chinese patients. These steps include publishing annual performance reports, further expansion of clinical trial exemptions for medical devices, enhancing pre-submission consultation opportunities for medical device applicants, and ensuring relevant reform measures are published transparently. China also agreed that imported medical devices will be treated the same as domestically produced medical devices. These outcomes on pharmaceuticals and medical devices pave the

way for significant increases in U.S. exports in healthcare, a key sector for future growth in China as its population ages and its economy matures.

IPR Protection and Enforcement: China agreed to a number of IPR-related commitments that will facilitate much needed improvements in a wide range of industries that rely on the ability to protect and enforce their IPR in China. Building on several prior commitments, China clarified several ongoing and intended efforts to revise China's trade secrets system and provide more effective aspects of its civil judicial system to deter and respond to the misappropriation of trade secrets. In addition, in recognition of several recent developments to address challenges faced by online counterfeiting, China agreed to participate in a government-industry dialogue to enhance the systems available to address these challenges and to increase information sharing and cooperation on cross-border enforcement between our two countries. The United States also secured China's commitment to a transparent and expeditious process for developing Geographical Indication-related measures that will help keep this significant market open to U.S. agricultural and other products.

Competition Policy: The United States and China made meaningful progress in China's enforcement of its Anti-Monopoly Law (AML). China agreed that commercial secrets obtained in the process of AML enforcement are protected under the law, and shall not generally be disclosed to other agencies. China also attached great importance to maintaining coherence in the rules related to IPR in the context of AML. China also clarified that in the process of creating guidance in relation to IPR in the context of antimonopoly law, it will solicit comments from relevant parties, including the public.

Technology Policy: China committed to nondiscriminatory and transparent policies for ICT information security, including assurances that Chinese banks are free to purchase ICT products regardless of the country of origin, affirmations that encryption regulations are narrow in scope, and agreement to notify the WTO of a concerning draft insurance "secure and controllable" regulation for review by WTO members.

State Council Passes TCM Law

The State Council passed a draft of China's first law covering traditional Chinese medicine (TCM) at an executive meeting on December 9.

The law, aimed at promoting and regulating TCM at the same time, includes provisions for entry certifications of TCM physicians and clinics, as well as TCM management and personnel training. The law will also attempt to uphold the characteristics of TCM as it seeks to integrate/coordinate with existing healthcare and pharmaceutical related laws and regulations, according to the State Administration of Traditional Chinese Medicine (SATCM).

The draft will now be submitted for deliberation by the Standing Committee of the National People's Congress, the country's top legislature. Officials have been proposing laws on TCM since the early 1980s. However, TCM hasn't received wide recognition in more recent decades, which has stalled legislative efforts.

"We are hoping the law can help address problems hindering TCM's development, including how to better incorporate TCM into industrial chains," said CHEN Qiguang, a research fellow with the Chinese Academy of Social Sciences.

Product and R&D News

CFDA Approves EV71 Vaccine against HFMD

The CFDA approved the production of a novel vaccine on December 3 that can effectively curb the hand-foot-and-mouth disease (HFMD).

The vaccine, human diploid cell, is the world's first against enterovirus 71 (EV71), a primary cause of the HFMD, said WANG Junzhi, deputy head of National Institutes for Food and Drug Control.

Clinic tests show that the vaccine is very safe and can prevent 97.3 percent of testers from infecting the EV71, according to the Institute of Medical Biology, Chinese Academy of Medical Sciences, the vaccine developer.

The HFMD is caused by a group of enterovirus including EV71, which causes severe heart and lung complications that can lead to death.

It has become one of the most universal infectious diseases in China due to lack of vaccines. Infants and children under five years are most vulnerable to the disease.

Sinovac Approved to Initiate Clinical Trials of sIPV

Sinovac Biotech Ltd. (NASDAQ: SVA), a leading provider of biopharmaceutical products in China, today announced that the Company has obtained approval to begin human clinical trials on its Sabin Inactivated Polio Vaccine (or "sIPV") candidate.

In preparation of beginning human clinical trials, Sinovac is currently finalizing the clinical trial protocol based on the clinical trial license. The Company plans to start the clinical trials in the first half of 2016 and expects to complete these trials by 2018. According to the approval, Sinovac will conduct human clinical trials to select the dosage and evaluate safety and immunogenicity of the vaccine candidate. The Company will use conventional Salk-IPV and Sabin-IPV on the market as control groups in the clinical trials. The Company will also evaluate the manufacturing consistency of three lots in the trials.

The Company plans to build a new commercial production facility of sIPV in an existing building at the Company's Changping site. The plant will have a designed annual capacity of ten million doses. The construction is expected to begin in 2016.

The clinical trial application for the sIPV was officially accepted by the China Food and Drug Administration (CFDA) in October 2014 and received fast track approval by the CFDA as part of the government's polio eradication efforts.

As previously announced, Sinovac has entered into a license agreement with Intravacc (Institute for Translational Vaccinology) from The Netherlands to develop and commercialize the Sabin Inactivated Polio Vaccine (sIPV) for distribution to China and other countries. According to the agreement, Sinovac has committed to commercializing the vaccine in China, inclusive of conducting clinical trials, obtaining regulatory approval, and launching the sIPV vaccine.

Chi-Med Initiates Phase III Trials of Fruquintinib and Sulfatinib for NSCLC

Hutchison China MediTech Limited (Chi-Med) (AIM: HCM) announced on December 8 that Hutchison MediPharma Limited (HMP), its drug R&D subsidiary, has initiated FALUCA, a Phase III registration study for fruquintinib (HMPL-013) in third-line non-squamous non-small cell lung cancer (NSCLC) patients in China. Fruquintinib is an investigational small molecule which selectively inhibits vascular endothelial growth factor receptors (VEGFR). Preparations and site selection began in August this year, with the first patient dosed on 8 December 2015.

FALUCA is a randomized, double-blind, placebo-controlled, multi-center, Phase III registration study targeted at treating patients with advanced non-squamous NSCLC, who have failed two lines of systemic chemotherapy. Patients will be randomized at a 2:1 ratio to receive either 5mg of fruquintinib orally once per day, on a three-weeks-on / one-week-off cycle, plus best supportive care ("BSC"); or placebo plus BSC. The primary endpoint is overall survival, with secondary endpoints including progression free survival, objective response rate, disease control rate and duration of response. HMP plans to enroll approximately 520 patients in about 45 centers across China, with top-line results expected in 2017.

In September this year, Chi-Med announced that the Phase II proof-of-concept ("POC") trial of fruquintinib in patients with third-line non-squamous NSCLC in China had successfully achieved the primary endpoint of progression free survival ("PFS") with no unexpected safety issues. The detailed results of this Phase II study will be presented in a global scientific conference in 2016.

Later on December 18, Chi-Med announced that HMP has initiated SANET-ep**,** a Phase III sulfatinib (HMPL-012) registration trial in China in patients with extra-pancreatic neuroendocrine tumors (NETs), which are all non-pancreatic NETs, including, for example, NETs originating in the lymph, lung and across the gastrointestinal tract. Preparations and site selection had begun in the middle of this year and the first patient was dosed on December 17, 2015.

SANET-ep is a randomized, double-blind, placebo-controlled, multi-center Phase III sulfatinib registration study to treat pathologically low or intermediate grade NET patients whose disease has progressed, locally advanced or distant metastasized and for whom there is no effective therapy. Approximately 270 patients will be enrolled in the SANET-ep study from more than 20 centers across China, with top-line results expected in 2018.

Additionally, the second Phase III sulfatinib registration trial, SANET-p, in pancreatic NET patients, is expected to be initiated imminently in China. SANET-p employs a similar treatment regimen and has primary and secondary endpoints similar to those for SANET-ep trial. Approximately 195 patients will be enrolled in SANET-p and is expected to start by the end of 2015, with top-line results expected in 2017.

Sulfatinib is an oral drug candidate that demonstrates dual inhibition of the tyrosine kinase activity associated with vascular endothelial growth factor receptor (VEGFR) and fibroblast growth factor receptor (FGFR) 1, a receptor kinase which also plays a role in tumor angiogenesis. In 2014, HMP completed the first-in-human Phase I clinical trial of sulfatinib in China. The Phase I clinical data indicates that sulfatinib has the highest ORR reported to date in NET patients. An ORR of 44% was observed for sulfatinib in 18 evaluable patients, compared to less than 10% for sunitinib and everolimus, the two approved targeted therapies for pancreatic NET patients.

In October 2014, HMP initiated a multi-center, single-arm, open-label Phase Ib/II study in NET patients in China to further evaluate the efficacy, safety, tolerability and pharmacokinetic characteristics of sulfatinib.

In addition to these four NET studies, HMP also plans to initiate a Phase Ib study in China to evaluate the safety, pharmacokinetics and efficacy of sulfatinib in patients with both medullary and differentiated thyroid cancer by the end of 2015.

TaiGen's IV Taigexyn Achieved Primary Endpoint in Phase 3 Trial for Community Acquired Pneumonia

TaiGen Biotechnology made a public announced on December 3 that the intravenous formulation of Taigexyn has achieved the primary endpoint (clinical success rate at Visit 4 in the evaluable-mITT population) in the Phase 3 clinical trial of community acquired pneumonia (TG-873870-C-6). This trial was a randomized, double-blinded study comparing intravenous formulations of Taigexyn 500mg vs. levofloxacin 500mg and has recruited 525 patients from Taiwan and mainland China.

Taigexyn (nemonoxacin) is designated as a Class 1.1 new drug under China's FDA. It is a novel non-fluorinated quinolone with both oral and intravenous formulations. TaiGen have completed multiple clinical trials (Phase 1-3) for community acquired pneumonia in Taiwan and mainland China and have filed for NDA of the oral formulation in both markets in March and April 2013 respectively. The Taiwan FDA granted new drug license for the oral formulation of Taigexyn to TaiGen in January 2015.

Shanghai Synthetic Biology Innovation Alliance Established

Proposed by Shanghai Jiaotong University and Shanghai Institute of Plant Physiology and Ecology under the Chinese Academy of Sciences (CAS), the Shanghai Synthetic Biology Innovation Strategic Alliance was formed on December 3, drawing members from research institutions/facilities in Shanghai with solid capacity in this field.

The alliance was set up within on campus of Shanghai Jiaotong University and other key members include Fudan University and the Institute of Biochemistry and Cellular Research under the Shanghai Life Science Research Institutes of CAS.

The alliance hopes to integrate upstream R&D institutions with downstream technology development and manufacturing facilities in synthetic biology in order to conduct relevant frontier research, resolve major related issues and enhance revolutionary innovation in biotechnology.

On the same date, the Metabolism Science Research Center of Shanghai Jiaotong University was also established to target interdisciplinary technologies and lay a solid foundation for synthetic biology.

General Health

NHFPC Outlines Healthcare Reform Tasks in the 13th FYP

The NHFPC hosted the *National Healthcare Reform Planning Symposium* on November 19 with participation by responsible officials from its relevant departments, other central government agencies including NDRC, MOF, MOHRSS, SATCM and the healthcare reform office of the State Council, as well as the healthcare reform offices of provincial level governments.

NHFPC Minister LI Bin delivered a keynote speech at the event. She called for deepened healthcare reform and conclusive victory of it in the 13th Five Year Plan period (FYP)(2016-2020).

She outlined progresses to be made in the period including: 1) nationwide implementation of urban hospital overall reform which encompasses establishment of public hospital administrative committees, streamlined medical service prices, building of a human resource and remuneration system meeting characteristics of healthcare sector and support of social capital in medical service provision; 2) integration of different medical insurance programs, deepening BMI payment system reform and promoting merger of urban and rural basic medical insurance programs; 3) raising consumption of essential drugs, advancing reform of pharmaceutical distribution sector, promoting quality equivalence study of generic drugs, and securing shortage and pediatric drugs; 4) perfecting legal framework, transforming government roles and boosting infrastructural building of regulatory regimes; and 5) further defining government responsibilities, strengthening organization and implementation, and facilitating leadership, assurance, administrative and regulatory responsibilities of the government.

Furthermore, NHFPC Vice Minister MA Xiaowei required all local governments to ensure nationwide implementation of county level public hospital overall reform, launch of urban public hospital overall reform in 100 trial site cities, full introduction of urban and rural major medical insurance, and completion of the new round of centralized hospital drug tender purchase, all before the end of this year. Furthermore, he wants local governments to make their best efforts in compilation of the healthcare reform plan for the 13th Five Year Plan period and in the planning of key reform tasks for 2016.

NHFPC Issues Guiding Policy for Community Healthcare

The NHFPC issued a new policy document, *Guiding Opinions for Further Streamlining Management of Community Healthcare Services and Promoting Service Quality*, on November 25.

The document includes 17 specific measures in four areas including:

- Streamlining the setup and management of community healthcare service facilities;
- Strengthening capacity building for community healthcare facilities encompassing elevated medical service capabilities, improved integration with public hospitals, facilitation of public health services, and promotion of TCM services;
- Transforming service model of community healthcare to promote the model of general practitioner contract services; and
- Enhancing community healthcare service assurance and regulation.

NHFPC Solicits Public Comments for the 13th FYP Health China Plan

The National Health and Family Planning Commission (NHFPC) is currently compiling the "*13th Five Year Plan for Building Health China*", which will become the guiding policy for advancing health China building in the 13th Five Year Plan (FYP) period (2016-2020).

The NHFPC is now inviting comments and suggestions from the public for this plan which should be submitted via the following means before December 31, 2015.

The Planning and Information Department, NHFPC

Yingbin Building, Friendship Hotel
No.1 Zhongguancunnan Dajie, Haidian District
Beijing 1000873, China

Email: jkzgjsgh@sina.com

Guangdong to Eliminate Drug Sales Margins at Urban Public Hospitals

The Government of Guangdong Province announced on November 20 *the Implementation Opinions for Urban Public Hospital Overall Reform in Guangdong Province* which provides that the reform experiment will be expanded to urban public hospitals in at least 50% of prefectural level municipalities in 2016 and in all cities of the province by 2017. Besides, the document pledges to reduce the share of personal out-of-pocket expenses in all healthcare expenditures to below 30% in 2017.

Where overall public hospital reform is carried out, hospital drug sales margins should be eliminated and reduced revenues of public hospitals will be compensated in principle by medical service price adjustments (80%), designated government subsidies (10%) and hospital internal absorption (10%).

The share of drug income in total revenues of urban public hospitals in trial site cities should be reduced to below 30% by 2017, the document mandates.

It is also required that the share of referrals in total outpatient visits is raised to above 20% and differentiated BMI payment schemes are introduced for tiered healthcare service facilities in trial site cities by the end of 2015.

The document calls for introduction of BMI payment system reform, on the basis of overall budgetary control, including headcount-based payment scheme for outpatient services as well as disease group-based and service unit-based payment schemes for inpatient and outpatient major medical services. It says that the scheme of diagnosis-related groups (DRGs) can be explored in areas with mature conditions.

Implementation of clinical pathways should be accelerated with share of inpatients treated under clinical pathways reaching at least 30% and 50% respectively at the end of 2015 and 2017. In line with clinical pathway implementation progress, the coverage of disease group-based payment scheme should be expanded and the number of such groups should be increased to more than 100.

New Group Established Under CMA to Promote Precision Medicine for CVD

The group for precision cardiovascular medicine was established

with the Chinese Society of Cardiology on Sunday in Nanjing, east China's Jiangsu Province, committed to advance precision medicine for cardiovascular disease (CVD) in China.

The Chinese Society of Cardiology is part of the Chinese Medical Association, the largest non-governmental medical organization in China.

The group plans a database of monogenic inherited CVD and cardiovascular pharmacogenomics for Chinese and to map genetic variation by recruiting volunteer patients nationwide.

It also aims to facilitate the basic research of precision cardio-vascular medicine advancing towards clinical application, and to help the government to roll out regulations and standards for CVD molecular screening and diagnostics.

The group will set up several demo centers nationwide, tapping the collective wisdom of its members, hospitals, third-party testing agencies as well as drug enterprises.

People in the News

Recent Executive Moves

Ashley Preston is now Head of Global Regulatory Science, Process, Compliance & Training (ReSPCT) with EMD Serono, Inc. Before joining the company, he had been Head of International Regulatory & Scientific Policy with Merck Serono for two and half years and Director of Regulatory Affairs with Takeda Global Research & Development Center (Asia) Pte Ltd for over four years.

Sam Jiang has joined IPSEN China as Therapeutic Area Leader-URO. Previously, he had been with Eli Lilly China for six years, most recently as Marketing Director and Access Director. Before joining Eli Lilly in 2009, he had been Product Manager with MSD China for three and half years and regional sales manager with Eisai China for nearly five years.

Tianjin Tianyao Pharma appoints ***WANG Fujun*** as chairman. The company's former chairman ***ZHANG Jianjin*** was taken away by government investigators for suspected corruption back in August.

Wilfred Chow resigned from his position as the Aoxing Pharma's chief financial officer. ***ZHANG Guoan***, Aoxing Pharma's senior vice president for finance, will assume the position of CFO.

FENG Guosheng has retired as the Deputy Director General of the Beijing Municipal Health and Family Planning Commission and Director General of Beijing Municipal Hospital Authority and he is replaced by ***YU Luming***, formerly Deputy Director General of Beijing Municipal Hospital Authority. Feng reportedly will remain as the Chairman of Trustee Board of Beijing Chaoyang Hospital Affiliated to the Capital Medical University.

HUYA Bioscience International appointed ***Dr. Dmitri Kharkevitch*** as Vice President, Clinical Development Oncology. Dr. Kharkevitch has over 30 years of experience in oncology which includes 15 years in leadership positions within pharma and biotech covering clinical and medical affairs at Roche, Pfizer, Bristol-Myers Squibb, Vical, Antigenics and MD Anderson Cancer Center.

Tristan Zhang is now Medical Director, APAC with BioMarin Pharmaceutical Inc. He had previously been Medical Affairs Director, HK & SG with Gilead Sciences for a year, Medical Director, Lung Cancer Franchise with Novartis Oncology APSA region for over a year and Head of Medical Affairs, Oncology with Novartis Pharmaceutical HK, Oncology for four years.

LI Zheng joined GSK China as Vice President and Head of Neuroexcitation DPU. Before this appointment, Zheng had been with Lundbeck for nearly seven years most recently as General Manager and Head of Research China and with Pfizer for nearly ten years as Global Disease Team Leader.

Sanofi China promoted ***Eileen Long*** to Vice President of CNS BU from her prior position as Marketing Director. She has been with the company for eight years. Before joining Sanofi, Eileen has been Marketing Director with Wyeth China for one and half years; GPM, Marketing Manager and Regional Sales Manager with BMS China for nearly eight years; and Medical Advisor and Brand Manager with Novartis China for nearly four years.

ConvaTec promoted ***Wenli Vivian Meng*** Commercial Operation Director and Country Manager China from her prior position of Sales Director, China. Before joining ConvaTec in late 2012, Vivian had worked with Genzyme for nearly six years as Director of Commercial Effectiveness and Business Unit Director, with XiAn Janssen for one and half years as Oncology Marketing Brand Manager and with AstraZeneca China for two and half years as Group Product Manager.

Harold Chan joined CSL Behring as Commercial Director, China from his prior employment as Executive Deputy General Manager with China Fortune Bio-pharmaceutical where he had worked nearly four years. Before that, he had been with Cephalon Hong Kong for five years as Senior Regional Director, Business Development and Strategic Planning and with MSD China/Hong Kong for six years as Senior Manager – Strategic Marketing and Compliance.

Sherry Zhang joined Johnson & Johnson Medical as Senior Strategic Marketing Manager from her prior employment as Strategic Planning Manager of Sanofi-Aventis where she spent one and half years. Earlier, she had been an Analyst and Consultant with IMS Consulting Group for three years.

Alan Yan has joined Sanofi Pasteur as Marketing & Business Operation Executive Director China. He had previously been Co-founder, President and CEO of Beijing SynerCare Pharma Tech Co., Ltd. for less than two years and earlier General Manager China of Actelion for four and half years. Before joining Actelion in 2009, Alan had been with Sandoz China for one and half years as Head of Business Development / Commercial & Retail Business and with Merck Serono/Merck KGaA for nearly seven years most recently as Marketing & Commercial Operations Director China. Before Merck Serono, he also worked with Roche China, Amgen China and GSK China for a total of five and half years.

Wynstan Cheuk is now Head of Business Unit Oncology and Immunology with Janssen in Hong Kong. He has worked with Janssen and XiAn Janssen for 15 years. Before this appointment, he had been with XiAn Janssen as Director/Associate Director, Market insights for three and half years and Marketing Manager/ Associate Director of Marketing for one and half years.

QIN Dinghui joined Ferring Pharmaceuticals China as a director. He had previously worked for GSK in the U.S. as a manager for four and half years and for Wuxi PharmaTech as GSK Embeded scientist for nearly three years.

Flora Lu is now a Sr. Manager Biz Analytic with a J&J China subsidiary. She had previously been with Bayer HealthCare for two years as Sr. Market Research Manager and with Novartis China for over six years most recently as Marketing Science Manager.

Feature Articles

Review of Chinese Pharma Deals, R&D and Regulatory Developments in Q3 / 2015

By *Jenny Wang, Associate Editor, Pharma China*

Pharma China monitors the Chinese pharmaceutical industry and market landscape on a continuous basis through our three online databases, the *Deals, Agreements & Disputes Monitor* (Deals Monitor), the *Regulatory Monitor* and the *New Drug R&D Monitor*.

The following quarterly reviews summarize the important events recorded in these three online databases in the third quarter and the first three quarters of 2014. More details of these events can be found in the Online Database section at www.pharmachinaonline.com.

Pharma M&A, Licensing and Collaborative R&D Deals in Q3/2015

The Deals Monitor of *Pharma China*, which routinely collects information on various types of transactions between Chinese and foreign pharma companies (as well as major domestic events) including M&A, joint venture/ strategic alliance, licensing, contract research/collaborative R&D, IPO, OEM and lawsuits/legal disputes, recorded a total of 71 events in the third quarter and 172 events in the first three quarters of 2015.

Events were classified into eight categories and the following table shows a breakdown of these events in Q3/2015 and 3Qs/2015.

Summary of Chinese Pharma Events in Q3/2015 and 3Qs/2015

	Q3/2015	3Qs/2015	Q3/2014	3Qs/2014	2014	2013	2012
OEM	1	2	1	3	4	1	1
Licensing	13	34	16	33	43	38	32
Contract Research/ Collaborative R&D	5	11	5	13	16	26	29
M&A	39	77	35	57	90	38	38
Lawsuits & Disputes	0	2	0	0	2	2	1
JV/Strategic Alliances	11	32	13	23	31	23	33
IPO	0	5	4	8	13	5	2
Others	2	9	3	10	15	12	7
Total	71	172	77	147	214	145	143

Source: Deals Monitor, *Pharma China*

The leading categories of events last quarter were M&A deals (39) and licensing deals (13), followed by joint venture/strategic alliance agreements (11) and contract research/ collaborative R&D agreements (5).

The number of M&A deals (39) in the third quarter this year was up by 11% compared with the same period. On the other hand, the number of licensing deals (13) and JV/strategic alliance deals (11) in the third quarter was lower year on year (down by 12% and 15%). The number of contract research/ collaborative R&D deals (5) in Q3/2015 was held steady.

In the first three quarters of 2015, the number of M&A deals (77) dramatically increased compared with the same period, and the number of JV/Strategic Alliances events (32) was up by 38% year on year. On the other hand, the number of licensing deals (35) was roughly on par with the same period in 2014. The number of CR/collaborative R&D activities (11) in the first three quarters of this year, however, was slightly lower than the same period last year (13).

A total of thirteen Sino-foreign and foreign-foreign (relating to China rights) licensing deals were recorded last quarter and a summary is shown in the following table.

There were five M&A deals between Chinese and foreign companies in the last quarter as shown below.

Summary of Sino-foreign Licensing Deals in Q3/2015 (1)

Time	Parties Involved	Agreement Summary
7/2015	CANbridge Life Sciences and Apogenix	The two entered into an exclusive license agreement to develop, manufacture and commercialize Apogenix's lead product, APG101, in glioblastoma multiforme in China, Macao, and Hong Kong, with options for other indications.
7/2015	Yabao Pharma and Lawson Health Research Institute	Yabao entered into an exclusive license with Lawson to discover, develop and commercialize products based on annexin A5 for the treatment of sepsis in July 2014, which it has successfully completed discovery validation work and moved the program into preclinical development.
7/2015	TESARO Inc and Jiangsu Hengrui Medicine	The two reached an exclusive license agreement for the development, registration, manufacture, and commercialization of rolapitant in China.
8/2015	Sorrento Therapeutics, Inc and Mabtech Limited	The two entered into an exclusive licensing agreement to develop and commercialize multiple prespecified and undisclosed biosimilar or biobetter antibodies.
8/2015	BioQuiddity and Lee's Pharma (HK)	The two signed a strategic license and supply agreement for the registration and commercialization of BioQuiddity's ropivacaine and propofol infusion pharmaceutical products in Great China.
8/2015	Correvio International and Eddingpharm	The two entered into an exclusive license and supply agreement to distribute and commercialize AGGRASTAT (tirofiban HCl) in China.
9/2015	Incyte Corp. and Jiangsu Hengrui Medicine	Incyte reached a global license and collaboration agreement with Hengrui for the development and commercialization of SHR-1210. Incyte will acquire worldwide rights except Great China.
9/2015	Fresenius Kabi China and China National Pharma Industry Co. Ltd.	The two reached a long term cooperative agreement for marketing of latter's narcotic drug pipeline in China. SinoPharm Industry will be responsible for producing and supplying the said narcotic drugs, while Fresenius will be responsible for promoting these products in China exclusively.
9/2015	Armetheon and China Cardiovascular Focus Limited	The two entered into an agreement to initiate advanced-stage clinical testing, manufacturing and commercialization of Armetheon's investigational oral anticoagulant, tecarfarin, in the greater China and Thailand.

Source: Deals Monitor, *Pharma China*

Summary of Sino-foreign Licensing Deals in Q3/2015 (2)

Time	Parties Involved	Agreement Summary
9/2015	Yabao Pharma and Primary Peptides	The two reached an exclusive license to develop and commercialize innovative products targeting PTEN nuclear trans- location for the treatment of stroke. Yabao receives exclusive rights todevelop and commercialize in China, Taiwan and Hong Kong while Primary Peptides retains rights in all other markets.
9/2015	Celyad and Medisun International	The two entered into a new collabo-ration and distribution agreement to expand the global footprint of Celyad's lead cardiac disease cell therapy candidate for the treatment of ischemic heart failure, C-Cure. Celyad will conduct all clinical development and undertake regulatory steps necessary for market approval in Greater China.
9/2015	Zai Lab Ltd. and UCB	The two entered into a worldwide collaboration and license agreement to develop and commercialize a first-in-class monoclonal antibody for the potential treatment of auto-immune and other inflammatory diseases. Zai Lab will lead all future clinical development, regulatory activities and commercialization.

Source: Deals Monitor, *Pharma China*

Summary of Sino-foreign M&A Deals in Q3/2015

Time	Parties Involved	Value	Agreement Summary
7/2015	Kunming Pharma and Baker Norton US (2015)	CNY 294M	It has signed an agreement with Baker Norton US to acquire a 49% stake in their JV Kunming Baker Norton Pharma for CNY 294 mln.
7/2015	Benitec Biopharma and Biomics Biotech	US$ 4M	Benitec is to acquire its China JV partner, Biomics Biotech, for US$4 mln.
8/2015	Zhejiang Jingxin Pharma and Pharmula Labs	US$ 1.02M	Zhejiang Jingxin Pharma will spend US$1.02 million to acquire 51% of Pharmula Laboratories.
8/2015	Cytovance Biologics and Hepalink USA Inc	US$ 206M	Hepalink USA Inc, has agreed to acquire 100% of Cytovance Biologics for US$205.68 mln.
9/2015	Amicogen	CNY 160M	It has agreed to acquire a 51.5% stake in Shandong Lukang Record Pharma CNY 159.6 mln.

Source: Deals Monitor, *Pharma China*

Among the four Sino-foreign joint venture/strategic alliance events, three are strategic alliance agreement and the others are joint venture deal. The following table summarizes the Sino-foreign JV/strategic alliance agreements in Q3/2015.

Summary of Selected Sino-foreign JV/Strategic Alliance Deals in Q3/2015

Time	Parties Involved	Agreement Summary
7/2015	GSK's HIV unit ViiV Healthcare and Desano Pharma	The two reached a strategic manufacturing agreement to enable production in China of dolutegravir. The agreement will offer an additional source of the dolutegravir (API), and will allow ViiV Healthcare to offer a competitive supply of the finished product for China and a number of developing countries.
7/2015	Shanghai Pharma and Wonders Information	The two entered into a strategic alliance in the areas of pharma B2C e-commerce and healthcare IT and they will jointly develop IT solutions for centralized drug purchase tenders and B2B e-commerce.
7/2015	Jiangsu Yuyue Medical Equipment and Supply Co Ltd and Pfizer China	The two entered into a three year-framework agreement for strategic cooperation under which they will team up in chronic disease health management, development of therapeutic products combining drugs and medical instruments, online health services and pharma/medical device e-commerce.
8/2015	Bloomage Biotechnology (50%) and Medytox (50%)	The two established a joint venture, Medybloom, to develop and promote botulinum toxin type A business in China. Bloomage and Medytox each have 50% shareholding interest in Medybloom.

Source: Deals Monitor, *Pharma China*

A total of three Sino-foreign contract research and collaborative R&D deals were recorded last quarter and a summary is shown in the following table.

Summary of Sino-foreign CR/Collaborative R&D Agreements in Q3/2015

Time	Parties Involved	Agreement Summary
8/2015	Vela Diagnostics and Luye Group	The two signed an investment and collabora-tion agreement to bring Diagnostics and Pharmaceutical synergies to the patient.
8/2015	Janssen Pharma and Hutchison Medipharma	Janssen Pharma terminated the R&D alliance with China based Hutchison Medipharma (HMP) related to small molecule, HMPL-507 for inflammation.
8/2015	WuXi PharmaTech and Lee's Pharmaceutical	Two companies have signed an agreement whereby WuXi's Laboratory Testing Division will be the exclusive supplier of lab testing services for Lee's Pharma.
9/2015	Yabao Pharma and University of South Australia (USA)	The two reached a new collaboration to develop new treatments for cancer under which the USA will identify drug candidates in a co-funded lab. Yabao will provide contributions including cash and in-kind for drug discovery and development and it will have exclusive China rights, while USA will retain rights in all other markets.

Source: Deals Monitor, *Pharma China*

New Drug Projects Recorded in China Q3/2015

Pharma China's New Drug R&D Monitor captured a total of five new drug projects under development or with patents and clinical trials in China in the third quarter of 2015. (*Please note this list is by no means exhaustive and our information is sourced mainly from published information and news releases.*)

Among the five new drug projects recorded, one project is from one Chinese company while the rest four are with foreign developers.

Two of the projects entered into preclinical research phase, while the rest three are in clinical investigation phase.

Number of Recorded New Drug Projects in China in Q3/2015

	Q3/2015	3Qs/2015	Q3/2014	3Qs/2014	2014	2013	2012
Chinese Developers	1	7	7	20	27	28	26
Foreign Developers	4	15	4	18	21	16	15
Total	5	22	11	38	48	44	41

Source: New Drug R&D Monitor, *Pharma China*

Chinese New Drug Projects by R&D Phase in Q3/2015

	Discovery	PreClinical	Phase I	Phase II	Phase III
Q3/2015	0	2	2	1	0
3Qs/2015	4	8	5	4	1
Q3/2014	3	4	3	1	0
3Qs/2014	5	19	5	7	2
Q3/2013	2	2	2	2	0
3Qs/2013	7	7	6	5	2
2014	9	20	9	8	2
2013	9	14	9	9	3
2012	13	12	7	5	4

Source: New Drug R&D Monitor, *Pharma China*

The following table provides more details of the recorded new drug projects in the third quarter of 2015.

Summary of Chinese New Drug Projects Recorded in Q3/2015

Product	Developer	Therapeutic Category	Status	Time Recorded
Brinavess	Cardiome	Cardiology	PreClinical	7/2015
Annexin A5	Lawson and Western University	Sepsis	PreClinical	7/2015
Recombinant Staphylococcus Aureus Vaccine	Third Military Medical Univ. and a local pharma Co	Staphylococcus Aureus	Phase I	7/2015
MRX-I	MicuRx Pharma	Antibiotic	Phase II	9/2015
Gerilimzumab	RuiYi	Rheumatoid Arthritis	Phase I	9/2015

Source: New Drug R&D Monitor, *Pharma China*

New Chinese Pharma/Healthcare Regulations in China Q3/2015

Eight records of polices and regulations which have significant impacts on the pharmaceutical sector in the country last quarter, according to *Pharma China*'s Regulatory Monitor. "*Good Supplying Practice of Pharmaceutical Product*" issued by CFDA became effective on July 1st, 2015.

The following table provides some insights on these regulations/ policies.

Pharma-related Regulatory Introductions in China in 2012-2014 and 3Qs/2015

Issuing Agency	Q3/2015	3Qs/2015	Q3/2014	3Qs/2014	2014	2013	2012
CFDA	5	13	1	4	8	8	14
NHFPC (MOH)	5	9	1	3	3	3	7
NDRC	0	3	0	0	0	0	3
State Council	1	2	0	0	1	1	2
Others	2	2	0	0	2	2	3
Total	8	21	2	7	14	14	29

Source: Regulatory Monitor, *Pharma China*

The following table offers more details to the eight new pharma-related regulations and policies in the third quarter of 2015 in China.

Pharma-related Regulations and Policies Newly Issued in Q3/2015

Document Name	Issuing Agency	Effective / Issue Date
Good Supplying Practice of Pharmaceutical Product	CFDA	7/1/2015*
Interim Rules for CDE Reviewers (Interim)	CFDA	8/18/2015*
Opinions for Reform of Drug and Medical Device Evaluation System	State Council	8/18/2015
Provisions for Stem Cell Clinical Research (Interim)	NHFPC and CFDA	8/21/2015*
Guidelines for Stem Cell Formulation Quality Control and Preclinical Research (Interim)	NHFPC and CFDA	8/21/2015
Requirements and Appraisal Parameters for Clinical Application Control of Antibacterial Drugs	NHFPC and SATCM	8/27/2015
Guidelines for Clinical Application of Antibacterial Drugs (2015 Edition)	NHFPC and SATCM	8/27/2015
Rules for List Control of Non-medicinal Narcotic and Psychotropic Drugs	Ministry of Public Security, NHFPC, CFDA and the National Office for Drug Control	10/1/2015*

Source: Regulatory Monitor, *Pharma China* * Effective Date

NH Reports on Chinese OTC Eye Care and Sleep Aids Markets

Chinese OTC Eye Care Market

Nicholas Hall (NH) estimated that the Chinese OTC eye care sales grew by 10% to CNY 3.2 billion (US$500 million) in the 12 months to September 2015, according to Nicholas Hall (NH)'s global OTC database DB6.

Smog, heavy screen usage and cataracts are key reasons for eye drop usage in China. The ongoing issue of city smog, which can irritate the eyes, looks set to be a long-term growth driver.

Chinese Eye Care Market Facts MAT September 2015

OTC eye care sales MAT 09/2015 (US$):	500 mln
OTC eye care sales MAT 09/2015 (CNY):	3.2 bln
US$: CNY (rate on 12/01/2015)	1 : 6.39
Index 2015/2014 (local currency):	109
Population:	1,364.1 mln
Per capita spend:	US$0.37

Source: Nicholas Hall (www.nicholashall.com)

No.1 brand Shapu Aisi Bendazac Lysine (Zhejiang Shapu Aisi) is cataract-oriented, and therefore aimed at the older generation. However, A+P for the remainder of the category tends to focus on students and young professionals, who often experience tired, uncomfortable eyes as a result of heavy screen usage.

Top 3 Chinese OTC Eye Care Brands in MAT 09/2015

Rank	Brand	Marketer
1	Shapu Aisi Bendazac Lysine	Zhejiang Shapu Aisi
2	Rohto-Eyedrops	Mentholatum/Rohto
3	Shanliang	Renhe

Source: Nicholas Hall (www.nicholashall.com)

Chinese OTC Sleep Aids Market

Latest data from NH shows that growth of Chinese OTC sleep aids sales rose to 6% in the 12 months to September 2015 as high-pressured working and social environments continued to affect sleep quality.

Swisse Wellness sleep aids are very popular in China. Pressured lifestyles are driving sales in China but the category has some untapped potential as many consumers tolerate sleep problems instead of treating them. The category is dominated by local and TCM brands and lacks product development, but investment in marketing and distribution from key players is boosting sales and the appetite for natural remedies from Australia is growing.

Chinese OTC Sleep Aids Market Facts MAT 09/2015

OTC sleep aids sales MAT 09/2015 (US$)	429.3 mln
OTC sleep aids sales MAT 09/2015 (CNY)	2.7 bln
US$: CNY (rate on 12/01/2015)	1 : 6.39
Index 2015/2014 (local currency):	106
Population:	1,364.1 mln
Per capita spend:	US$0.31

Source: Nicholas Hall (www.nicholashall.com)

The Top 3 brands compete closely. However, Jolly Wu Ling Capsule has edged ahead to secure the lead thanks to its status as an exclusive product (it is the only capsule format product to contain TCM extract wu ling) and the fact that it is included in Essential Drugs Lists in various provinces. Melatonin brand Nao Bai Jin has declined in recent years owing to a lack of brand activity.

Top 3 Chinese OTC Eye Care Brands in MAT 09/2014

Rank	Brand	Marketer
1	Jolly Wu Ling Capsule	Zhejiang Jolly
2	Nao Bai Jin	Stone Group
3	Aodong An Shen Bu Nao	Jilin Aodong

Source: Nicholas Hall (www.nicholashall.com)

... continued from Page 32

increasingly infringing on Chinese consumers' sleep. Additionally, many consumers are more likely to opt for coffee and energy drinks as stimulants to refresh themselves during waking hours. However, these drinks make falling asleep more difficult. Furthermore, mobile phone addiction is also affecting sleep, as well as interrupting it through continuous notifications. These factors, and more, will lead to more people suffering from a lack of sleep or even sleep disorders.

Sleep aids is expected to post a strong value CAGR of 11% at constant 2015 prices over the forecast period. Increasing insomnia will be the key driver of sales of sleep aids. The increasing ageing population, resulting in gift giving to parents, elders and leaders, will be another driver of sales. With rising demand pushing sales, manufacturers will focus on product innovation. More products will be developed and launched over the forecast period, with these partly eroding the value shares of the leading players. Melatonin, another useful ingredient with few side effects, is also being accepted by more consumers and is gradually replacing some sleep aids.

When competing within the OTC channel, pharmaceutical companies might ramp up their promotional activities, cooperate with major chained chemists/pharmacies and develop online platforms to increase their penetration. As consumers are usually happy to go along with the recommendations made by a pharmacist, Jilin Aodong Pharm Group Co Ltd has succeeded in building good relations with chained chemists/pharmacies to boost sales. Marketing campaigns and consumer education programmes will also remain routine activities for pharmaceutical companies.

Other News

Upcoming Events

Event: VacChina 2016 – Human/Veterinary Vaccine Forum
Dates: April 12 – 13, 2016
Venue: TBD, Shanghai, China
Weblink: http://vacchina.shinemediaworld.com/
Contact: Constance Shen
Tel: +86 21 5242 8147
Email: constance.shen@shinemediaworld.com

Event: Generic International Summit Asia 2016
Dates: April 21 – 22, 2016
Venue: Wyndham Bund East Shanghai Hotel, Shanghai, China
Weblink: www.genericsummit.com
Contacts: Luke Xia
Tel: +86 21 6053 8962 ***Email***: luke.xia@bestmediaworld.com

Event: BioPharma Asia Convention 2016
Dates: March 22 – 24, 2016
Venue: Suntec International Convention & Exhibition Centre, Singapore
Weblink: http://bit.ly/1Lphxcp
Contact: Lydia Sebastian
Tel: +65 6322 2750
Email: Lydia.sebastian@terrapinn.com

Euromonitor: Review of OTC Sleep Aids in China

Because of fast-paced lifestyle and high pressure of working and study, more and more Chinese people, including white collar workers, students, and menopausal women, are facing the challenges of low-quality sleep or insomnia. The demand of sleep aids continually increase year by year, according to Euromonitor International, provides independent strategic market analysis to 28 fast moving consumer goods industries and players on a global scale.

Most people prefer patented traditional Chinese medicine over western medicine due to fewer side-effects. More detailed analysis can is given below.

Headlines

- In 2015 sleep aids registers current value growth of 13% to reach sales of CNY 936 million;
- Sales fuelled by rising work pressures and accelerating pace of life;
- Jilin Aodong Pharm Group Co Ltd remains the leading player in 2015 with a value share of 23%; and
- Sleep aids set to register a value CAGR of 11% at constant 2015 prices over the forecast period.

Trends

Sleep disorders affect a wide number of consumers in China, with those typically affected including students, white-collar workers, menopausal women and the elderly. Demand for sleep aids continues to rise due to study and work pressures, the generally accelerating pace of life and the ageing population. The category's expanding consumer base underpinned its dynamic growth both in 2015 and over the review period.

Sleep aids registered robust current value growth of 13% in 2015, this being a stronger performance than the review period CAGR of 10%. The category's stronger performance can be attributed to manufacturers seeking to better educate consumers. Previously, consumers did not consider sleep disorders as a disease and thus refused to take any sleep aids. Thanks to manufacturers' efforts, the fixed stereotype of sleep aids has gradually changed, with more people now seeking solutions to improve their quality of life.

However, there are still many people who are concerned about the safety and side-effects of sleep aids and thus prefer other measures such as listening to music, having a milky drink before going to bed, adjusting their diet or taking more exercise. When facing severe insomnia, consumers tend to consult a doctor and then take any medicine as instructed. Knowledge gained through seeing a doctor also helps with further self-medication through OTC drugs.

Gui Pi Capsules from Anhui Piom Pharmaceutical Co Ltd was switched from Rx to OTC status in September 2014. This features several active ingredients used in traditional Chinese medicine, such as semen zizyphi spinosae and polygala. When diagnosed with insomnia as a result of spleen deficiency, self-medicating patients tend to prefer patented traditional Chinese medicines rather than Western medicines.

CATEGORY DATA

Table 1 Sales of Sleep Aids: Value 2010-2015

CNY million	2010	2011	2012	2013	2014	2015
Calming and Sleeping	578.7	627.9	686.6	755.3	829.8	936.4

Source: Euromonitor International from official statistics, trade associations, trade press, company research, store checks, trade interviews, trade sources
Note: 2015 data is provisional and based on part-year estimates.

Table 2 Sales of Sleep Aids: % Value Growth 2010-2015

% current value growth	2014/15	2010-15 CAGR	2010/15 Total
Calming and Sleeping	12.8	10.1	61.8

Source: Euromonitor International from official statistics, trade associations, trade press, company research, store checks, trade interviews, trade sources
Note: 2015 data is provisional and based on part-year estimates.

Table 3 NBO Company Shares of Sleep Aids: % Value 2011-2015

% retail value rsp	2011	2012	2013	2014	2015
Jilin Aodong Pharm Group Co Ltd	21.3	22.4	22.7	23.3	23.1
Jilin Xiuzheng Pharmaceutical Co Ltd	15.2	15.6	15.7	15.6	15.2
Yangtze River Pharmacy Co Ltd	8.0	8.2	8.4	8.7	8.6

Table 4 LBN Brand Shares of Sleep Aids: % Value 2012-2015

% retail value rsp	Company	2012	2013	2014	2015
An Shen Bu Nao Ye	Jilin Aodong Pharm Group Co Ltd	22.4	22.7	23.3	23.1
Xiuzheng	Jilin Xiuzheng Pharmaceutical Co Ltd	15.6	15.7	15.6	15.2
Bailemian Capsule	Yangtze River Pharmacy Co Ltd	8.2	8.4	8.7	8.6

Table 5 Forecast Sales of Sleep Aids: Value 2015-2020

CNY million	2015	2016	2017	2018	2019	2020
Calming and Sleeping	936.4	1,035.2	1,145.6	1,269.0	1,406.9	1,561.3

Source: Euromonitor International from trade associations, trade press, company research, trade interviews, trade sources
Note: 2015 data is provisional and based on part-year estimates.

Table 6 Forecast Sales of Sleep Aids: % Value Growth 2015-2020

% constant value growth	2015/2016	2015-20 CAGR	2015/20 TOTAL
Calming and Sleeping	11.0	10.8	66.7

Source: Euromonitor International from trade associations, trade press, company research, trade interviews, trade sources
Note: 2015 data is provisional and based on part-year estimates.

Competitive Landscape

Jilin Aodong Pharm Group Co Ltd with its iconic An Shen Bu Nao Ye brand continued to lead sleep aids in 2015 with a value share of 23%. This leading position can be attributed to continuous advertising and a good reputation among consumers. The company also broadened its distribution reach and offered more generous profits to chemists/pharmacies to help boost sales.

Most consumers prefer patented traditional Chinese medicines over Western medicines because of their fewer side-effects. Hence, domestic brands continued to outperform international brands. Most sleep aids based on traditional Chinese medicine benefit from having mild side-effects, being relatively cheap and readily available without a prescription. Thus, they are widely accepted by Chinese consumers.

Over the review period advertisements were aired by all the leading brands. The advertising slogan of An Shen Bu Nao Ye was "Taking Care of the Entire Family's Sleep", seeking to expand the product's consumer base to all age groups, while that of Bailemian is "Enjoy Sleeping Like a Baby". An Shen Bu Nao Ye also has its own official website.

Sales of private label sleep aids remained negligible in 2015. Generic manufacturers are often unknown pharmaceutical companies competing via lower prices, although consumers believe cheaper products to be of an inferior quality as well as less safe. As brand image is important to Chinese consumers, generics held only a very small value share.

Prospects

Fast-paced lifestyles will continue to have a detrimental effect on sleep. More social engagements, longer working hours and more responsibilities are

... to be continued on Page 31