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In This Issue

Hengrui Licenses Anticancer Candidate from Oncolys

Tokyo-based Oncolys BioPharma licensed greater China rights of its oncolytic virus candidate OBP-301 to Hengrui Medicine. *P12*

Bayer Inaugurated Extension of Its Pharma Supply Site in Beijing

The EUR 100 mln extension program enables Bayer's Beijing supply site to double its production capacity. *P14*

Pfizer Enters R&D Partnership with PegBio for Select Diabetes Drugs

Pfizer will grant PegBio Greater China rights of selected Phase IIa stage GKA candidates to treat diabetes. *P15*

Sanofi, CR Sanjiu Enter Strategic Alliance for Consumer Healthcare Business in China

Sanofi and China Resources Sanjiu entered into a strategic partnership with a JV focused initially in pediatric and gynecological OTC products. *P15*

Sanofi, JHL Biotech Form Strategic Partnership for Biologics in China

Sanofi and JHL Biotech, Inc. join hands for biological therapeutics in China with potential international expansion. *P15*

BMS Terminates OTC Business Division in China

BMS China closed its China OTC drug business and disbanded sales teams, affecting around 150 employees. *P15*

CONTENTS

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Editorial

A New Storm Is Breeding for China Healthcare in the New Year

James J. Shen

The month of December could have been applauded as a relatively quiet time for China healthcare if the China Central Television (CCTV) did to take a seemingly premeditated snipe at the sector on the Eve of Christmas. The government mouthpiece released an investigative report, prepared by its journalists who went undercover in six large hospitals of Shanghai and Hunan Province for eight months, which captures doctors taking kickbacks from drug companies. Other state media quickly picked up the news and flooded the media space with well-coordinated negative attacks against the status quo.

According to the CCTV report, medical representatives (MRs) of selected pharmaceutical companies including two leading domestic players and a MNC were found to offer large amounts of kickbacks to doctors to promote sales of their branded drug products. Generally, the report suggests, MRs will earn roughly 10% of the drug price, while the kickback for doctors can reach as high as 40%. The report does not forget to point fingers at inflated drug prices and flawed hospital drug purchase tender process which it says should be responsible for feeding prescription drug kickbacks.

In response to the media exposure of irregular practices in hospitals, the NHFPC ordered local health authorities in Shanghai and Hunan province to "seriously investigate and deal with the cases in accordance with law". It also sent two inspection teams to the areas in coordination with local investigations. So far, a doctor in Hunan and three doctors in Shanghai have been suspended from duty with hospital use of relevant drugs stopped. As the next step, the agency said it would deepen the crackdown of healthcare irregularities, fully implement its "*Nine Bans*", further improve the drug purchase tender process to ensure transparency, step up supervision of drug procurement process and elevate penalties of violations.

The NHFPC response appears to be typical crisis management of it after such incidents, but the latest scandal is by no means at an occasion for business as usual. With the Chinese economy having been in a mud pool since the new leadership took power in 2013, the government is increasingly under financial pressure to balance its books for healthcare.

Before we delve into and seek to decipher this incident further, let's first check out the latest movements of broad Chinese economy.

Tough economic outlook for China in 2017 despite somewhat stabilization in Q4/2016

Official statistics showed China's GDP witnessed a 6.7% increase in all three quarters of 2016, although many observers believe growth is more likely to be half that figure. The country's industrial development, consumption and investment maintained stable growth in October-November, with a rapid rise in the service industry, according to the National Bureau of Statistics (NBS).

"Economic development was steady and sound in November," the NBS said in a statement, noting that supply-side structural reform, stimulus policies, and improved factory efficiency contributed to the results.

China's industrial output and retail sales growth both accelerated in November, government data showed, in a sign of stabilization. Industrial output rose 6.2% in the month, ahead of both October's figures and economists' predictions of 6.1% in a Bloomberg News survey. Retail sales rose 10.8% on-year in nominal terms, up from 10.0% in October, while fixed-asset investment, a gauge of infrastructure spending, rose 8.3% in the first 11 months of the year, the NBS said.

Aided by ample credit policies and the weakening of CNY, the Chinese economy has remained resilient in the final quarter of the year as exports were cushioned by a weaker CNY and factory prices snapped out of their deflationary funk. With the expansion on pace of the government's full-year objective, attention is shifting to curbing excess corporate borrowing and industrial capacity and

reining in surging property prices.

But maintaining stable growth wouldn't be easy for China in 2017, state media Xinhua news agency said recently, "given persistently weak external demand, ongoing deleveraging and capacity-reduction pressure, and a slowing property sector". Despite experts' concerns, Chinese officials are confident in the country's economy, saying the positive trends of this year will continue into next year.

Indeed, China's economy in 2017 will more resemble the turbulent 2015 than the relatively calm 2016. Beijing can continue its rescue efforts for some time – perhaps years – because it runs an increasingly state-dominated economy, but state economies tend to fail spectacularly when they go.

How did the Chinese pharma fare in 2016 and what about its outlook next year?

The Chinese hospital drug sales were up 6.4% in the MAT Q3/2016, which was 0.2 percentage point higher than that in the MAT Q2/2016, according to IMS. The generally flat growth was attributed by IMS to be government policies for restricted use of antibiotics, hospital tender purchase, overall hospital expenditure cap, rationalized TCM use and anti-corruption in the healthcare sector. In the third quarter of 2016, Chinese hospital drug sales reached CNY 179.0 billion, rising at 5.7% year on year. MNCs (7.6%) led domestic companies (6.1%) in terms of growth rate for in the third quarter of 2016.

The sales of OTC drugs and health foods of Chinese retail pharmacy sector reached CNY 76.8 billion in MAT Q3/2016, up 4.2%, considerably lower compared with 6.3% of Q2/2016 due to slow price increases and negative volume growth, according to IMS PharmaTrend. Growth of unit prices outpaced that of sales value in the period. Among the total, sales of OTC drugs in the period were CNY 64.1 billion, up 4.6% year on year, with growth primarily driven by price increases and undermined by fallen volume.

Meanwhile, SMEI data shows that the drug consumption by representative urban representative hospitals is projected to grow 8.76% in 2016 (compared with 6.32% in 2015), reaching a total of CNY 129.8 billion. Under pressures of the upcoming introduction of a new national drug reimbursement list, scale up of the national drug price negotiation scheme, more stringent healthcare cost containment, anticipated diversion of patients to primary healthcare facilities and nationwide implementation of the two-invoice measure, SMEI expects the urban hospital drug consumption growth to be under 7.6% in 2017, reaching a new total of around CNY 140 billion in representative urban public hospitals. The overall Chinese hospital chemical drug consumption in the same year is forecasted to approach CNY 1 trillion.

The Chinese pharmaceutical market grew 13.2% CAGR in the last five years, reaching a total of CNY 1,220.7 billion in 2015, according to a new report from AskCI. In the 13th Five Year Period (FYP) (2016-2020), the Chinese pharmaceutical market is estimated to rise at a CAGR of 8%, reaching CNY 1,791.9 billion in 2020. All three subsectors, namely chemical drugs, formulated TCMs and biologics, are expected to see considerable growth with the biologics subsector forecasted to grow the fastest, followed by formulated TCMs. Chemical drug subsector is expected to see the lowest growth in the 13th FYP period at only 5.1% CAGR and as a result, its market share will fall to 49.0% in 2020 from 56.0% in 2015.

Although the growth of Chinese pharmaceutical market has been slowing, certain market segments including the drug sales at county level hospitals and primary healthcare facilities are expected to surge faster, according to a new report, *China ex-Hospital Prescription Drug Market Study 2020*, from Beijing Baolaitong Data Research Institute. It expects that the Chinese distribution channels for prescription drugs will see significant changes in the near future with pharma e-commerce and DTP (Direct-To-Patient) business model to become hot spots. The report also forecasts the Chinese ex-hospital prescription drug sales will exceed CNY 400 billion by 2020, accounting for 25% of the total estimated prescription drug sales of CNY 1,600 billion, up from around 15% at present. It also predicts that the Chinese drug market will reach CNY 1,477.4 billion at reduced growth in 2016.

The Baolaitong report also highlights a number of future growth drivers including expanded BMI coverage, new drug product launches, higher prevalence of chronic diseases, improved healthcare infrastructure and growing demands for better quality private healthcare. Future Chinese prescription drug market growth is expected to be driven by county level hospitals, primary healthcare and retail pharmacies, as drug sales at urban hospitals experience saturation.

Generic drug quality and efficacy equivalence study became priority for the CFDA

First of all, China's top legislature, the Standing Committee National People's Congress, adopted by the *PRC Law on Traditional Chinese Medicine* (TCM Law) to give traditional Chinese medicine (TCM) a bigger role in the healthcare system.

The CFDA, on the other hand, continued to turn out new and proposed regulations at high speed in the final month of 2016 as generic drug quality and efficacy equivalence study moved to the top of its agenda.

The CFDA issued an official notice on December 16 to introduce the revised *Guideline for GSP Onsite Inspections*. The revision was developed following a recent amendment of the GSP (CFDA Order #28) which revised its provisions on drug electronic regulation and vaccines. Thereafter on December 29, the agency issued a document, *CFDA Decision on Revision of GSP* (CFDA Order #28). It also made a number of revisions to the five appendices of GSP relating to inventory and transportation of drugs that need cold or freeze storage.

In a separate development, ZHANG Zhijun, Vice President of China National Institutes of Food and Drug Control under the CFDA, delivered a presentation over the topic of generic drug quality and efficacy equivalence at a recent industry event. During his presentation, he praised the role of the "Orange Book" in the U.S. and Japan. Zhang disclosed that China is considering the introduction of its own "Orange Book" which will first include reference drug products and "a preliminary plan was already developed".

Numerous draft rules and guidelines were released in December by the CFDA and its subordinate institutions. These proposed documents, which focus on but are not limited to generic drug equivalence studies, include:

- *Guidelines for R&D Onsite Inspection of Generic Drug Quality and Efficacy Equivalence Studies*;
- *Guidelines for Production Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*;
- *Guidelines for Clinical Trial Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*;
- *Guidelines for Cause-Triggered Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*;

- *Technical Guidelines for Research and Evaluation of Cellular Products*;
- *Provisions for Food and Drug Safety Supervision Information Transparency*;
- *Provisions for Batch Release of Biologics*;
- *Provisions for Advertising Evaluation of Drugs, Medical Devices, Health foods and Foods for Special Medical Purposes*;
- *Sterile Process Simulation Test Guideline* (Sterile APIs) and *Sterile Process Simulation Test Guideline* (Sterile Formulations);
- *Technical Guidelines for Compatibility Research of Chemical Drugs and Elastomer Seals*
- *Rules for Drug Evaluation Program Management*;
- *Amendment of the* Good Clinical Practices for Drug Clinical Trials (GCP);
- *Rules for Confidentiality Management in Review of Drug and Medical Devices*; and
- *CFDA Decision to Change Certain Drug Evaluation and Approval Procedures.*

In other regulatory moves, the CFDA issued a total of 135 new drug approvals in the first three quarters of 2016. Among them, there were 127 chemical drug approvals, five TCM approvals and three biologic approvals. The agency also approved 20 drug registration applications in the month of November. Among all, 17 approvals were for domestic chemical drugs, one for biological product and two for import chemical drugs.

The Center for Drug Evaluation under the CFDA reported on December 2 that 32 registration applications have been granted priority review status following review by expert panels. Among the total, 14 are from domestic companies and 18 are from MNCs.

The Center for Food and Drug Inspection under the agency also announced its latest plan for onsite clinical data inspection of 30 drug applications following the publication period, which lasts ten working days between November 30 and December 13.

Six provincial capital cities in central China, including Taiyuan, Changsha, Wuhan, Zhengzhou, Nanchang and Hefei, will join hands in the fight against "business dishonesty and violations" of food and drug companies. Their food and drug agencies signed a memorandum of understanding to set up cooperative and coordination mechanisms for food and drug regulation and anti-counterfeiting.

Finally, the Ministry of Commerce released on December 29 its 13th Five Year Plan (FYP) for pharmaceutical distribution under the name of *National Drug Distribution Industry Development Plan (2016-2020)*, while the NDRC and MOFCOM released on December 8 a draft revision of the *Foreign Investment Industrial Guidance Catalog*, which includes numerous requirements for pharma related industries, for public comments.

Government prepares the country for a new phase of healthcare reform

The Chinese government is laying ground for a phase of healthcare reform in 2017 by making multiple new moves in December. First and foremost, the Executive Meeting of State Council on December 21, which was chaired by Premier LI Keqiang, approved a number of government agendas in the 13th Five Year Plan (FYP) period (2016-2020). Among the approved agendas were the *Public Health and Healthcare Plan in the 13th FYP* and major healthcare reform tasks.

Earlier in the month, the Healthcare Reform Office of State Council issued an official notice and a compilation of representative local healthcare reform experiments highlighting cases in Fujian, Yunnan, Henan, Jiangsu Province, Anhui, Zhejiang and Qinghai Provinces, as well as Shanghai. The document calls for local governments to study and promote such reform experiences.

The NHFPC issued a notice over implementation of certain clinical pathways. So far the agency has published a total of 1,001 clinical pathways on the website of Chinese Medical Association (CMA), which includes clinical pathways the NHFPC entrusted the CMA to develop recently and clinical pathways developed and released previously. These pathways are for reference and application by local health and family planning departments and medical institutions, according to the notice.

The NHFPC also confirmed in late December that 23 provincial level governments have included the three negotiated drugs for reimbursement by BMI, NRCMS or CII (excluding provincial level governments which have already covered the three drugs before negotiation).

Most recently, the NHFPC launched a thorough investigation of fraud and misconduct in public hospitals after the China Central Television (CCTV) exposed drug kickback scandals in regional hospitals on December 24. The pharmaceutical industry is alerted with worries that the Chinese government will begin a fresh campaign against the healthcare corruption with its true targets at containing drug prices and healthcare expenditure growth. Meanwhile, the state media has advocated the healthcare reform experiment of Fujian's Sanming City, which is well-known for being harsh with drug prices and healthcare cost containment and has been upheld as a local healthcare reform role model by the central government.

In other developments, a new report, *BMI Fund Operating Performance Analysis 2016*, discloses that the national BMI fund income and outlay are estimated to have grown 13.5% and 11.0% respectively in 2016, reaching CNY 1,270.4 billion and CNY 1,033.6 billion.

Five central government agencies led by State Council's Healthcare Reform Office also released recently their *2015 Public Hospital Reform Report*, which declares the reform trial to have covered one third of Chinese cities by now. The growth of outpatient and inpatient medical expenditures in trial site cities were contained to be under that of urban resident disposable income in 2015, while the share of government subsidies in overall public hospital expenditures reached 9.2%, which is 1.1 percentage points higher than the same figure in 2014.

Lastly, the NHFPC issued the *Pediatric Immunization Procedure and Explanations under the National Immunization Plan (2016 Edition)* on December 29. The document is for implementation immediately.

Pharma players reposition for changing business environment

Compared with Chinese GDP growth of 6.7% in the first three quarters of 2016, the core business revenues of the Chinese pharmaceutical industry rose 10.1% in the period to CNY 2.1 trillion and the growth rate was 6.4 percentage points higher than that of Chinese industry average, official data from the MIIT shows. The industry's profits reached CNY 220 billion in the period, up 15.6%, which was 7.2 percentage points higher than the Chinese industry average. The industry is forecasted to see its core revenues and profits rise again by 10.5% and 15.8% respectively in 2017, according to CPIIC, which researches official data for the MIIT.

In the meantime, most of Pharma MNCs active in China recorded single-digit or negative growth for their performance in China in the third quarter of 2016, with the exception of a few including Pfizer, Novo Nordisk and AstraZeneca, which witnessed 16%, 13% and 10% growth respectively in the period. However, the divide between winners and losers is expanding, according to industry observers. The losers, which saw negative growth ranging from -7% to -1% in the quarter, included Eli Lilly, Novartis, Sanofi and MSD. Roche and GSK are in the middle with 4% growth for both.

Witnessing changing market dynamics, MNCs are modifying their business models in China by investing in facility expansion and engaging in more local partnerships.

Bayer Healthcare inaugurated the EUR 100 million extension program of its pharmaceutical products supply site in Beijing recently, enabling the site to double its production capacity and making it the largest prescription drug packaging facility in its global production network.

Sanofi and China Resources Sanjiu Medical & Pharma entered into a framework agreement for a strategic partnership to jointly explore the opportunities in the consumer healthcare market in China. The parties will form a joint venture company, which will serve as the platform for the continued operation of the businesses of China Resources Sanjiu (Beijing) Pharma and Sanofi subsidiary Sunstone (Tangshan) Pharma, focusing initially in the areas of pediatric and gynecological OTC products. Sanofi also entered and a strategic alliance with JHL Biotech to collaborate on the development and commercialization of biological therapeutics in China and with potential international expansion. Under the agreement, Sanofi will invest US$80 million in newly issued JHL shares. In addition, Sanofi will make an upfront payment of US$21 million to acquire exclusive rights for the proposed biosimilar of Rituximab and options to certain JHL pipeline products.

Pfizer signed a R&D partnership deal with Suzhou-based PegBio on December 13, joining hands to develop innovative drugs for diabetes therapy. According to the agreement, Pfizer will grant PegBio Greater China rights of selected glucokinase agonist (GKA) to treat diabetes. The partnership is part of a Pfizer strategy to use local partners to advance medicines addressing unmet needs.

In a business setback, BMS China officially closed its OTC drug business and disbanded sales teams on December 6 at a company conference in Hangzhou. The move will affect around 150 employees.

As numerous Western MNCs regroup in China, more Japanese companies are making moves to enter the Chinese market. Fujifilm Holdings will expand into the Chinese herbal medicine market through a partnership with China Resources (Holdings). By utilizing Fujifilm's technologies for extracting active ingredients and refining them for better body absorption, the duo aims to develop Chinese medicines that are more effective than traditional varieties. On the other hand, Kobayashi Pharma, a Japanese maker of OTC drug and health supplement products popular among Chinese tourists, will spend Yen 30 billion (US$254 million) over the three years through fiscal 2019 to buy businesses in China and elsewhere to bolster drug sales outside its home market of Japan. It plans to acquire a Chinese company as early as 2017 so that it can obtain a license for production and marketing.

Licensing deals among foreign and Chinese drug companies continued to flourish in December. Ferring Pharmaceuticals and Shanghai-based IMAB (天境生物) announced a licensing agreement which grants IMAB exclusive rights to olamkicept (pINN) in Asia, while Uni-Bio Science Group signed a multiple drug co-development deal with Beijing Sun-Novo Pharmaceutical Research to extend Uni-Bio's current R&D capabilities in small molecule drug development including co-development of various oral anti-diabetes drugs. Tokyo-based Oncolys BioPharma also entered an exclusive license agreement with Jiangsu Hengrui Medicine Co Ltd for greater China rights to its oncolytic virus candidate, OBP-301, to Jiangsu Hengrui Medicine.

Not all deals turn out positive, nonetheless. Yuhan Corp., a South Korean leading pharmaceutical company, said on December 28 that it has terminated a license agreement with China's Luoxin Biotechnology Co. signed in July for the development of YH25448, Yuhan's investigational lung cancer drug. The termination was due to non-fulfillment of Luoxin's obligations, the Korean drugmaker said, adding the Chinese partner was not sincere in pursuing final agreement terms and only demanding technical information of the drug one-sidedly.

On the front of domestic players, companies continued to seek overseas business expansion through M&A and strategic business deals. Luye Pharma completed its acquisition of the transdermal drug delivery systems (TDS) business from Swiss company Acino. The acquired business is a global leader in niche transdermal markets and will greatly enhance Luye's R&D efforts and international expansion plan.

Harbour BioMed, a recently established Shanghai-based company, announced on December 19 the acquisition of Harbour Antibodies BV for cash and an equity interest in Harbour BioMed to create a new, global oncology-focused biotechnology company.

Tianjin Pharmaceutical Group International Holdings (TJPH) completed in late December a US$20 million strategic investment into Neuralstem, a biopharma company focused on the development of CNS therapies based on its neural stem cell technology, while Prinston Pharma, the U.S. subsidiary of Zhejiang Huahai Pharma, entered into a deal recently to buy Par Pharma's manufacturing facility in North Carolina's Charlotte for US$14 million in an effort to establish manufacturing, improve supply chain in the U.S. and enrich product pipeline.

Sichuan Kelun Pharma, on the other hand, plans to set up another majority-controlled US$11 million subsidiary in the U.S. under the name of Kebous Biological Medicine Co., Ltd., via its subsidiary Sichuan Kelun Botai Biopharma.

Other smaller Chinese companies replenished more firepower for expansion. Jiangsu province-based Ascentage Pharma, which is dedicated to the discovery of targeted small-molecule cancer therapeutics, raised CNY 500 million (US$72 million) in series B funding round, while CRO dMed secured US$8 million in series A funding round with participation from Qiming VC, Tairui Investment and ZAI Lab.

Another storm ahead and what does it take to survive?

At a time of intensified tension between physicians and patients, along with long distained reputation of the pharmaceutical industry, the recent negative publicity surrounding drug sales kickbacks could not come at a worse time and threatens to incite more distrust and even violence against healthcare professionals. Doctors widely denounced the government move on social media, while response from the pharmaceutical industry was more muted despite utmost agitations of its executives.

Many in the healthcare sector suspect that the renewed media attack is well-planned by the government to pave the way for implementation of its next important healthcare reform agenda – in particular promotion of the healthcare reform model of

Fujian province's Sanming city, which is characterized by 1) healthcare reform must be led by the top ranking officials of local governments; 2) merging the three basic medical insurance schemes, namely Urban Employee BMI, Urban Resident BMI and NRCMS; 3) stringent cost containment of drugs and medical consumables (with focused control of supplemental drug consumption and physician drug prescription practices) in exchange for increased medical service fees; 4) two-invoice or even one-invoice measures for hospital drug purchase system; and 5) post-tender (provincial level) drug price negotiations to ensure lowest drug prices. The true damage of this reform model to other healthcare stakeholders is that it is almost entirely self-centered on the government will to balance its BMI funds.

In the meantime, the pharmaceutical industry is also watching the Chinese government nervously for signs of another major campaign against healthcare corruption as a way to force through its single-minded reform goals. If this is indeed what the central government has in mind, the latest negative publicity against the healthcare sector must have been intended to set the battleground. The anticipated war may be against corruption on the surface but in reality is aimed at maximizing cost containment of healthcare expenditures, primarily drug costs.

Everyone on the healthcare industry WeChat groups I belong to appear to feel completely frustrated and exhausted by the fruitless but yet never-ending healthcare reform turbulences created by the government. With so many cost containment measures and drug regulatory upgrades in recent years, most pharma companies are merely struggling to stay above their bottomlines and any additional turbulence may disrupt their last breath to hold on.

When the second round of healthcare reform began in 2009, we all hoped for the land of milk and honey at the end of tunnel. It's becoming increasingly clear that a self-serving healthcare reform championed by the government will probably never get us there. It seems the structural flaws are unlikely to be fixed by superficial reforms which center on drug cost cutting and instead a revolution of the Chinese healthcare system is needed.

Judging by the sentiments of many healthcare and pharma professionals, I feel the tipping point is near when the old system will finally break down and hopefully along with it come the opportunity to be revolutionized for a new beginning.

Let's hope that day will come sooner than later.

News in Focus

State Council Approves Major Health-care Reform Tasks in the 13th FYP Period

The latest Executive Meeting of State Council on December 21, which was chaired by Premier LI Keqiang, approved a number of government agendas in the 13th Five Year Plan (FYP) period (2016-2020).

Among the approved agendas were the Public Health and Healthcare Plan in the 13th FYP and major healthcare reform tasks.

Major tasks for the Public Health and Healthcare Plan in the 13th FYP include: 1) strengthening prevention and treatment of critical illnesses; introducing risk assessment of chronic disease high risk population groups for high blood pressure, diabetes and stroke as well as early diagnosis/treatment of major cancers; stepping up prevention and treatment of major infectious diseases, mental diseases, endemic diseases and occupational diseases; implementing and expanding the national immunization program; and accelerating education of shortage human resources including pediatric, mental disease, geriatric medicine and nursing personnel; 2) boosting capacity of primary healthcare and clinical services, as well as advancing health of senior citizens, handicapped, mobile population and poverty-stricken residents; 3) expediting approval of innovative new drugs and drug products in urgent clinical demands and advocating development of TCM; promoting wider use of internet+healthcare services; and perfecting tiered medical service system; 4) meeting new demands for two-child policy and rationalizing the allocation of mother & child healthcare, education and social security public services; and 5) expediting development of healthcare industries, supporting multiple forms of social capital in healthcare services, promoting integration of medical, senior nursing and tourism services, and increasing effective supply of medical nursing services.

Major healthcare reform tasks determined by the meeting include: 1) on the basis of first visit to primary healthcare and voluntary participation, family doctor contract service should be promoted widely to residents; and multiple forms of tiered medical service system trial should be launched in at least 85% of urban cities in 2017; 2) overall reform should be implemented in all levels and types of public hospital from 2017; vertically-integrated medical consortiums should be established, prices of drug products, medical consumables and diagnostic examinations should be reduced, and irrational growth of healthcare expenditures should be contained; and prices of medical treatment, surgery, rehabilitation, nursing and TCM services should be rationally raised to motivate medical professionals; 3) perfecting the mechanisms for stable and sustainable BMI fund raising and reimbursement adjustment; fully implementing BMI payment system reform with disease group-based payment scheme in the center which is complemented by multiple other forms of payment schemes; essentially accomplishing direct out-of-area settlement for inpatient medical expenditures meeting referral conditions; and upholding the role of critical illness insurance and other schemes as bottomline security; 4) improving the drug supply security system; supporting the production of low price drugs, orphan drugs and pediatric drugs; expediting the promotion of hospital doctor drug prescription filling at retail pharmacies; and 5) innovating overall regulation; liberalizing the entry requirements for social capital investment in medical institutions; and stepping up regulation in and after events; and utilizing better quality and more convenient medical services to build healthy China.

State Council Issues Representative Local Healthcare Reform Model Cases

The Healthcare Reform Office of State Council issued an official notice and a compilation of representative healthcare reform model cases at the local levels on December 21 to provincial level governments.

Local reform showcases in the compilation include those experiments in:

- Fujian Province's Sanming City (overall healthcare reform and two-invoice system);
- Yunnan Province's Lufeng County, Henan Province's Yiyang County and Jiangsu Province's HuaiAn City (BMI payment

system reform);

- Anhui Province (diversified contract management of BMI);
- Shanghai (reform of public hospital director performance evaluation);
- Jiangsu Province and Fujian Province's Youxi County (reform of public hospital remuneration system);
- Shanghai, Jiangsu Province's Zhenjiang City, Zhejiang Province and Qinghai Province (Tiered Medical Service System Building); and
- Zhejiang Province's Hangzhou City (improving medical services through IT applications).

The document calls for local governments to study and promote such reform experiences.

For full text of this notice and the compilation of such healthcare reform cases in Chinese, please visit the following NHFPC weblink: http://www.nhfpc.gov.cn/tigs/s3577/201612/1435148e16fe4274965685bcecc2f676.shtml

NHFPC Issues Notice over Implementation of 1,001 Clinical Pathways

The NHFPC issued a notice on December 8 over implementation of certain clinical pathways.

According to the notice, the NHFPC has published a total of 1,001 clinical pathways on the website of Chinese Medical Association (CMA) (http://www.cma.org.cn/kjps/jsgf/), which includes clinical pathways the NHFPC entrusted the CMA to develop recently and clinical pathways developed and released previously. The recently developed clinical pathways were finalized following comment seeking from relevant associations, local health and family planning commissions, and selective medical institutions. These pathways are for reference and application by local health and family planning departments and medical institutions, the notice says.

The notice also provides the following:

1. Implementation of clinical pathways should be integrated with medical service quality control and performance evaluation (of hospitals);

2. Implementation of clinical pathways should be integrated with medical service expenditure adjustments;

3. Implementation of clinical pathways should be integrated with BMI payment system reform, making such pathways as the foundation of single-disease based payment and diagnosis-related group (DRG) payment schemes; and

4. Implementation of clinical pathways should be integrated with IT infrastructure building of medical institutions in order to raise efficiency, institute real time control and conduct comprehensive analysis.

For full text of the notice in Chinese, please visit the following NHFPC webpage: http://www.nhfpc.gov.cn/yzygj/s7659/201612/e02b9324fc344f45979b6c20d7497b71.shtml

China Approves TCM Law with Effect in July 2017

China's top legislature adopted the *PRC Law on Traditional Chinese Medicine* (TCM Law) to give traditional Chinese medicine (TCM) a bigger role in the medical system. The TCM law was approved at the end of a seven-day session of the National People's Congress Standing Committee.

HUANG Wei, deputy director of the NPC Standing Committee commission for legislative affairs, said the law, which will go into effect on July 1, is a significant step in the development of TCM. It is key to reform of medical and health sectors and the drive toward a "healthy China", Huang said.

The law aims to substantially elevate the role of TCM in Chinese healthcare through the following provisions: 1) increasing central and local government fiscal support by including TCM sector in the fiscal budget and government's national economic & social development planning; 2) raising the number of TCM consumption facilities with county and above governments to include TCM facilities in medical resource allocation plans and sponsor appropriate sized TCM institutions; 3) rationalizing the fee items and standards of TCM services; 4) increasing reimbursement of TCM services and TCMs; 5) strengthening TCM human resources training and boosting TCM scientific research & ancient technique inheritance; 6) developing TCM life preservation and healthcare services, and encouraging social capital investment in such facilities; and 7) boosting development of minority medicines.

Most notably, the "TCM Protection and Development" chapter of the law provides that "compound TCM preparations which are originated from ancient classics and meet national production standards can be approved for registration on the ground of only dossiers for non-clinical safety studies. The provision will sharply reduce the cost and time of developing new TCMs.

China Readies New Campaign against Healthcare Corruption after CCTV Exposure of Drug Kickbacks

China's National Health and Family Planning Commission (NHFPC) launched a thorough investigation of fraud and misconduct in public hospitals following a state media report on December 24 which exposed drug rebate scandals in regional hospitals. A program by China Central Television (CCTV) showed an investigative report which captures doctors in regional hospitals taking kickbacks from drug companies. CCTV journalists reportedly spent eight months undercover in six large hospitals of Shanghai and Hunan for the investigative report.

According to the report, medical representatives (MRs) of selected pharmaceutical companies offered large amounts of kickbacks to doctors to promote drug sales. Generally, the report suggests, MRs can earn 10% of the drug price, while the kickback for doctors can reach as high as 40% of the price in such deals. The report also pointed out that inflated drug price may be feeding prescription drug kickbacks.

In response to the media exposure of illegal practices in hospitals, the NHFPC ordered local health authorities in Shanghai and Hunan to seriously investigate and deal with the cases in accordance with law. It also sent two inspection teams to the areas in coordination with local investigations. So far, a doctor in Hunan and three doctors in Shanghai have been suspended from duty with hospital use of relevant drugs stopped.

As the next step, the agency said it would deepen the crackdown of healthcare irregularities, fully implement its "Nine Bans", further improve the drug purchase tender process to ensure transparency, step up supervision of drug procurement process and elevate penalties of violations.

Meanwhile, the pharmaceutical industry is alerted with worries that the Chinese government will begin a new round the health-care corruption crackdown campaign with its true targets at containing drug prices and healthcare expenditure growth. The goal of state media and government seems to be preparing the public and creating the right publicity to wage a major new battle of cost containment against the healthcare related industries.

The latest negative publicity further alienates physicians from the public and threatens to elevate the tension between doctors and patients, which already led to increasing violence against doctors in recent years. At the same time, MRs have also had a bad reputation for years and the latest hype is expected to further damages its image.

The Market

Chinese Pharma Market Forecasted to Grow at 8% CAGR in the Next Five Years

The Chinese pharmaceutical market grew 13.2% CAGR in the last five years, reaching a total of CNY 1,220.7 billion in 2015. The CAGR was much faster than the Chinese GDP growth of 8.7% in the period.

In the 13th Five Year Period (FYP) (2016-2020), the Chinese pharmaceutical market is estimated to rise at a CAGR of 8%, reaching CNY 1,791.9 billion in 2020, according to a new report from AskCI, a Chinese market research and management consulting firm.

All three subsectors, namely chemical drugs, formulated TCMs and biologics, are expected to see considerable growth with the biologics subsector forecasted to grow the fastest, followed by formulated TCMs. Chemical drug subsector is estimated to see the lowest growth in the 13th FYP period at only 5.1% CAGR and as a result, its market share will fall to 49.0% in 2020 from 56.0% in 2015.

Anti-infectives continued to lead all other therapeutic classes (TCs) of the chemical drug subsector in 2015, followed by digestive system & metabolism drugs and cardiovascular system drugs. On the other hand, cardio- & cerebro-vascular disease drugs led all TCs of formulated TCM subsector in 2015, followed by oncology and respiratory system drugs.

China Pharma Market Size by Sector 2011-2020E

Subsector	Market Size (CNY bln)			CAGR (%)		Share (%)		
	2011	2015	2020E	2011-2015	2015-2020E	2011	2015	2020E
Chemical Drugs	473.3	683.6	878.0	+9.6	+5.1	63.7	56.0	49.0
Formulated TCMs	210.3	391.8	580.6	+16.8	+8.2	28.3	32.1	32.4
Biologics	59.4	145.3	333.3	+25.1	+18.1	8.0	11.9	18.6
Total	**743.1**	**1,220.7**	**1,791.9**	**+13.2**	**+8.0**	**100.0**	**100.0**	**100.0**

Source: AskCI

Chemical Drug Sales by TCs in China 2015

Therapeutic Categories	Market Size (CNY bln)	Share (%)
Anti-infectives	114.2	16.7
Digestive System and Metabolism	101.2	14.8
Cardiovascular System	77.2	11.3
Central Nervous System	71.1	10.4
Blood & Blood-making System	60.2	8.8
Oncology	54.7	8.0
Respiratory System	38.3	5.6
Muscle-skeletal System	30.1	4.4
Systemic Hormones (excluding sex hormones)	25.3	3.7
Genitourinary System and Sex Hormones Drugs	20.5	3.0
Others	90.9	13.3
Total	**683.6**	**100.0**

Source: AskCI

Formulated TCM Sales by TCs in China 2015

Therapeutic Categories	Market Size (CNY bln)	Share (%)
Cardio- & Cerebro-vascular Diseases	134.0	34.2
Oncology	65.8	16.8
Respiratory System	47.0	12.0
Musculo-Skeletal System	32.5	8.3
Gastrointestinal System	25.5	6.5
Gynecology	21.9	5.6
Genitourinary System	20.4	5.2
ENT	12.1	3.1
Dermatology	7.8	2.0
Blood and Qi Supplementing Drugs	5.9	1.5
Others	18.8	4.8
Total	**391.8**	**100.0**

Source: AskCI

SMEI: Chinese Hospital Drug Market Expected to Grow No More Than 7.6% in 2017

According to SMEI's Chinese Urban Public Hospital Chemical Drug Terminal Monitoring and Analytical System (HDM), the drug consumption by representative urban representative hospitals is projected to grow 8.76% in 2016 (compared with 6.32% in 2015), reaching a total of CNY 129.8 billion.

Under pressures of the upcoming introduction of a new national drug reimbursement list, scale up of the national drug price negotiation scheme, more stringent healthcare cost containment, anticipated diversion of patients to primary healthcare facilities and nationwide implementation of the two-invoice measure, SMEI expects the urban hospital drug consumption growth to be under 7.6% in 2017, reaching a new total of around CNY 140 billion in representative urban public hospitals. Meanwhile, the overall Chinese hospital chemical drug consumption in the same year is forecasted to approach CNY 1 trillion.

The top five therapeutic categories (TCs) of urban hospital drug consumption in 2016 are predicted to be oncology drugs, systemic anti-infectives, digestive system drugs, blood and blood making system drugs, and nervous system drugs. Together the five TCs are expected to account for 73.65% of all hospital drug consumption in 2016, which is at a level comparable with 2015.

The consumption of top 50 drugs by value in representative urban public hospitals is projected to grow 7.94% in 2016 to CNY 43.3 billion, SMEI data shows. All of the top 50 is expected to have sales above CNY 500 million in the year.

In 2017, SMEI anticipates the top 50 drugs to see higher than average growth. Their overall consumption in Chinese urban public hospitals, county level public hospitals, community health-care facilities and township health centers is forecasted by SMEI to reach CNY 350 billion in the year. Such drugs remain the critical growth driver of market growth, SMEI says.

Chinese Ex-Hospital Prescription Drug Sales Forecasted to Exceed CNY 400B by 2020

As the Chinese pharmaceutical market growth slows in general, certain market segments including the drug sales at county level hospitals and primary healthcare facilities are expected to surge faster, according to a new report, *China ex-Hospital Prescription Drug Market Study 2020*, from Beijing Baolaitong Data Research Institute. It expects that the Chinese distribution channels for prescription drugs will see significant changes in the near future with pharma e-commerce and DTP (Direct To Patients) business model to become hot spots.

The report forecasts the Chinese ex-hospital prescription drug sales will exceed CNY 400 billion by 2020, accounting for 25% of the total estimated prescription drug sales of CNY 1,600 billion, up from around 15% at present.

However, it is anticipated that the Chinese pharmaceutical market growth will maintain the slowing trend under pressure from continuous implementation of various cost containment measures that are designed to curb fast growth of healthcare expenditures. However, the report also highlights a number of future growth drivers including expanded BMI coverage, new drug product launches, higher prevalence of chronic diseases, improved health-care infrastructure and growing demands for better quality private healthcare.

Future Chinese prescription drug market growth is expected to be driven by county level hospitals, primary healthcare and retail pharmacies, as urban hospitals sees market saturation.

The Chinese DTP pharmacy segment began with sales of new and special drugs, thereafter gradually expanded to cover chronic disease drugs and all prescription drugs. This market segment is estimated by the report to reach CNY 30 billion by 2020.

The Chinese pharma e-commerce has risen to CNY 13.3 billion in 2015 from only CNY 400 million in 2011, the report says. The biggest future bottleneck for this market segment comes from the restriction of online prescription drug sales, but the report pins hope on rising influence of Chinese chronic disease patients to crack the barrier eventually and unleash explosive potential demands.

It also predicted that the Chinese drug market will reach CNY 1,477.4 billion at reduced growth in 2016.

Nicholas Hall Reports Growth of Chinese OTC Dermatologicals Market in MAT 06/2016

According to Nicholas Hall, a leading market research firm specializing in global OTC healthcare market, the Chinese OTC dermatological sales surged 7% in the 12 months to June 2016 as all categories except hair loss record upturns.

Online sales channels are becoming increasingly important to marketers' long-term growth strategies in recognition of the limited potential offered by traditional drugstores.

The decline for hair loss treatments slowed to 6% as leading brand Bawang managed to recover from some of the negative publicity that has held back sales in previous years.

Chinese OTC Dermatologicals Market MAT 06/2015

Category	US$ mln	+/- (%)
Antifungals*	757.9	+7
Acne remedies	116.9	+5
Antiseptics & disinfectants	250.1	+9
Antipruritics	360.7	+10
Feminine intimate care	298.3	+6
Hair loss treatments	50.5	-6
Topical antibiotics	96.1	+5
Others	672.5	+6
TOTAL	**2,603.0**	**+7**
TOTAL (CNY)	**17,600**	
Per capita spend US$	1.90	-1.5

Source: Nicholas Hall & Co.
*Including VYI treatments and nail antifungals

*Data in this report 12 months to June 2016 (MSP): Nicholas Hall's OTC INSIGHT based on industry estimates and **DB6** Global OTC database. Exchange rate:* US$1.00 = CNY6.77. *Not directly comparable to last year owing to updated coverage. Exchange rates from oanda.com on 1st November 2016.*

Antifungals grew by 7% to CNY 5.1 bln (US$758 mln), driven by a good performance for nail antifungals (+17%). Liangjia (Harbin Letai) accounts for almost half of the sales in this segment and was boosted in September 2016 via an initiative in which the marketer provided free onychomycosis treatment to athletes returning from the Rio Olympics. Multinational brands include Nalox (Menarini) and Loceryl (Galderma / Nestle) and in January 2016, China Bencaogangmu Group gained the distribution rights for the latter in China.

Lower growth in general antifungals (+3%) may have been the result of confusion over the CFDA's ban of oral ketoconazole in July 2015. Only oral preparations were included in the ban owing to the risk of liver damage, but the announcement made consumers concerned over the safety of topical ketoconazole products, as well as similar ingredients such as miconazole, with advice not to use such medicines quickly spreading via the internet.

Top 3 OTC General Antifungal Brands in MAT 06/2016

Rank	Brand	Marketer
1	Daktarin	Xian-Janssen / J&J
2	Pi Kang Wang	Kunming Dihon / Bayer
3	Weidaning	Xiu Zheng

Source: Nicholas Hall & Co.

NH Reports on Chinese OTC Eye Care and Sleep Aids Markets 2016

Chinese OTC Eye Care Market

Nicholas Hall (NH) estimated that the Chinese OTC eye care sales grew by 6% to CNY 3.4 billion (US$495.4 million) in the 12 months to September 2016, according to Nicholas Hall (NH)'s global OTC database DB6.

The ongoing issue of city smog, which can irritate the eyes, continues to be a growth driver. There is also a trend for local marketers to expand their eye care portfolios beyond eye drops to more daily consumer products such as eye masks (not tracked in our topline), with online retail channels relied upon to drive sales.

Chinese Eye Care Market Facts MAT September 2016

OTC eye care sales MAT 09/2016 (US$)*:	495.4 mln
OTC eye care sales MAT 09/2016 (CNY)*:	3.4 bln
US$: CNY (rate on 12/01/2016)	1 : 6.89
Index 2016/2015 (local currency):	106
Population:	1,364.1 mln
Per capita spend:	US$0.36

Source: Nicholas Hall (www.nicholashall.com)

* Sales of eye drops only. Lenses, lens solutions and supplements For ocular health not tracked in this report.

The 2016 Rio Olympics in August provided a common A+P focus for multiple brands during the reporting period. This included No.1 entry Shapu Aisi Bendazac Lysine (Zhejiang Shapu Aisi), which associated with the Olympic gold medal-winning women's volleyball team. No.2 brand Rohto-Eyedrops (Mentholatum / Rohto) also leveraged the Olympics, with A+P encouraging consumers to use the drops to prevent eye fatigue while staying up late to watch the events.

Top 3 Chinese OTC Eye Care Brands in MAT 09/2016

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.

Sales of OTC sleep aids grew by 5% to CNY 3.1 bln (US$450 mln), as high-pressured working and social environments continue to affect sleep quality. The issue is increasingly affecting students; according a report published by China Youth & Children Center in November 2016, nearly 60% of primary and middle school students do not get sufficient sleep thanks to mounting homework and extra studies outside of school.

In the wider population, a survey commissioned by the Chinese Medical Doctor Association published in March 2016 found that around one-quarter of people go to sleep late or stay up all night. This provides ample opportunities for marketers of OTC sleep aids, but the category may not be reaching its full potential. The same survey reports that 30% of respondents use intelligent sleep products such as smartwatches and smartphone apps (not tracked in our topline) to improve sleep quality.

Chinese OTC Sleep Aids Market Facts MAT 09/2016

OTC sleep aids sales MAT 09/2016 (US$)	450.4 mln
OTC sleep aids sales MAT 09/2016 (CNY)	3.1 bln
US$: CNY (rate on 12/01/2016)	1 : 6.89
Index 2016/2015 (local currency):	105
Population:	1,371.9 mln
Per capita spend:	US$0.33

Source: Nicholas Hall (www.nicholashall.com)

Pressured lifestyles are driving sales in China but the category has some untapped potential as many consumers choose intelligent sleep products such as smartwatches instead of OTCs.

The Top 3 brands – Nao Bai Jin (Stone Group), Jolly Wu Ling Capsule (Zhejiang Jolly) and Aodong An Shen Bu Nao (Jilin Aodong) – compete closely and collectively account for around 42% of category sales.

Top 3 Chinese OTC Eye Care Brands in MAT 09/2016

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

Source: Nicholas Hall (www.nicholashall.com)

Industry News

CPIIC: Chinese Pharmaceutical Industry Forecast for 2016 and 2017

China's pharmaceutical industry will see its core revenues and net profits rise 10.3% and 15.6% respectively in 2016 and again by 10.5% and 15.8% respectively in 2017, according to a recent presentation by Minli Lu, Chief Consultant of China National Pharmaceutical Industry Information Center (CPIIC).

The following tables provide more details of CPIIC's forecasts as well as its various 2015 Chinese pharmaceutical market data.

Core Revenues and Profit of Chinese Pharma Industry 2008-2017E

Year	Sales Revenue (CNY bln)	+/- (%)	Net Profits (CNY bln)	+/- (%)
2008	758.3		75.4	
2009	938.7	+23.8	101.7	+34.9
2010	1,195.0	+27.3	130.3	+28.1
2011	1,493.8	+25.0	163.9	+25.8
2012	1,795.5	+20.2	182.4	+11.3
2013	2,169.0	+20.8	218.5	+19.8
2014	2,455.3	+13.2	244.8	+12.0
2015	2,688.5	+9.5	275.4	+12.5
2016E	2,965.4	+10.3	318.3	+15.6
2017E	3,276.8	+10.5	368.6	+15.8

Source: CPIIC

China Pharma Market by Terminal Market Segments 2015

Terminal Market Segments	Share (%)
Terminal 1: Large Hospitals	63
Terminal 2: Retail Pharmacies	17
Terminal 3: Primary Healthcare Facilities	20

Source: CPIIC

Structure of Chinese Drug Market by Product Types 2015

Sector	Sale Value (CNY bln)	Share (%)
Pharma Formulations	888.0	66.5
Formulated TCMs	337.9	25.3
Biologicals & Biochemicals	109.5	8.2
Total	1,335.4	100.0

Source: CPIIC

Chinese Pharma Companies by Subsector in 2015

Sector	# of Producers	Share (%)
APIs	1,297	25.6
Pharma Formulations	1,136	22.4
Formulated TCMs	1,658	32.7
Biologicals & Biochemicals	974	19.2
Total	5,065	100.0

Source: CPIIC

Top 5 TCs in Representative Urban Hospitals 2015

Therapeutic Category	Share (%)
Anti-infectives	12.57
Cardiovascular System	12.52
Oncology	10.02
Nervous System	9.08
Digestive System	8.59
Top 5 Subtotal	52.78

Source: CPIIC

MIIT: Chinese Pharma Industry on Healthy Growth in the First 3Qs of 2016

Compared with Chinese GDP growth of 6.7% in the first three quarters of 2016, the country's pharmaceutical industry grew much faster, according to WU Haidong, Deputy Director General of the Department of Consumer Products of the Ministry of Industry and Information Technology (MIIT) at a latest pharma industry event.

He said the Chinese pharmaceutical industry is the only sector with double digit revenue growth in the period and its share of GDP rose from 3.0 last year to 3.3% in the first three quarters of 2016.

The core business revenues of the industry rose 10.1% in the period to CNY 2.1 trillion and the growth rate is 6.4 percentage points higher than that of Chinese industry average. The pharma industry's profits reached CNY 220 billion in the period, up 15.6%, which is 7.2 percentage points higher than the Chinese industry average.

Besides, the sales margin of the Chinese pharmaceutical industry was sustained at healthy 10.4%, Wu said.

MOFCOM Issues 13th FYP for National Drug Distribution Industry Development

The Ministry of Commerce (MOFCOM) released on December 29 its 13th Five Year Plan (FYP) for pharmaceutical distribution under the name of National Drug Distribution Industry Development Plan (2016-2020).

The plan began with a review of the industry's achievements at the end of 2015, highlighting the following key figures: 1) 13,500 pharmaceutical distributors had drug wholesale licenses; 2) there were 4,981 retail pharmacy chain operators with 448,000 retail outlets; 3) 517 pharma companies have been approved for internet transactions; 4) share of top 100 pharmaceutical distributors in all drug distributor sales has reached 46%, up from only 33% in 2010; and 5) there were three national drug distributors with over CNY 100 billion annual sales and 25 regional drug distributors with at least CNY 10 billion in annual sales.

Overall objectives of the drug distribution industry by 2020 include: 1) fostering a number of large pharmaceutical distributors which have nationwide coverage; 2) the top 100 drug distributors should account for at least 90% of overall wholesale business; 3) top 100 drug retailers should represent at least 40% of overall pharmaceutical retail sales; and 4) more than 50% of retail pharmacies should be chained.

Major tasks provided by the document include: 1) rationally planning the industry with mature nationwide pharmaceutical distribution network; 2) elevating pharmaceutical distribution management level to build modernized drug distributors; 3) innovating business models of pharmaceutical distribution industry and expanding distribution services; 4) further opening up the industry to absorb foreign players and encourage overseas expansion of domestic companies; and 5) strengthening infrastructural building and raising service capacity of the industry.

For full text of this document in Chinese, please visit the following MOFCOM weblink: http://www.mofcom.gov.cn/article/guihua/201612/20161202419508.shtml

Industry Experts: Ten Upcoming Trends of Chinese Pharma Industry in 2017

Under a matrix of market pressures including intensified government cost containment measures, more stringent compliance requirements and changing pharmaceutical business process (e.g. the two-invoice mandate), industry experts predict the following ten emerging trends of Chinese pharmaceutical industry in 2017.

- Generic drug quality and efficacy equivalence study requirement will dramatically reduce the size of product portfolios of Chinese pharmaceutical companies and many smaller players will be forced out of business;
- TCM production process inspections will raise the cost of formulated TCMs dramatically, leading to price hikes and forcing many smaller and uncompetitive players out of business;
- More irregular TCM herbal crude drug producers will be eliminated through regulatory enforcements and those surviving are likely to evolve into producers of branded TCM granule products;
- Clinical pathways will be widely implemented in medical institutions and those drug products not included in the pathways will be gradually phased out of the hospital drug market;
- The practice of drug sales kickbacks will become increasingly

unpopular, as the approach of separated sales and academic promotion become more popular;

- Existing regional drug sales agents will set up consulting firms and act as consultants in the drug sales, marketing and distribution processes for pharmaceutical companies in order to comply with the two-invoice mandate for pharmaceutical sales;
- MNCs will increasingly license their off-patent originator drugs to domestic drug companies, while more small- and medium-sized Chinese pharmaceutical companies will make attempts to outsource their drug sales and marketing to CSOs (contract sales organizations);
- As primary healthcare drug market scales up, more and more pharmaceutical companies will employ the so called "green therapeutics" approach (mostly for TCMs) which seeks to reduce injection and avoid antibiotics;
- More and more large prescription drug companies will expand their OTC drug business, while OTC switches of prescription drugs will become more popular; and
- Ex-hospital drug market will become the new battleground for pharmaceutical companies in future.

Pharma MNC's China Performance Rose Only 4% on Average in Q3/2016

Most of Pharma MNCs active in China saw their performance in China on single-digit or negative growth in the third quarter of this year, with the exception of a few including Pfizer, Novo Nordisk and AstraZeneca, which witnessed 16%, 13% and 10% growth in the period respectively.

However, the divide between winners and losers is expanding. The losers, which saw negative growth ranging from -7% to -1% in the quarter, included Eli Lilly, Novartis, Sanofi and MSD. Meanwhile, Roche and GSK both recorded 4% growth.

China Sales Growth of Pharma MNCs Q3/2016

Company	China Sales Growth (%)
Pfizer	+16
Novo Nordisk	+13
AstraZeneca	+10
Roche	+4
GlaxoSmithKline	+4
Merck, Sharp & Dhome	-1
Sanofi	-2
Novartis	-3
Eli Lilly	-7
Average	**+4**

Source: Informa

Despite single digit growth, GSK is doing well returning to growth again following many quarters of free fall in the aftermath of its China bribery scandal. The growth is believed to be partly related to Viread volume expansion following provincial facilitations of the national drug price negotiation, which agrees on 67% price cut of GSK's frontline hepatitis B drug Viread (Tenofovir Disoproxil Fumarate Tablets, 300 mg x 30/bottle at CNY 490). GSK China president Herve Gisserot recently told the Chinese press that the China sales volume of Viread tripled as a result of the negotiation. Earlier in late October, GSK CEO Andrew Witty told analysts that his company is fundamentally back to growth in China.

Sanofi experienced a -2% growth because its vaccine business dropped 15% due to a recent regulatory shakeup in the aftermath of an earlier vaccine distribution scandal. Its drug sales in the country, however, actually rose 13.6% in the quarter.

Novo Nordisk's continued double digit growth is reported to be driven also by volume expansion as diabetes prevalence continued to surge in China. AstraZeneca also reported volume growth after it agreed to a 55% price cut to its anticancer Iressa under the national drug price negotiation. However, volume growth of Iressa failed to compensate the price reduction in the third quarter with sales value of the product actually falling 13%.

Local Company News

Hengrui Licenses China Rights of Oncolyptic Virus Candidate from Japan's Oncolys

Tokyo-based Oncolys BioPharma has entered an exclusive license agreement with Jiangsu Hengrui Medicine Co Ltd for China rights (China mainland, Hong Kong and Macao) to its oncolytic virus candidate, OBP-301, to Jiangsu Hengrui Medicine for a therapy area that saw a first-in-class approval for Amgen's Imlygic (talimogene laherparepvec) by the U.S. FDA last year.

Telomelysin is currently in Phase I/II trials in Taiwan and South Korea in partnership with Taipei-based Medigen Biotechnology for esophageal cancer in combination with radiotherapy, according to the release.

The license agreement follows two research pacts by Jiangsu Hengrui Medicine this year, including one with the MD Anderson Cancer Center at the University of Texas with an immuno-oncology focus on combination therapies, personalized medicine and new treatment opportunities.

That agreement followed a research pact with New York's Albert Einstein College of Medicine to study cancer therapies aimed at discovering new targets for development.

Ferring Licenses Asian Rights of Autoimmune Disease Drug Olamkicept to IMAB

Ferring Pharmaceuticals and IMAB a Shanghai-based biotech company (天境生物) founded by world-class immunologists in China, announced on December 19 that they have signed a licensing agreement which grants IMAB exclusive rights to olamkicept (pINN) in Asia.

Olamkicept is a new recombinant protein inhibitor of the interleukin-6 pathway. Interleukin-6 is associated with numerous inflammatory conditions such as inflammatory bowel diseases (IBD) and rheumatoid arthritis.

The agreement provides IMAB with a Phase 2 ready asset with differentiated product profile. Under the terms of the arrangement, IMAB will fund further product development in exchange for an exclusive license in Asia with an option for worldwide use, with the goal of realizing the potential of olamkicept as a biomarker-guided and differentiated interleukin-6 blocker to treat autoimmune disease.

Uni-Bio Science in Multiple Drug Co-development Deal with Beijing Sun-Novo

Uni-Bio Science Group Limited has announced on December

1 that it has signed a multiple drug co-development deal with Beijing Sun-Novo Pharmaceutical Research Co., Ltd., a China-based company engaged in research and development (R&D), manufacturing and commercialization of pharmaceutical products, to extend Uni-Bio's current R&D capabilities in small molecule drug development.

This cooperation includes co-development of various oral anti-diabetes drugs ("OAD") to build a comprehensive diabetes treatment portfolio for the Group, which would represent an all-encompassing strategy in satisfying the unmet needs in treatment of this increasingly prevalent disease.

The first co-development project of the two companies is to develop high quality Acarbose tablets for treatment of Type 2 diabetes, an emerging and increasingly important diabetes treatment in China. Under this collaboration, Beijing Sun-Novo is to be responsible for completing the chemistry, manufacturing and control (CMC) processes and the bioequivalence study of Acarbose, as well as transferring the production technology to Uni-Bio Science's subsidiary. On the other hand, Uni-Bio Science is to apply for drug licenses from the CFDA with support from Beijing Sun-Novo and commercialize the product once it is approved. The project is targeted to start in 2017 and launch sales in the market around 2020 to 2021.

Acarbose is an oral anti-diabetic drug which belongs to the Alpha-Glucosidase Inhibitors ("AGI") class. It is used to treat Type 2 diabetes and is reimbursed under the National Reimbursement Drug List ("NRDL"). In terms of diabetes treatment, AGI is important for the early stage of diabetes. It targets patients with pre-diabetes condition who need to be treated early, and those with post prandial hyperglycemia under control.

Chinese Startup Firm Acquires Harbour Antibodies to Create Global, Oncology-focused Biotech Firm

Harbour BioMed, a recently established Shanghai-based company, announced on December 19 the acquisition of Harbour Antibodies BV for cash and an equity interest in Harbour BioMed to create a new, global oncology-focused biotechnology company. The new company plans to leverage Harbour Antibodies' patented transgenic mouse platforms to build an internal portfolio of next generation therapeutic antibodies for cancer, expand the range of partnerships and licenses around Harbour's platforms, and capitalize on the Harbour BioMed management team's extensive worldwide drug discovery and development expertise.

Harbour BioMed is led by Jingsong Wang, MD, PhD, CEO, and Liang Schweizer, PhD, CSO and other founding members. Prior to co-founding the company, Dr. Wang was at Sanofi, serving as Head of China R&D and Head of Translational Medicine, Asia Pacific. Collectively, the founding team at Harbour BioMed has overseen the transition of more than 30 compounds into clinical trials worldwide and has been instrumental in the development of more than 10 globally marketed drugs and another 40 marketed in China.

The acquisition was financed by Harbour BioMed investors, Advantech Capital and Legend Capital, two leading China-focused investors with a particular emphasis on life sciences. Harbour Antibodies' existing shareholders, including Atlas Venture, are retaining an interest in Harbour BioMed to participate in its continued growth and value creation.

"Our initial focus is on building an innovative therapeutic portfolio in immuno-oncology, an area of enormous promise which is transforming cancer therapy," said Dr. Wang, noting that Harbour BioMed will continue licensing Harbour Antibodies' transgenic platforms and investing in the platforms' continued development.

Luye Pharma Completes Acquisition of Acino's TDS Business

Luye Pharma Group Ltd. (2186.HK) announced the completion of its acquisition of the transdermal drug delivery systems (TDS) business from Swiss company, Acino. The acquired business is a global leader in niche transdermal markets and will greatly enhance Luye's developmental efforts in R&D, manufacturing, international registration, and market promotion of new formulation products to international standards, thereby helping to pave the way for Luye's expansion into global markets.

The acquired business is one of the largest independent TDS manufacturers in Europe, with a product portfolio primarily focused on more sophisticated and higher margin specialty patch categories such as CNS, pain and hormone spaces under several successfully commercialised and hard-to-make formulations such as Rivastigmine, Buprenorphine, Fentanyl and fertility control patches.

The completion of the acquisition is extremely encouraging for Luye Pharma, as it fully represents the core of Luye Pharma's globalization strategy – leveraging on M&A, R&D, brand marketing and world-class quality control capabilities to keep pace with development within both Chinese domestic and global markets.

Zhejiang Huahai's Unit Buys Charlotte Facility from Par Pharma Subsidiary

Prinston Pharmaceutical, the U.S. subsidiary of Zhejiang Huahai Pharmaceutical Co Ltd, entered into a deal recently to buy Par Pharmaceutical's manufacturing facility in North Carolina's Charlotte for US$14 million.

The acquisition is an effort of Zhejiang Huahai to establish manufacturing, improve in the U.S. supply chain and enrich product pipeline.

The facility now has around 300 employees and Prinston plans to keep 125 of them. The deal is expected to be completed in the first quarter of 2016.

The Charlotte facility has a production capacity of 7 billion tablets and has been engaged in the production of mental disorder and narcotic drugs. It has multiple certifications from the U.S. FDA and DEA.

Kelun Pharma to Set Up Another R&D Subsidiary in the U.S.

Sichuan Kelun Pharmaceutical Co., Ltd. revealed in its recent corporate filings recently that it plans to set up another majority-controlled subsidiary in the U.S. under the name of Kebous Biological Medicine Co., Ltd., via its subsidiary Sichuan Kelun Botai Biopharma.

The total investment in the new U.S. subsidiary will be at US$11 million. The new company will be engaged in early research and development of biological macromolecule medicines and innovative micromolecule drugs, as well as international business development including technology transfer and licensing businesses.

The proposal was approved by Kelun's board on December 2.

China Court Papers Identify Sinovac in Bribery Case

Chinese buyout target and vaccine maker Sinovac Biotech Ltd. (NASDAQ: SVA) has been named in court documents regarding a bribery scandal in China that may jeopardize the two live buyout offers for the NASDAQ-listed US$300 million company.

The details of the bribery case have appeared in Chinese court documents obtained by Heng Ren Partners LLC and GeoInvesting, and are outlined in an extensive report published by GeoInvesting (see link http://bit.ly/2ifnrTk).

To date, the Chinese court has reported that the spouse of a China Food and Drug Administration (CFDA) official has been convicted in a Chinese court. Chinese media reports are only just starting to cover the case.

Heng Ren believes the revelations in the court documents demand:

- Immediate disclosure by Sinovac to U.S. investors and regulators, in particular the U.S. Securities and Exchange Commission (SEC), about its reported involvement in the case.
- A review and investigation by the SEC regarding this lack of disclosure of this material event to them and U.S. investors.
- A review of the case by the U.S. Securities and Exchange Commission (SEC), and the U.S. Department of Justice (DoJ), for possible violations of the Foreign Corrupt Practices Act (FCPA) regulations that apply to SEC-registered foreign companies like Sinovac.

Heng Ren had been challenging Sinovac's lowball offer made in February of US$6.18 per share in their attempt to squeeze out shareholders in the U.S. Sinovac's lowball offer came only two business days after the approval of a transformational vaccine for Hand, Foot, and Mouth Disease (HFMD), called EV-71. A competing bid from a consortium of Chinese companies appeared with a US$7.00 per share bid, which was followed by a poison pill implemented by Sinovac's Board of Directors.

Ascentage Pharma Raises $72M in Series B Round Financing Led by SDIC Fund

A fund under China's SDIC Fund Management Co. has led a CNY 500 million (US$72 million) series B funding round in Ascentage Pharma, a Jiangsu province-based biopharmaceutical company dedicated to the discovery of targeted small-molecule cancer therapeutics.

A number of new investors, all of which are RMB funds, and existing investors Oriza Holdings, Yuming Capital and others also participated.

Ascentage Pharma spun off from Ascenta Therapeutics in 2009 and kept the entire Ascenta (Shanghai) research and develop-ment team and all of its facilities.

Currently, Ascentage Pharma has three molecules in phase I-II trials in the U.S., Australia and China, and another four molecules at IND reviewing or IND-enabling stages.

Ascentage Pharma focuses on clinically validated cancer targets. Its established research and development platforms include inhibitors to a number of key proteins, including Bcl-2/Bcl-xL, IAP and MDM2-p53.

Financial-related Company News in Brief

A number of recent financial-related news events of the Chinese pharma industry were recorded by WiCON|*Pharma China* in December 2016 and they are shown in the following table:

Company Financial News Brief December 2016

Announcement Date	Parties	Deal Size	Subject	Description
12/1/2016	Livzon Pharma Group	n/a	JV	It plans to set up a genetic testing tech JV in Zhuhai city with partners.
12/2/2016	Jilin Zixin Pharma	CNY 20M	Investment	It plans to invest CNY 20 mln in Beijing-based medical investment management partnership.
12/5/2016	North China Pharma	CNY 200M	Investment	It plans to boost finance JV's capital by CNY 200 mln.
12/5/2016	Kunming Pharma	$3M	M&A, JV	The company (SHSE: 600422) declared to invest $3 mln taking a 9.91% stake in RiMO, planning to form JV in China. RiMO held RT-RDT cancer curing technology.
12/13/2016	Shenzhen Hepalink Pharma	CNY 1B	Fund raising	It issued CNY 1 bln worth bonds via public offering.
12/20/2016	China Resources Double-crane Pharma	CNY 850M	M&A	Its unit plans to buy Hainan Sinochem United Pharma for CNY 850 mln. It plans to take out a loan of up to CNY 800 mln from parent company.
12/22/2016	Yunnan Hongxiang Yixintang Pharma	CNY 400M	Fund raising	It issued CNY 400 mln worth commercial paper with interest rate at 5.99%.
12/28/2016	Nanjing Hicin Pharma	n/a	IPO	It has issued prospectus for Shenzhen IPO.

Source: WiCON | Pharma China

Foreign Company News

Bayer Inaugurated Extension of Its Pharma Supply Site in Beijing

Bayer inaugurated the extension program of its pharmaceutical products supply site in Beijing on November 18, indicating the importance of China's market to the German company's global strategy in prescription drug supply.

The extension program, with an investment of Euros 100 million (US$105.9 million), enables the Bayer Beijing supply site to double its production capacity, including products such as Glucobay, Adalat and Bayaspirin. The Beijing supply site also became the largest prescription drug packaging site in the division's global production network.

In 2013, the World Health Organization released a target for 2025, calling on countries and regions to reduce premature deaths from non-communicable diseases by 25 percent. China's health commission set a target of reducing premature death from chronic diseases by 30 percent by the year 2030.

Pfizer Enters R&D Partnership with PegBio for Select Diabetes Drugs

Pfizer signed a R&D partnership deal with Suzhou-based PegBio on December 13, joining hands to develop innovative drugs for diabetes therapy.

According to the agreement, Pfizer will grant PegBio Greater China rights of selected glucokinase agonist (GKA) to treat diabetes. PegBio said financial terms were not disclosed and that the GKA program has completed Phase IIa development.

The partnership is part of a Pfizer strategy to use local partners to advance medicines addressing unmet needs. The partners did not respond to inquiries about the program. Pfizer expects to form additional local partnerships in China to support innovative drug development in the region.

Shan Guohong, China Lead, Pfizer Innovative Health, said the cooperation would provide a new possibility of introducing innovative drugs to China.

"In the past, multinational pharmaceutical companies usually introduced to China drugs already on European and American markets. This project, however, is to develop drugs mainly for the needs of Chinese patients," said Shan.

Diabetes has already become a major public health problem in China. More than 114 million adults, 11.6% of the population, are afflicted with the disease. It is estimated that only one-quarter of the patients with diabetes reportedly receive treatment. Moreover, only little more than one-third of those treated have adequate glycemic control.

"Combining Pfizer's world leading R&D capabilities with our R&D and management experience, the cooperation will create a win-win and even multi-win situation, offering more choices for patients and doctors," said Xu Min, president and CEO of PegBio.

Sanofi, CR Sanjiu Enter Strategic Alliance for Consumer Healthcare Business in China

Sanofi entered into a framework agreement with China Resources Sanjiu Medical & Pharma to establish a strategic partnership to jointly explore the opportunities in the consumer healthcare market in China.

The parties will form a joint venture company, which will serve as the platform for the continued operation of the businesses of China Resources Sanjiu (Beijing) Pharma and Sanofi subsidiary Sunstone (Tangshan) Pharmaceutical Co. Ltd., focusing initially in the areas of pediatric and gynecological OTC products. CR Sanjiu and Sanofi will regularly assess the operations of the JV and, if necessary, adjust or expand the product offerings and scale of business of the JV as appropriate.

Under the framework agreement, CR Sanjiu will transfer 100% of its wholly-owned subsidiary CR Sanjiu (Beijing) Pharmaceutical into the JV and hold a 70% stake in it, and Sanofi's Sunstone China will transfer its 100% stake in Sunstone (Tangshan) Pharmaceutical into the JV and hold the rest 30%.

Sunstone China holds pediatric drug brand Good Baby and gynecological drug brand Confort, so the transfer will enrich the JV's pediatric and gynecological product lines and complement its sales channels. The JV will obtain exclusive distribution rights for Essentiale Forte N, which will supplement its liver disease drug products.

Sanofi will grant the JV and its affiliates an exclusive distribution rights to promote Essentiale Forte N capsules in China. Essentiale Forte N is one of Sanofi's flagship products and will supplement the JV's liver disease drug products.

Sanofi will grant the JV right of first negotiation to obtain exclusive distribution rights for its leading consumer health products in China. Sanofi has a wide range of consumer healthcare products in the world, including Lactacyd, Nature's Own, Icy Hot and other brands in the fields of anti-allergy, digestive health system, and cough and cold. The JV is expected to introduce Sanofi's consumer health product brands.

Sanofi, JHL Biotech Forms Strategic Partnership for Biologics in China

Sanofi and JHL Biotech, Inc., a biopharmaceutical company with development and manufacturing facilities in Wuhan and Taiwan, announced on December 5 a strategic alliance to collaborate on the development and commercialization of biological therapeutics in China and with potential international expansion.

Under the agreement, Sanofi will invest US$80 million in newly issued JHL shares at NT$90 per share. In addition, Sanofi will make an upfront payment of US$21 million to acquire exclusive rights for the proposed biosimilar of Rituximab and options to certain JHL pipeline products. JHL will lead the development, registration, and manufacturing activities while Sanofi will lead commercialization efforts in China. JHL is entitled to receive milestones of up to US$236 million and sales royalties.

The collaboration brings together complementary capabilities of the two companies and represents a commitment to expanding patient access to affordable high quality modern therapies through local development of biologics in China.

BMS Terminates OTC Business Division in China

BMS China is reported to have officially closed its OTC drug business and disbanded sales teams on December 6 at a company conference in Hangzhou.

The move will affect around 150 employees, all of whom will not be offered the opportunities of transferring to positions in the company's other departments. Compensation will be paid to laid off employees on the basis of N+1 x monthly salary (N=number of BMS employment years) and those reaching early agreements will be offered two months of additional salaries. Reportedly dismissed employees were generally satisfied with the arrangement.

The highest ranking executives dismissed this time are two regional managers, while the former OTC business director Jun Zhou already left the company a month before.

The reason offered for BMS China's OTC business termination is "strategic considerations for transformation into diversified biopharma company which encompass termination of OTC drug marketing in order to optimize and concentrate resources on innovative new drugs".

The move by BMS China to terminate its OTC business is somewhat expected by insiders after it shut down two non-core prescription drug business units earlier this year.

The share of OTC business in overall BMS China revenues is reportedly tiny. The company's annual OTC drug sales are estimated to be between CNY 200 – 300 million with about 40% gross profit margin.

Yuhan Terminates Anticancer Licensing Deal with Chinese Partner Luoxin

Yuhan Corp., a South Korean leading pharmaceutical company, said on December 28 that it has terminated a license agreement with China's Luoxin Biotechnology Co. signed in July for the development of YH25448, Yuhan's investigational lung cancer drug.

The termination was due to non-fulfillment of Luoxin's obligations, the Korean drugmaker said, adding the Chinese partner was not sincere in pursuing final agreement terms and only demanding technical information of the drug one-sidedly.

Yuhan would have received a milestone payment and royalties on sales of US$120 million from Luoxin in addition to an upfront payment of about US$6 million.

Yuhan said it will consider legal action for compensation on the grounds of non-performance of obligations and request Luoxin to return all technical data related to YH25448.

Yuhan also said the termination has nothing to do with the drug's integrity or market conditions and will explore other candidates for partnership upon robust data from a Phase I clinical study due next year.

The investigational drug was approved for a Phase I clinical trial in Korea. The third-generation EGFR tyrosine kinase inhibitor (TKI) is being evaluated on its efficacy to treat patients with non-small cell lung cancer (NSCLC), who are resistant to existing targeted cancer drugs.

Recent non-clinical studies showed that the drug is very effective against cancer cells in the brain, suggesting it could treat patients whose lung cancer has spread to the brain, the company said.

Fujifilm Expands to Chinese TCM Market Thru Partnership with China Resources

Japan's Fujifilm Holdings will expand into the Chinese herbal medicine market through a partnership with China Resources (Holdings), a major state-run conglomerate in the world's second-largest economy.

The China Resources group manufactures and markets a range of herbal medicines as part of its vast business empire, which also includes China Resources Beer, hospital and other operations. By utilizing Fujifilm's technologies for extracting active ingredients and refining them for better body absorption, the duo aims to develop Chinese medicines that are more effective than traditional varieties. The fruits of their cooperation will be sold in China, Japan and elsewhere in Asia.

Their tie-up will also involve China Resources helping Fujifilm obtain Chinese sales licenses for medical equipment, as well as medicines such as treatments for influenza and rheumatism. Once licenses are issued, China Resources will promote the drugs and use them at its hospitals.

In addition, the Chinese conglomerate plans to start selling Fujifilm's health supplements through its domestic sales networks by next summer, since the products do not require sales licenses.

Fujifilm invested roughly Yen 11 billion (US$99.2 million) in October for a roughly 1% stake in China Resources Pharmaceutical Group. By tying up with the parent, the Japanese company hopes to build broader cooperation covering not only drugs but also medical equipment and regenerative medicine.

Kobayashi Pharma Eyes China Expansion Via M&A

Kobayashi Pharma, a Japanese maker of OTC drug and health supplement products popular among Chinese tourists, will spend Yen 30 billion (US$254 million) over the three years through fiscal 2019 to buy businesses in China and elsewhere to bolster drug sales outside its home market of Japan. This marks the company's first time revealing investment plans.

Kobayashi Pharma will acquire a Chinese company as early as 2017 so that it can obtain a license for production and marketing. It will then develop and sell medicines made in compliance with China's pharmaceutical laws and regulations.

The company wants to "sell drugs in China's large market to expand its business overseas," President Akihiro Kobayashi said. Japanese medications are popular with Chinese tourists. These include many Kobayashi products, such as Inochi No Haha A for menstrual cramps and the Ammeltz pain relief rub.

Kobayashi Pharma hopes to capture demand from Chinese tourists eager to buy more products from Japan after returning from vacations there.

Neuralstem Closes $20M Strategic Investment from Tianjin Pharma

Neuralstem, Inc. (Nasdaq: CUR), a biopharmaceutical company focused on the development of central nervous system therapies based on its neural stem cell technology, announces the closing of Tianjin Pharmaceutical Group International Holdings Co., LTD.'s (TJPH) US$20 million strategic investment.

Upon the close of the transaction, Tianjin receives 28,500,000 shares of common stock and 1,000,000 shares of Series A convertible preferred stock. The preferred stock is convertible into 50,551,383 shares of the company's common stock subject to certain beneficial ownership limitations. The transaction was initially announced on September 12, 2016.

Pursuant to the terms of the investment, TJPH is entitled to appoint one member to the company's board of directors. Additionally, shares of the Series A Preferred Stock have no voting rights and cannot be converted if after such conversion, the shares received as a result of the conversion and the common shares received in this transaction would result in TJPH having voting power in excess of 19.99% of the issued and outstanding shares entitled to vote of the company.

TJPH is a Chinese state affiliated pharmaceutical group that focuses on four major product categories: chemical and biological medicines, green traditional Chinese medicines, innovative medical devices and modern logistics.

CASI Pharma Files Import Drug Application for EVOMELA in China

CASI Pharmaceuticals, Inc. (Nasdaq: CASI), a biopharmaceutical company dedicated to innovative therapeutics addressing cancer and other unmet medical needs, announced on December 5 that CFDA has accepted for review the Company's import drug registration application for EVOMELA (melphalan) for Injection.

CASI's China rights to EVOMELA (melphalan) for Injection was previously licensed from its partner Spectrum Pharmaceuticals, Inc. along with two other commercial-stage Spectrum drugs, MARQIBO and ZEVALIN. EVOMELA received U.S. FDA approval earlier this

year for multiple myeloma patients as a high-dose conditioning treatment prior to autologous stem cell transplantation (ASCT) and as palliative treatment for patients who are not candidates for oral therapy. It was launched in the U.S. this year by Spectrum.

EVOMELA, an innovative and proprietary new formulation of melphalan, offers significant advantage in that it (i) does not contain propylene glycol which causes significant side effects; (ii) has longer stability; and (iii) is the only intravenous melphalan product approved for use in the high-dose conditioning indication. We look forward to working with the CFDA to advance EVOMELA towards market approval."

Service Provider News

Chinese CRO dMed Raises $8M in Series A Funding Round

Qiming Venture Capital has led a US$8 million series A funding round in dMed Co., Ltd., a Chinese clinical contract research organization (CRO), with participation from Tairui Investment and ZAI Laboratory.

The company says that it will use the latest proceeds to expedite the expansion of its current team, including assurance and clinical operations professionals, according to an announcement.

dMed was founded in August of 2016 by Dr. Lingshi Tan, formerly the founder and general manager of Pfizer's Global R&D Center in China. He led the center to become a large organization with over 1,000 professionals.

In a short period of time, the company has secured clients including ZAI Laboratory's PARP inhibitor for ovarian cancer and HUA Medicine's GKA for diabetes. Both of these companies are Qiming's portfolio companies.

Mandarin Capital Acquires Stakes in Italian Drug Firm Mipharm

Mandarin Capital Partners has acquired a majority stake in Mipharm Spa, an Italian contract manufacturing organization engaged in the manufacturing and packaging of a wide range of drugs, the Sino-Europe private equity firm said on December 8.

Mandarin invested via Mandarin Capital Partners II, its second fund closed in January with €200 million (US$218 million) in commitments. It plans to initially invest €16.4 million, with the goal to increase the total investment with acquisitions of other select assets.

The private equity firm plans to support international growth of the company, leveraging its global network and business development channels in the European and Asian markets.

Mipharm Spa provides product development services and clinical studies based on customer requirements, as well as in-house research and development. Current CEO Pierangelo Costa will continue to manage the company, which posted sales of around €37.9 million in 2015, with approximately 45 clients including big pharmaceutical firms and global generic drug makers in 30 countries.

Regulatory News

Review of CFDA Drug Approvals 2013 – 3Qs/2016

The CFDA issued a total of 135 new drug approvals in the first three quarters of 2016. Among them, there were 127 chemical drug approvals, five TCM approvals and three biologic approvals.

The following tables provide more details and analysis of the approvals in both the first three quarters of this year and in the previous two years.

Chinese Drug Approvals in 2013 – 3Qs/2016

Category	2013	2014	2015	3Qs/2016	2016*
Chemicals	512	582	382	349	127
TCMs	75	46	162	92	5
Biologicals	26	23	26	5	3
Total	**613**	**651**	**570**	**446**	**135**

Source: CFDA/SMEI * Excluding approval reissuance

Chemical Drug Approvals by TCs 2013 – 3Qs/2016*

Rank	Therapeutic Category	2013	2014	2015	M1-9/2016
1	APIs & drugs not used on human body directly	32.78	45.14	31.22	46.46
2	Systemic Anti-infectives	11.94	8.56	24.47	14.96
3	Digestive System and Metabolism	8.33	12.73	9.70	7.09
4	Respiratory System	5.28	5.32	2.53	5.51
5	Cardiovascular System	8.89	6.71	6.33	4.72
5	Blood & Blood-making System	2.78	3.47	8.02	4.72
7	Nervous System	7.78	6.48	5.49	3.94
8	Oncology & Immuno-Regulatory Agents	7.50	5.56	1.27	3.94
9	Miscellaneous	0.56	0.69	5.49	3.15
10	Systemic Hormones (excluding sex hormones)	1.94	0.23	0.84	2.36
11	Genitourinary System and Sex Hormones Drugs	2.22	0.93	2.11	0.79
11	Dermatology	1.94	0.23	1.69	0.79
11	Sensory System	3.33	0.93	0.84	0.79
11	Muscle-skeletal System	4.17	2.78	0.00	0.79
15	Antiparasitic, Insecticides and Repellents	0.56	0.23	0.00	0.00
Total		100.00	100.00	100.00	100.00

Source: CFDA/SMEI * Excluding approval reissuance

Drug Registration Approval and Application Update 11/2016

The CFDA announced (CFDA Announcement 2016 #192) on December 19 that it had approved 20 drug registration applications in the month of November. Among the total, the approvals were for 17 chemical drugs, one biological products and two import chemical drugs.

Please visit the following CFDA weblink to view more details of these approved applications in Chinese: http://www.sda.gov.cn/WS01/CL0087/167714.html

Review report and package inserts in Chinese of new drugs approved in November can be found at the CDE website (www.cde.org.cn).

CFDI Announces Latest Clinical Data Inspection Plan

The Center for Food and Drug Inspection (CFDI) under the CFDA announced on November 30 its latest plan for onsite clinical data inspection of 30 drug applications following the publication period, which lasts ten working days from the date of announcement between November 30 and December 13.

Most of the drug registration applications to be inspected this time are from MNCs.

Contact persons for this matter are:

WANG Feng (王峰) and GAO Wei (高微)
Tel: +86 10-87559031 Fax: +86 10-67152467
Address: 3rd Floor, Building 11, Fahuadongli, Dongcheng District, Beijing 100061

Full list of the 30 drug applications in Chinese to be inspected can be viewed by visiting the following weblink: http://www.cfdi.org.cn/resource/news/8124.html

CDE Grants Priority Review Status to 32 Drug Registration Applications

The Center for Drug Evaluation under the CFDA announced on December 2 that 32 registration applications have been granted priority review status following review by expert panels. Among the total, 14 are from domestic companies and 18 are from MNCs.

The publication period of such is five days from the date of publication. During the period, relevant disagreements can be submitted to CDE website (http://www.cde.org.cn/news.do?method=changePage&pageName=service#) using the Drug Registration Application Priority Review Dispute Form.

Please visit the following CDE weblink to download the above form and view the list of 32 drug registration applications granted priority review status with brief reasons cited.

http://www.cde.org.cn/news.do?method=viewInfoCommon&id=313739

China Eyes Introduction of the "Orange Book"

At a recent industry event, 2016 China Pharma Strategy Summit, ZHANG Zhijun, Vice President of China National Institutes of Food and Drug Control under the CFDA, made a presentation over the topic of generic drug quality and efficacy equivalence.

During his presentation, he praised the role of "Orange Book" in the U.S. and Japan. Zhang disclosed that China is considerating the introduction of its own "Orange Book" and "a preliminary plan was already developed".

He said that the Chinese "Orange Book" will first include reference drug products which will come from three sources: 1) originator drugs (foreign and domestic) approved by the CFDA; 2) reference drug products used previously in the generic drug quality and efficacy equivalence studies; and 3) reference drug formulations ascertained for such studies from manufacturer filings which are reviewed and accepted by experts.

Zhang said the CFDA is in the process of introducing numerous new guidelines and rules over generic drug quality and efficacy equivalence studies.

CFDA Issues Revision of Guideline for GSP Onsite Inspections

The CFDA issued an official notice on December 16 to introduce the revised Guideline for GSP Onsite Inspections. The revision was developed following a recent amendment of the GSP (CFDA Order #28) which revised its provisions on drug electronic regulation and vaccines.

The revision to the Guideline for GSP Onsite Inspections involves changes to provisions relating to drug wholesalers and retailers, and addition of new provisions relating to external diagnostic reagent (drug) distributors.

The CFDA notice mandates the implementation of this revised rule by local food and drug agencies soon.

Please visit the following CFDA weblink for full text of this revised regulation in Chinese: http://www.sda.gov.cn/WS01/CL0844/167669.html

CFDA Announces Revisions to the Five Appendices of GSP

The CFDA issued a document, *CFDA Decision on Revision of GSP* (CFDA Order #28), on December 29.

It makes a number of revisions to the five appendices of GSP relating to cold storage as well as inventory and transportation of drugs that need cold or freeze storage.

For details of these revisions in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0087/168144.html

Round Up of CFDA Draft Regulations for Public Comments

CFDA Solicits Public Comments for Draft Amendment of GCP

The CFDA released a draft amendment of the Good Clinical Practices for Drug Clinical Trials (GCP) on December 2 and it is now seeking public comments which need to be submitted via the following email to the Drug and Cosmetic Registration Department of CFDA before January 31, 2017.

Contact: XIE Xingyong (谢兴勇)
Email: xiexy@cfda.gov.cn

The proposed GCP amendment has a total of 81 articles in eight chapters which covers: 1) General Principles; 2) Ethical Committee; 3) Investigator; 4) Sponsor; 5) Trial Protocol; 6) Investigator Handbook; 7) Management of Required Documents; and 8) Appendices.

Please visit the following CFDA weblink for full text of the draft amendment in Chinese: http://www.sda.gov.cn/WS01/CL0778/166981.html

For a summary and analysis of the proposed revision by Ropes & Gary, please visit the following link: http://www.pharmachinaonline.com/WebEdition/index_1_news.asp?id=2123&sortid=34

CDE Seeks Public Comments on Draft Drug Evaluation Document

In an effort to reform the drug evaluation and approval system, as well as raising drug evaluation quality and efficiency, the Center for Drug Evaluation (CDE) under the CFDA has drafted a new document, Rules for Drug Evaluation Program Management, which was released for public comments on December 6.

Feedbacks must be be sent to the CDE before December 20, 20167 via fax or email as follows:

Contact: YUAN Lijia (袁利佳)
Fax: +86 10-68921383
Email: yuanlj@cde.org.cn

Full text of the documents and feedback form in Chinese are available for download at the following CDE weblink: http://www.cde.org.cn/news.do?method=viewInfoCommon&id=313742

CFDI Solicits Comments on New Technical Guideline Documents

The Center for Food and Drug Inspection (CFDI) under the CFDA released on December 6 two new draft documents, Sterile Process Simulation Test Guideline (Sterile APIs) and Sterile Process Simulation Test Guideline (Sterile Formulations), for public comments which must be submitted before May 31, 2017.

Full text of the documents and feedback form in Chinese are available for download at the following CFDI weblink: http://www.sda.gov.cn/WS01/CL0778/167079.html

Earlier on December 5, the CFDI released a separate draft document, Aseptic Filtration Technology and Application Guideline, for public comments which must be submitted before May 31, 2017.

Full text of the documents and feedback form in Chinese are available for download at the following CFDI weblink: http://www.sda.gov.cn/WS01/CL0778/167037.html

Feedbacks to all above draft documents should be sent to the CFDI via fax or email as follows:

Fax: +86 10-87559054
Email: gmp-cfdi@cfdi.org.cn

CFDA Drafts Four Guidelines for Onsite Inspection of Generic Drug Quality and Efficacy Equivalence Studies

CFDA drafted four guidelines for onsite inspection of generic drug quality and efficacy equivalence studies and is now soliciting public feedbacks on the draft documents before January 20 via the following email.

Email: gmp-cfdi@cfdi.org.cn

The proposed guidelines are as follows:

1. *Guidelines for R&D Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies* (Draft)

2. *Guidelines for Production Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies* (Draft)

3. *Guidelines for Clinical Trial Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies* (Draft)

4. *Guidelines for Cause-Triggered Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies* (Draft)

For full text of these documents in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0778/167816.html

CFDA Solicits Comments on Rules for Confidentiality in Review of Drugs and Medical Devices

The CFDA released a draft of the *Rules for Confidentiality Management in Review of Drug and Medical Devices* on December 29.

According to the proposed rule, the following items are considered information that are subject to confidentiality management in drug evaluation: 1) information relating to production processes, key technical parameters, technical know-how, test data, etc. submitted by applicants; 2) undisclosed evaluation and approval information, including review conclusions, discussions/comments/consultations and technical reports not yet released; and 3) complaints and tips during the review process.

It is also provided that the following items do not belong to information that need to be kept confidential: 1) patent matters, national drug standards such as those in the ChP, national medical device standards and other items publicized in industrial standards which are submitted as parts of registration dossier; 2) information well-known in the industry; 3) information that need to be publicized by the government; and 4) information approved for publication in accordance with relevant legal processes.

The CFDA is now seeking public comments before January 12 through the following means:

1. Via regular mail: The Legislation Department of the CFDA, Building #2, No. 26 Xuanwumen Xi Dajie, Xicheng District, Beijing 100053, China. (Marking "Public Comments" and name of the draft rule in Chinese "国家食品药品监督管理总局药品医疗器械审评审批保密管理办法" on the envelop).

2. Via fax: +86 10-88330705 with the subject line as "国家食品药品监督管理总局药品医疗器械审评审批保密管理办法反馈意见".

3. Via email: xuxy@cfda.gov.cn with the subject line as "国家食品药品监督管理总局药品医疗器械审评审批保密管理办法反馈意见".

For full text of the notice in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0783/168140.html

CFDA Solicits Comments on Decision to Change Certain Drug Evaluation and Approval Procedures

The CFDA released on December 29 a draft decision to change certain drug registration approval procedures.

Instead of issuing certain drug registration approvals directly as before, the CFDA will authorize the Center for Drug Evaluation (CDE) under it to issue the following approvals under its name in future: 1) drug clinical trial approvals (domestic and import); 2) supplemental drug registration approvals (domestic and import); and 3) import drug license renewal approvals.

The decision will become effective on March 1, 2017 and it will take precedence over other contradictory provisions in previous regulations.

For full text of the decision in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0783/168140.html

Feedbacks need to be submitted via one of the three following means before February 6, 2017:

1. Chinese government's legislation information portal online at http://www.chinalaw.gov.cn ("法规规章草案意见征集系统 Departmental Regulation Draft Public Comment Collection System" is at the top left corner of the home page).

2. Via regular mail: The Legislation Department of the CFDA, Building #2, No. 26 Xuanwumen Xi Dajie, Xicheng District, Beijing 100053, China. (Marking "Public Comments" and name of the draft document in Chinese "审批程序调整决定意见" on the envelop).

3. Via email: xuxy@cfda.gov.cn with the subject line as "审批程序调整决定意见反馈意见".

CFDA Issues Draft Regulation for Batch Release of Biologics for Public Comments

CFDA issued a notice to solicit public comments for a new proposed regulation, *Provisions for Batch Release of Biologics*, on December 15.

Feedbacks need to be submitted via one of the following means as of December 13, 2016:

Chinese government's legislation information portal online at http://www.chinalaw.gov.cn ("法规规章草案意见征集系统Departmental Regulation Draft Public Comment Collection System" is at the top left corner of the home page).

For full text of the notice in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0783/167540.html

CDE Solicits Comments on Production Process Registration of Marketed Drugs

In an effort to streamline and improve drug production process control and to enhance drug safety, the Center for Drug Evaluation (CDE) under the CFDA drafted a new document, *Registration Templates for Production Process Information of TCMs, Chemical Drugs and Biological Products*. It was released on December 26 for public comments.

The agency requires all public feedbacks to be submitted before January 23, 2017 via the following means:

Contact: JIANG Yi (蒋煜) and/or HOU Peng (侯鹏)
Email: jiangy@cde.org.cn and/or houp@cde.org.cn
Tel: +86 10-68921545, 10-68921520

For full text of these draft templates, please visit the following CDE weblink: http://www.cde.org.cn/news.do?method=viewInfoCommon&id=313753

CDE Solicits Comments on Guidelines for Compatibility Research of Chemical Drugs and Elastomer Seals

The Center for Drug Evaluation under the CFDA released on December 30 that a draft document, *Technical Guidelines for Compatibility Research of Chemical Drugs and Elastomer Seals*, for public comments.

Feedbacks need to be submitted within two months of publication date via the following means:

Via CDE website: visit the following weblink and click on relevant document to submit feedbacks: http://www.cde.org.cn/zdyz.do?method=initValue&frameStr=0

Via Email: Xiuming HUO (霍秀敏), huoxm@cde.org.cn or Yi JIANG (蒋煜), jiangy@cde.org.cn

For full text of this notice and draft document in Chinese, please visit the following CDE weblink: http://www.cde.org.cn/news.do?method=viewInfoCommon&id=313775

CDE Solicits Comments on Draft Guideline for Research and Review of Cellular Products

In an effort to guide and streamline research of cellular products, the Center for Drug Evaluation (CDE) under the CFDA has drafted the *Technical Guidelines for Research and Evaluation of Cellular Products* on the basis of relevant domestic and foreign guidelines and following preliminary research, review of key technical points and multiple conference discussions.

Feedbacks can be submitted via the following two means before January 25, 2017.

1. Via CDE website www.cde.org.cn (Guideline Comment Seeking Section "指导原则征求意见"栏目)

2. Via Email: WEI Wei (韦薇) at weiw@cde.org.cn

Please visit the following CDE weblink to download the draft guideline and feedback form in Chinese: http://www.cde.org.cn/news.do?method=viewInfoCommon&id=313749

CFDA Seeks Comments on Transparency Regulation for Food and Drug Safety Supervision

CFDA issued a notice to solicit public comments for a new proposed regulation, *Provisions for Food and Drug Safety Supervision Information Transparency*, on December 15.

Feedbacks need to be submitted via Chinese government's legislation information portal online at http://www.chinalaw.gov.cn ("法规规章草案意见征集系统 Departmental Regulation Draft Public Comment Collection System" is at the top left corner of the home page) before January 13, 2017.

For full text of the notice in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0783/167407.html

CFDA Issues Draft Provisions for Evaluation of Healthcare Product Advertising

CFDA issued a notice to solicit public comments for a new proposed regulation, *Provisions for Advertising Evaluation of Drugs, Medical Devices, Health foods and Foods for Special Medical Purposes*, on December 14.

The proposed regulation covers all forms of advertising for such products including online advertisements. It is provided that prescription drugs can only be advertised on medical and pharmaceutical related professional publications which are jointly designated for such advertising by the State Council's health department and food & drug department. Advertising of foods for special medical purposes should be regulated as drug advertising. Among all such products, advertising of full nutritional formula foods should be subject to the same advertising control as prescription drugs.

Besides, advertising of drugs, medical devices, health foods and foods for special medical purposes, which shows only product names and does not involve indications (functions), scope of

applications, healthcare functions, appropriate users and other relevant information, are not required for approvals, according to the draft regulation.

Public comments need to be submitted via one of the three following means:

1. Chinese government's legislation information portal online at http://www.chinalaw.gov.cn ("法规规章草案意见征集系统 Departmental Regulation Draft Public Comment Collection System" is at the top left corner of the home page) before January 13, 2017.

2. Via email: rendp@cfda.gov.cn with the subject line as "《药品医疗器械保健食品特殊医学用途配方食品广告审查管理办法》反馈意见".

3. Via regular mail: The Legislation Department of the CFDA, Building #2, No. 26 Xuanwumen Xi Dajie, Xicheng District, Beijing 100053, China. (Marking "Public Comments" and name of the draft rule in Chinese "《药品医疗器械保健食品特殊医学用途配方食品广告审查管理办法》反馈意见" on the envelop).

4. Via fax: +86 10-88330718 with the subject line as "《药品医疗器械保健食品特殊医学用途配方食品广告审查管理办法》反馈意见".

For full text of the notice in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0783/167374.html

Six Chinese Cities Join Hands to Fight Dishonesty of Food and Drug Businesses

Six provincial capital cities in central China, including Taiyuan, Changsha, Wuhan, Zhengzhou, Nanchang and Hefei, held a joint food and drug inspection conference recently to discuss the fight against "business dishonesty and violations" of food and drug companies.

The food and drug agencies of the six cities signed a memorandum of understanding (MOU) to set up cooperative and coordination mechanisms for food and drug regulation and anti-counterfeiting.

Under the mechanisms, red lists and blacks lists will be established for businesses with good and bad credits respectively. Such lists will be publicized through media and exchanged among the governments of six cities, which are seeking to coordinate reporting, regulation and punishment of dishonesty and untrustworthiness of food and drug businesses.

MOU highlighted likely joint penalty measures against dishonest and untrustworthy food and drug businesses including restriction of their participation in essential drug purchase tenders, ban of government award applications, withdrawal of prior honors and awards, and stiffening punishment of such business for their relevant violations. Besides, the governments of six cities will set up joint policy incentives to encourage honesty of food and drug producers and distributors, and offer administrative preference to honest businesses in routine inspections as well as in relevant government review and approvals.

CDE Forms Strategic Alliance with the Medical School of Tsinghua University

The Center for Drug Evaluation under the CFDA (CDE) signed a comprehensive memorandum of understanding (MOU) with the Medical School of Tsinghua University on December 8.

The MOU encompasses ambitions of both parties to jointly establish a research institute, found the discipline of drug evaluation science and regulation, and foster relevant human resources.

Specifically, the two parties will jointly establish the Tsinghua University Drug Evaluation and Regulatory Science Research Institute to build up an academic exchange and international cooperation platform, as well as to conduct systematic research relevant to drug R&D and evaluation.

The strategic partnership also seeks to broaden career scope of drug reviewers by maintaining their physician licenses through clinical practice participation arrangements with the Medical School of Tsinghua University.

Besides, the parties will jointly sponsor training of drug reviewers and set up a think tank for drug evaluation policy and reform in China, according to the MOU.

NDRC, MOFCOM Release Draft Revision of Foreign Investment Industrial Guidance Catalog

The National Development and Reform Commission (NDRC) and the Ministry of Commerce (MOFCOM) released on December 8 a draft revision of the Foreign Investment Industrial Guidance Catalog for public comments.

The move is reportedly intended to raise policy transparency and improve business environment. Restrictive measures contained in the document are reported to have been slashed to 62 from 93 at present. Since the initial publication of this catalog in 1995, the document has been amended five times in 2002, 2005, 2007, 2011 and 2015.

Proposed ***encouraged*** areas of foreign investment related to pharmaceutical manufacturing in this draft revision include: production of new chemical entity (NCE) drug formulations or APIs; for amino acids, production by fermentation methods of trytophane, histidine, methionine, etc.; development and production of new anticancers, new cardio/cerebro-vascular drugs and new nervous system drugs; production of new medicines using bioengineering technologies; production of new vaccines including those for AIDS, Hepatitis C, contraception, cervical cancer, malaria and hand, foot & mouth diseases; development and production of marine pharmaceuticals; production of new delivery system drug products and dosage forms using slow release, controlled release, target-orientation and transdermal delivery technologies; production of new pharmaceutical excipients; production of antibiotic APIs for animal use; production of new antibiotics, anti-parasitics, helminthics and coccidiostats for animal use, as well as relevant new dosage forms; as well as development and production of new diagnostic agents.

Proposed ***restricted*** areas of foreign investment related to healthcare/biopharma industries include: medical institutions (allowing only joint ventures and cooperative projects).

Proposed ***banned*** areas of foreign investment related to healthcare/biopharma industries include: applications of steam, fry, roast and fire forge processing techniques for TCM herbal crude drugs; production of formulated TCMs under secret recipe protection; and development and application of human stem cell, as well as genetic diagnosis technologies and therapies.

Feedbacks should be submitted to the Comment Seeking sections of either NDRC (http://www.ndrc.gov.cn) or MOFCOM (http://www.mofcom.gov.cn) websites before January 6, 2017.

Full text of the draft revision document in Chinese can be downloaded from the following MOFCOM weblink: http://wzs.mofcom.gov.cn/article/n/201612/20161202088897.shtml

Legal/IPR News

NDRC Fines MedTronic CNY 118.5M for Alleged Price-fixing

After looking into a local Medtronic unit for monopolistic activities, Chinese regulators are charging the company CNY 118.5 million (US$17.2 million) for price-fixing.

The fines pertain to Medtronic's cardiovascular and diabetes devices, Reuters reported. The National Development and Reform Commission said that Medtronic quashed competition by requiring its distributors in China to charge minimum prices for its products, according to the Associated Press. Medtronic also had its partners and distributors place lower limits on resale prices to hospitals, Reuters said.

"Competition in China's high-value consumables and implantable medical equipment market is inadequate," said a statement by the Cabinet's planning agency, as quoted by the AP. Enforcing minimum prices rather than allowing market forces to set them "increases the burden on patients and damages the interests of consumers."

While more than half of Medtronic's sales are concentrated (PDF) in the Americas, it reeled in US$1.5 billion – 5% of its revenues – from Greater China in fiscal 2016. Compare this to US$3 billion in sales from the rest of the Asia Pacific and US$6.7 billion from Europe, Africa and the Middle East.

The device maker is working on expanding reach in China. To drive up pacemaker use in China, Medtronic's cardiac rhythm and heart failure unit led multiple training sessions for pacemaker implantation.

Earlier this year, Medtronic revealed plans to build a new manufacturing plant in Chengdu, for the production of diabetes devices. Under a deal with the city, the devicemaker is collaborating with the city government to bring the tech to Chengdu's citizens as well as people in Sichuan province. The plant is Medtronic's second site in the city. In 2014, it announced it would create a factory for portable hemodialysis tech.

And though foreign companies – such as those from the U.S. and Japan – reign over the Chinese medical device market, competition from local firms is rising. The rapidly growing Chinese middle class is expected to be a major driver in medical device demand.

SAIC Fines Southwest No.2 Pharma for API Sales Monopoly

The State Administration of Industry and Commerce (SAIC) announced conclusion of an investigation of API monopoly by Southwest No.2 Pharma in Chongqing City and imposed a fine equivalent to 1% of the company's annual sales in 2015. Southwest No.2 Pharma did not defend its positions or request a hearing.

Southwest No.2 Pharma is the only producer of Phenol API in China and had been supplying the product to around 40 pharmaceutical formulation manufacturers before January 2014. Thereafter, the company signed an exclusive agency agreement with Henan Shangqiu New Pioneer Pharma and stopped supplying other companies in February 2014. As a result of that, the price of Phenol API jumped multiple times from CNY 127/kg to CNY 5,320/kg and subsequently the Phenol ointment price rose from CNY 1/box to CNY 9.

By the end of 2015, numerous pharmaceutical companies complained to industry and commerce agencies over abuse of market monopoly status by Southwest No.2 Pharma for supply of this API. In June this year, SAIC began an antitrust investigation of the case.

The Chinese government has increasingly invoked antitrust regulations against price gauging activities of pharmaceutical companies. In July, NDRC fined three pharma companies CNY 2.6 million for controlling price of Estazolam API price and earlier in January, it also fined another four pharma companies CNY 4 million for forming a price cartel of Allopourinol Tablets.

Most recently, NDRC charged Medtronic CNY 118.5 million for quashing competition by requiring its distributors in China to charge minimum prices for its products.

API/Bulk Drug News

Prospects of Chinese API Industry Up in the Next Five Years

The Chinese active pharmaceutical ingredient (API) market size was CNY 424,035 million in 2014, up 11.35% from the previous year, according to a new report from Qianzhan Industrial Research Institute, *Chinese Chemical Bulk Drug Industry Supply, Demand and Investment Forecast Analytical Report*.

The report expects the CAGR of the industry in the next five years (2016-2020) to reach 9.5%. The Chinese API market size is estimated to reach CNY 700 billion by 2020.

In general, the report predicts, the prospects of the Chinese API market is looking up after comprehensive upgrading of the industry. As the scale of economy increases, productivity of the industry will improve and leading Chinese API players are expected to move upstream into pharmaceutical formulation export business.

The industry upgrade will also transform product portfolios of Chinese API companies to more upscale premium products. This is forecasted to become a primary driver for industry revenue and profit growth in future.

Product and R&D News

The Beijing Hospital Establishes Clinical Research Center and Signs Cooperative Agreement with CDE

The Beijing Hospital, one of the largest, oldest and most reputable 3A hospitals in China, announced the establishment of its Clinical Trial Research Center on December 19.

The hospital is one of the first Chinese medical institutions to undertake clinical research of imported drugs and has completed a large number of phase I thru IV clinical trials in the past three decades. It is also among the first in China to conduct pharmacokinetic and bioequivalence studies, as well as early stage clinical research of innovative new drugs.

The new center will primarily be responsible for conducting phase I clinical research, and will also take charge of managing other phase I thru IV clinical trials for drug registration purposes and other clinical research projects initiated by researchers under the Beijing Hospital.

Besides launching the new clinical research center, the Beijing Hospital also signed on the same date a framework agreement with the Center for Drug Evaluation (CDE) under the CFDA for cooperative in areas of talent building, clinical research site building, major medical specialty building and pharmaceutical R&D.

CDE Director General XU Jiaqi praised the Beijing Hospital's contribution to new drug R&D and review policies and practices at the center's inauguration ceremony.

Elsevier: China's Cancer Research Advances, Closing In with the U.S.

China now has more than 17% of the global share of cancer research publications, up from around 5% in the mid-2000s, and now matches the output of the U.S. in 2005, according to a just-published report from science publisher Elsevier.

China's advancement has been driven by a rise in R&D spend as a share of Gross Domestic Product (GDP) as well as "a shift from socialist economic planning to a more market driven system over the past decade," says the report, which is benchmarking the current state of worldwide cancer research as part of an intelligence-gathering effort for the White House 'Cancer Moonshot'.

The data detailing emergence of China as a cancer research powerhouse comes against a backdrop of well-publicised advances by Chinese research teams, including the recent news that a Chinese team has become the first to test gene-editing technology CRISPR in human trials.

"The U.S. share of cancer research has been declining over the past decade," says the report, although all the countries covered show a steady increase in output. That slippage has come about largely because of the "significant increase in China's cancer research publication output." Other countries with a heritage in cancer R&D – including Japan, the UK, Germany, Italy, France and Canada – have seen their shares stay relatively stable.

"With the number of cancer cases projected to nearly double over the next 20 years, we understand the unprecedented urgency to control cancer by deploying all available advantages that might spur research breakthroughs," said Elsevier's Brad Fenwick, who is heading up the data-gathering initiative.

Chi-Med Presents Pre-Clinical Data for Selective Syk Inhibitor HMPL-523 at ASH Meeting

Hutchison China MediTech Limited (Chi-Med) announces that data from a recent pre-clinical study, investigating the in vitro and in vivo anti-tumour activities of novel Spleen Tyrosine Kinase (Syk) inhibitor, HMPL-523, was presented at the Annual Meeting of the American Society of Hematology (ASH), held in San Diego, CA, USA from December 3 to December 6, 2016.

In vitro in B-cell lymphoma cell lines with Syk/BCR dysregulation, HMPL-523 was found to block phosphorylation of B-cell linker protein as well as inhibit cell viability by inhibiting cell survival and increasing apoptotic rate. HMPL-523 also showed synergistic anti-tumour activity on human diffused large B-cell lymphoma cells, in combination with other drugs such as Phosphoinositide-3-Kinase d inhibitors, B-cell lymphoma 2 family inhibitors, or chemotherapies. Potent anti-tumour activity was also demonstrated in nude mice bearing B-cell lymphoma xenograft tumours with Syk/BCR dysregulation.

In haematological malignancies, HMPL-523 is currently being studied in a phase I dose escalation study, which was initiated in Australia in January 2016 and is expected to complete in the first half of 2017. This study is in patients with relapsed and/or refractory B-cell non-Hodgkin's lymphoma or chronic lymphocytic leukaemia for whom there is no standard therapy.

HMPL-523 is also being studied in immunological indications. Clinical data for HMPL-523 in a phase I dose-escalating study in healthy volunteers in Australia was recently presented at the 2016 Annual Meeting of the American College of Rheumatology/ Association of Rheumatology Health Professionals, which was held in November 2016.

Ascletis's Novel HCV Drug Awaits CFDA Approval

Reportedly the first China-originated oral antiviral drug, dubbed ASC08 (danoprevir) for treating Hepatitis C virus (HCV), is under priority review and waiting for final NDA approval by the CFDA, according to a Xinhua report.

The drug requires a 12 week course of treatment. Clinical trials show it can cure 90% of HCV patients, said chief of the development team, Wu Jinzi, who set up Ascletis Pharmaceutical in 2014 in east China's Hangzhou City for pharmaceutical development and production.

China has more than 8.5 million people with HCV. The Hepatitis C can develop into fibrosis and cirrhosis of the liver and even liver cancer. Wu said the new drug can provide an affordable and effective cure for HCV.

A similar HCV drug sold by American drug maker Gilead costs US$84,000 for a course of therapy, or around 1,000 dollars per day, far beyond the means of almost all sufferers. Wu said the price for ASC08 has not yet been set, but it will be much cheaper than the American drug.

ASC08, also known as Danoprevir, is a second-generation HCV NS3/4A protease inhibitor. It has previously been evaluated in 27 phase I and 7 phase II clinical trials with a total of approximately 2400 healthy volunteers and patients tested.

BeiGene Announces First Patient Dosing in China with PARP Inhibitor BGB-290

BeiGene, Ltd. (NASDAQ:BGNE), a clinical-stage biopharmaceutical company developing molecularly-targeted and immuno-oncology drugs for the treatment of cancer, announced on

December 21 the dosing of the first patient in a Phase I clinical trial of BGB-290, a potent and selective PARP inhibitor, in Chinese patients with advanced solid tumors.

The Phase I open-label, multi-center dose escalation and expansion study of BGB-290 is designed to investigate the safety, pharmacokinetics, and antitumor activity of BGB-290 in Chinese patients with advanced solid tumors and to determine the recommended Phase II dose in these patients. Professor Binghe Xu from The Chinese Academy of Medical Sciences Cancer Hospital is the principal investigator of the study.

U.S. FDA Completes Review of First IND for Anti-PD-L1 Domain Antibody from 3D and Suzhou Alphamab

3D Medicines (Sichuan) Co., Ltd. and Suzhou Alphamab Co., Ltd. announced on December 16 that the U.S. FDA has completed its review of the IND for their drug KN035 and informed the pharmaceutical company of their approval.

KN035, originally developed by Alphamab, is a fusion protein of anti-PD-L1 single domain antibody and Fc. KN035 has unique features, such as, better penetration, sc injection, high affinity, better stability and good PK profiles.

Alphamab and 3D Medicines reached a global co-development agreement early this year. Alphamab is responsible for manufacturing of KN035 and 3D Medicines for clinical development, registration, and marketing globally.

General Health

Review of BMI Fund Operation and Performance in the Past Five Years

A new report, *BMI Fund Operating Performance Analysis 2016*, was jointly developed and recently released by Northern Pharmaceutical and Health Economic Research Center and Bomu Tongxin Pharma Consulting.

The national basic medical insurance (BMI) fund income and outlay are estimated to have grown 13.5% and 11.0% respectively in 2016, reaching CNY 1,270.4 billion and CNY 1,033.6 billion. Income growth is expected to outpace that of outlay again, after outlay exceeded income in the previous two years.

The following tables provide a birds-eye-view of the BMI fund operating performance in the past five years.

BMI Fund Surplus 2011-2016

Year	Surplus Sufficient to Keep BMI Going(Months)	Surplus Rate (%)	Accumulated Surplus
2011	16.7	+20.0	+22.4
2012	16.5	+20.1	+23.7
2013	16.1	+17.5	+19.3
2014	15.7	+16.0	+16.8
2015	16.2	+16.8	+17.6
2016	17.3	+18.6	+18.9

Source: NMEI

Income and Outlays of Urban BMI Program 2011-2016

Year	Value (CNY bln)		+/- (%)	
	Payout	Income	Payout	Income
2011	443.1	553.9	+25.2	+28.6
2012	554.4	693.9	+25.1	+25.3
2013	680.1	824.8	+22.7	+18.9
2014	813.4	968.7	+19.6	+17.4
2015	931.2	1,119.3	+14.5	+15.5
2016E	1,033.6	1,270.4	+11.0	+13.5

Source: NMEI

Income and Outlays of Urban BMI Program M1-9/2016 (CNY bln)

	Value (CNY bln)		+/- (%)	
	Payout	Income	Payout	Income
Urban Employee	584.6	725.7	+10.7	+12.8
Urban Resident	149.5	200.9	+22.6	+22.8
Total	734.1	926.6	–	–

Source: NMEI

While most of the Chinese population is now enrolled in BMI programs, the share of population aged above 65 has risen from 4.9% in 1982 to 10.1 in 2014 and estimated to reach 14.0% in 2020. Meanwhile people aged 60 and above are estimated to consume 49.5% of inpatient expenditures and 61.6% of outpatient expenditures at present.

Besides, the growth of inpatient medical service and device expenditures are found to outpace that of inpatient drug expenditures considerably between 2010 and 2014.

Number of Enrollees of BMI Programs 2011-2015

	Number of Enrollees (bln)		+/-	CAGR (%)
	2011	2015		
Urban Employee	0.25	0.29	+0.04	–
Urban Resident	0.22	0.38	+0.16	–
RCMS	0.83	0.67	-0.16	–
Total	1.3	1.34	+0.04	+0.5

Source: NMEI

China's Population Structure by Age 1982-2020

Year	0-14	15-64	≥65
1982	33.6%	61.5%	4.9%
1990	27.7%	66.7%	5.6%
1998	25.7%	67.6%	6.7%
2006	19.8%	72.3%	7.9%
2014	16.5%	73.4%	10.1%
2020	11.5%	74.5%	14.0%

Source: NMEI

Current Structure of Patient Visits and Expense in Urban BMI

	Age ≤60		Age >60	
	Inpatient	Outpatient	Inpatient	Outpatient
Share in Total Patient Visits (%)	49.9%	64.5%	50.1%	35.5%
Share in Total BMI Expenditures (%)	50.5%	38.4%	49.5%	61.6%

Source: NMEI

Structure of Inpatient Expenses 2010-2014

Category	Inpatient Expenses (CNY bln)			Inpatient Expenses per Visit (CNY)	
	2010	2014	+/- (%)	2010	2014
Drug	124.4	254.1	+104.3	3,954	3,876
Treatment	96.7	240.6	+148.8	3,074	4,137
Medical Devices	30.2	86.7	+187.1	960	1,322
Total	251.3	612.0	+143.5	-	-

Source: NMEI

Central Government Publishes 2015 Public Hospital Reform Report

Five central government agencies led by State Council's Healthcare Reform Office recently released their *2015 Public Hospital Reform Report*, which declares the reform trial to have covered one third of Chinese cities by now.

The growth of outpatient and inpatient medical expenditures in trial site cities were contained to below that of urban resident disposable income in 2015, while the share of government subsidies in overall public hospital expenditures reached 9.2%, which is 1.1 percentage points higher than the same figure in 2014.

The growth of trial site urban public hospital outpatient and inpatient medical expenditures surged 4.5% and 4.2% respectively in 2015, while the medical expenditure growth of 213 county level public hospitals (which accepted government review) dropped 5.1 percentage points year on year (among the total, drug expenditure growth dropped 7.6 percentage points), according to the report.

Most of the trial site urban and county level public hospitals withdrew drug sales margins, said the report. Loss of such hospital revenues were made by adjusting medtech service prices, increased government subsidies and hospital cost cutting, which generally represented 75-80%, 10-20% and 5-10% respectively.

29 provincial level governments introduce centralized public hospital purchase plans, 83.4% of public hospitals made their purchases of drug products at the provincial level tender platforms. Besides, 292 public hospitals in 29 provincial level territories adjusted their medical service prices.

The public hospital revenue structure has been optimized and the share of drug sales in overall county level public hospitals were 39% in 2015, down 1.9 percentage points compared with 2014, the report claims.

As to implementation of tiered medical service system reform, the report disclosed that 65.5% of Chinese counties have now implemented trials for the measure of compulsory initial visit to primary healthcare facilities. Besides, 45% and 51% of Chinese counties introduced in-county telemedicine and medical examination result sharing.

Finally, 84.3% of Chinese cities have formulated regional healthcare plans and 63.0% of Chinese counties have developed countywide healthcare service system plans.

NHFPC: 23 Provincial Level Governments Have Facilitated National Drug Negotiation Outcome

The NHFPC made an announcement on December 23 that 23 provincial level governments have included the three negotiated drugs for reimbursement by BMI, NRCMS or CII (excluding provincial level governments which have already covered the three drugs before negotiation). Details are shown in the following tables:

Seven Areas Already Covering the Three Drugs Before Negotiation

Rank	Area	UEBMI	URBMI	NRCMS	CII
1	Inner Mongolia	Icotinib Gefitinib	Icotinib Gefitinib		
2	Heilongjiang	Gefitinib	Gefitinib		
3	Hunan				Icotinib Gefitinib
4	Tibet	Gefitinib	Gefitinib		
5	Gansu	Gefitinib	Gefitinib		
6	Qinghai	Gefitinib	Gefitinib	Gefitinib	
7	Ningxia	Gefitinib	Gefitinib	Gefitinib	

Source: NHFPC

23 Areas with Added New Coverage of the Three Drugs After Negotiation (1)

Rank	Area	UEBMI	URBMI	NRCMS	CII	Weblink
1	Yunnan			Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib	http://www.pbh.yn.gov.cn/contents/62/6221.html
2	Hainan			Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib	http://xxgk.hainan.gov.cn/hi/HI0110/201606/t20160613_2034286.htm
3	Guangxi			Tenofovir Icotinib Gefitinib		http://www.gxhfpc.gov.cn/zhuantiqu/xnhxchzl/zcfg/2016/0627/25207.html
4	Liaoning			Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib	https://www.lnypcg.com.cn/HomePage/Info.aspx?InfoID=530
5	Jiangxi			Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib	http://www.jxwst.gov.cn/cszw/yaozgl/tggg/201606/t20160628_461530.htm
6	Guizhou			Tenofovir Icotinib Gefitinib		http://www.gzhfpc.gov.cn/doc/2016/06/23/57302.shtml
7	Heilongjiang			Tenofovir Icotinib Gefitinib		http://www.hljhfpc.gov.cn/ywcon.php?id=22160&vid=25&ld=4 http://www.hljypcg.com/xw/queryXwnrForYl?XWID=261
8	Jiangsu			Tenofovir	Icotinib Gefitinib	http://www.jswst.gov.cn/jswshjhsywyh/ywgl/yzgl/gzdt/2016/06/23093053695.html
9	Shaanxi				Tenofovir Icotinib Gefitinib	http://www.sxwjw.gov.cn/newstyle/pub_newsshow.asp?id=1057153&chid=100541
10	Shanxi				Tenofovir Icotinib Gefitinib	http://www.sxwsjs.gov.cn/ggsl05/13057.hrh
11	Anhui				Tenofovir Icotinib Gefitinib	http://www.ahwjw.gov.cn/yzgl/ywwj/201607/e46366920d254ce89bbaafb844def4c3.html

Source: NHFPC

23 Areas with Added New Coverage of the Three Drugs After Negotiation (2)

Rank	Area	UEBMI	URBMI	NRCMS	CII	Weblink
12	Beijing			Tenofovir Icotinib Gefitinib		
13	Sichuan			Tenofovir		http://www.scwst.gov.cn/index.php/2012-07-24-12-54-29/13178-2016-07-13-02-33-14
14	Xinjiang	Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib		http://www.xjhfpc.gov.cn/context.jsp?urltype=news.NewsContentUrl&wbtreeid=1495&wbnewsid=4805
15	Gansu			Tenofovir		http://www.gsws.gov.cn/html//2016/07-29/3/7a5a1894-ba6d-4b8f-9811-87a069f1ddcc.html
16	Jilin			Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib	http://wsjsw.jl.gov.cn/wx_43550/ckxx/201609/t20160921_2435474.html
17	Henan			Tenofovir	Icotinib Gefitinib	http://www.hnggzy.com/hnsggzy/infodetail/?infoid=c529fa95-98f9-4761-9784-17a0c57e4cf4&categoryNum=002005001
18	Zhejiang	Tenofovir Icotinib	Tenofovir Icotinib	Tenofovir Icotinib	Gefitinib	
19	Fujian	Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib		http://www.fjrs.gov.cn/zyzw/ylbx_25013/xxgk_25014/tzgg_25016/201610/t20161014_1220726.htm
20	Inner Mongolia	Tenofovir	Tenofovir	Tenofovir		http://www.nmgyxcg.gov.cn/work/show5126.html
21	Qinghai	Icotinib Gefitinib	Icotinib Gefitinib			http://www.qhwjw.gov.cn/ywgl/yaoxiec/gzdt/2016/11/29/1480384450791.html
22	Chongqing	Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib		http://www.cqwsjsw.gov.cn/Html/1/tzgg/tzgg/2016-12-22/19917.html
23	Shanghai	Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib	Tenofovir Icotinib Gefitinib		http://www.smpaa.cn/xxgk/gggs/files/file536.pdf

Source: NHFPC

Full text of the announcement in Chinese can be viewed by clicking on the following NHFPC weblink: http://www.nhfpc.gov.cn/yaozs/s7652/201612/fe221f2d31af4956b2e9e02e76d9fb0c.shtml

NHFPC Issues Pediatric Immunization Procedure and Explanations of National Immunization Plan (2016 Edition)

The NHFPC Issued the Pediatric Immunization Procedure and Explanations under the National Immunization Plan (2016 Edition) on December 29. The document is for implementation immediately by local governments.

For full text of this document in Chinese, please visit the following NHFPC weblink: http://www.nhfpc.gov.cn/jkj/s3581/201612/329491d85ca8420a86fe981b3fedd1fb.shtml

The First Third Party Drug Exchange Established in Wuhan

Central China Drug Exchange Center, the first third party drug exchange and the third drug exchange in China, has been founded on November 29 in Wuhan by Gangling Group, an online pharmacy and pharma e-commerce operator which owns www.111.com.cn.

The Central China Drug Exchange Center will adopt both online and offline settlement models to meet variable needs of hospitals, pharma companies and logistic providers, according to Gang Yu, Chairman of the exchange. It will also build a tracking system for drugs and medical devices to secure quality.

Yu said the center has been approved by the CFDA in August for internet transaction services of drug products and it will provide multiple internet + drug supply chain services which encompasses product display, contract signing, transaction, settlement, finance, logistics and big data analysis.

The center will begin with facilitating the provincial and local levels of centralized drug purchase tenders in Hubei province, according to Yu. When conditions mature, it will further expand to central China region or even nationally.

At present, the center has eight medical institution partners, all of which are large local hospitals in Wuhan.

BMJ Expands into Primary Healthcare in China thru Local Partnership

BMJ, one of the world's leading healthcare knowledge providers, has partnered with Guangdong Family Doctor Association to make their fully translated Chinese edition of BMJ Best Practice available to over two million primary healthcare professionals across China.

The partnership builds on existing links between BMJ and China. It also forms part of the Chinese government's framework for *'Healthy China 2030'* that aims to use innovation to drive health system reform across the country.

BMJ Best Practice is a clinical decision support tool that gives doctors fast and easy access to the latest information when making diagnosis and treatment decisions. Updated daily, it draws on the latest evidence-based research, guidelines and expert opinion on over 10,000 different diagnoses to offer step-by-step guidance on diagnosis, prognosis, treatment and prevention.

The Chinese edition is the result of a collaboration between BMJ and the Chinese Medical Association (CMA). In addition to the full translation of all BMJ Best Practice content, it also contains the latest clinical guidelines and expert opinion from the CMA, providing access to both international standards and local clinical practice recommendations.

It is available both online and offline, and as a mobile app, giving busy clinical staff an immediate head-start on making diagnosis and treatment decisions.

BMJ Best Practice is already in regular use by clinicians in more than 60 countries and is accredited by the Health and Family Planning Commission of Guangzhou Municipality in China.

People in the News

Bribery Case of Former CDE Deputy Chief Exposed

In April 2015, YIN Hongzhen, former Deputy Director General of the Center for Drug Evaluation under the CFDA, was taken away for corruption investigation. Relevant details have not become available until recently.

Guo, Yin's wife, is reported to be the front for receiving bribes on behalf of Yin. She has recently been handed a three year prison sentence with five year probation. Court documents suggest that Yin and his wife received bribes totaling over CNY 1.5 million from a number of vaccine producers in Beijing and Shanghai.

In return for bribes receiving, Yin helped companies bribing him to accelerate and smoothen the review process.

An executive identified for bribing Yin repeatedly is also reported to be surnamed Yin who is the General Manager of a biological product company in Beijing. This company has filed various applications for hepatitis A, SARS, bird flu and HFMD vaccines, Chinese press reports suggest.

Before appointed Deputy Director General of CDE with primary responsibilities on review of biologics registration applications, Yin had been Director of Biological Product Division under CFDA's Department of Drug and Cosmetic Registration for many years.

China Announces Senior CFDA Official and Public Attorney Appointments

The State Council announced on December 27 the appointment of ***GUO Wenqi (郭文奇)*** to the position of Vice CFDA Minister and removal of ***WANG Mingzhu (王明珠)*** from the position of Vice CFDA Minister.

Guo was previously Member of Party Group, National Food Safety Commissioner and Director General of Personnel Affairs Department of CFDA.

Before joining the CFDA in May 2014, Guo was Director General of Food Production Supervision Department of the State Administration of Quality Supervision and Quarantine and earlier the Director General of the Shanxi Provincial Coal and Geology Bureau.

Besides, the Ministry of Justice announced a list of approved CFDA public attorneys. The list can be viewed by visiting the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0050/168093.html

Recent Executive Moves

Biogen appointed ***Michel Vounatsos*** as Chief Executive Officer and member of the Board of Directors. Vounatsos previously held the position of Executive Vice President and Chief Commercial Officer at Biogen. Vounatsos joined Biogen in April 2016 after a 20 year career at Merck holding positions of increasing responsibilities including President of MSD China.

AstraZeneca promoted ***Leon Wang***, currently President of AstraZeneca China, to the new position of Executive Vice President, Asia Pacific and member of global executive committee, reporting directly to the company's CEO. Before joining AstraZeneca in 2013, Wang has worked with Roche for nearly 20 years.

Former Sevier China GM ***Didier Dargent*** has joined Novartis Oncology as China GM with effect from December 1. He replaces ***Sara Hou***, who is promoted to head the Asia Pacific and South Africa region of Novartis Oncology. Both Dargent and Hou will report to John Ketchum, Head of Novartis Oncology Emerging Market Business. Before joining Sevier in 2008, Dargent worked with Lundbeck Pharma for six years and Astellas for two years. On the other hand, Hou has worked with Novartis for nearly 25 years.

Satoru Noguchi, Vice President of Great China business of Takeda will leave his position due to personal reasons from March 31, 2017. He will be temporarily replaced by ***Pony Lu***, who is President and GM of Takeda China. Lu will report to Giles Platford, President of Emerging Market Business. Before joining Takeda in 2011, Lu had been GM of Sevier China.

Irin Min Wang joined Takeda as VP and Head of Takeda Development Center Asia. She had previously been with GSK China for over three years as VP, Medicine Development and with Bayer Healthcare for more than 12 years, most recently as its VP and Medical of China and Hong Kong.

LI Honghui is now COE VP with Hisun-Pfizer Pharma where she has worked for more than four years. She was the company's Vice President of Medical affairs and Vice President of National Sales previously. She had previously worked with Pfizer China for more than 11 years, most recently as Associate Sales Director. Before joining Hisun Pfizer, she had been District Manager with Bayer China for over three years, District Manager with GlaxoSmithKline for seven years and a doctor with Nankai Hospital in Tianjin for over four years.

Sanofi China promoted ***Hairuo WANG*** to the new position of Marketing Excellence & Intelligence Senior Director from previously Director of Marketing Excellence. Before joining Sanofi in 2013, Hairuo had been with GSK for 11 years, most recently as Director of Commercial Capabilities, China/HongKong, and with Eli Lilly China for seven years as Marketing Consultant and sales rep.

MSD China promoted ***Youlin (Anna) Yang*** to the new position of Senior Marketing Director and she will continue to hold the position of marketing head of MSD China Diabetes BU. Before joining MSD in 2006, Anna had worked with AstraZeneca China for over four years as Senior Product Manager, Gastroenterology.

GE Healthcare China promoted ***NI Min*** to the new position of National Sales Leader from previously Marketing Head. He had worked with the company since May 2012.

Chiesi Group promoted ***Chris Zheng*** to the new position of BD & Alliance Director China from previously Business Development Director. Zheng had previously been BD Director with Invida Pharma for nearly two years, Manager with BearingPoint for over two years and consultant with Euro-Asia Consulting for nearly two years and Analyst with General Biologic Management Consulting for over two years and Assistant engineer with Shanghai Sine Pharmaceutical Co., Ltd for one and half years.

25 senior executives of domestically-listed Chinese pharmaceutical companies resigned in the month of November, according to recent corporate filings. Resignations of leading players are cited as follows: ***DENG Baojun***, Deputy General Manager of SinoPharm Accord; ***ZHU Yaoyi***, Vice President of Fosun Pharma; ***TU Xiongfei***, Deputy General Manager of Liaoyuan Pharma; ***HU Xuechun***, Director and Deputy General Manager of Tongren Pharma; ***ZHANG Shenggui***, Vice Chairman of Yibai Pharma; ***ZHENG Cheng***, Independent Director of Hisun Pharma; ***HE Xun***, Deputy General Manager of Weiming Pharma; ***ZHANG***

Ji, Executive Director of Grand Pharma; and ***ZHAO Zhiwen***, Independent Director of Tianjin Pharma.

Zhejiang Hisun Pharma appointed ***GUAN Xuhua*** as CFO to replace ***HU Liangbin***, while Lotus Pharma announced retirement of Tong-Ho Lin from chairman of the board. Zhejiang Jiuzhou Pharma announced resignations of ***HUA Dexuan*** from chairman of the board and ***HUA Lirong*** from General Manager. It appointed ***HUA Lirong*** as new chairman of the board and ***CHEN Zhihong*** as new General Manager.

China Pioneer Pharma Holdings promoted ***Mengjun ZHU*** from Chief Financial Officer to Chief Executive Officer, replaciing Yinping Wang who is appointed Non-executive Director. ***XUE Yi*** succeeds Zhu as the new Chief Financial Officer.

Zhejiang Xianju Pharma appointed ***ZHANG Yusong*** as Chairman of Board of Directors, while Jiangsu Lianhuan Pharma announced resignation of ***YAO Xingtian*** from and appointment of ***XIA Chunlai*** to Chairman of the Board. Guangdong Zhongsheng Pharma appointed ***CHEN Yonghong*** as Chairman and General Manager.

Domestically-listed Chinese pharmaceutical companies also made the following senior executive appointments in the month of November. Such appointments by leading players are cited as follows: ***ZHOU Xiaodong*** as Deputy General Manager of Kelun Pharma; ***NIU Zhanqi*** as Executive Director of Grand Pharma; ***ZHOU Bin***, ***LI Zhiming*** and ***JIA Zhidan*** as Chairman, Vice Chairman and General Manager of Modern Pharma respectively; ***WANG Xudong***, ***LI Xianlin***, ***CUI Yiling***, ***GONG Zhong***, ***DENG Baojun*** and ***WEI Dongsong*** as Deputy General Managers of Modern Pharma; ***ZHANG Minghao*** as Deputy General Manager of Changsheng Bio; and ***YU Xiong*** as Independent Director of Tianjin Pharma.

FENG Weiwei has joined Shanghai Centennial Scientific as Senior Director. She had previously been with Eli Lilly & Co as Director, Access Strategy Planning for two years, Head Market Access with Xian-Janssen Pharma for three and half years, Director Market Access/Government Affairs/HE with Novartis Oncology China for over two years, Associate Director, Global Health Economics & Pricing with Novartis Oncology for three years, Manager, Health Economics & Pricing with J&J Pharmaceutical Services for three years.

Bing Yuan joined CStone Pharmaceuticals as Senior Vice President, Global Head of Corporate Development. He had previously been with Merck for two and half years as Executive Director and Global Lead, with Novartis Oncology for over four years as Oncology Business Development and Licensing, Executive Director and Head, Life Cycle Strategy most recently, and with Eisai for more than three years as Senior Manager, Oncology Global Marketing.

Tony Ma joined KaVo NobelBiocare Group as Marketing Director. He had previously been Vaccine Marketing Head APAC Region with Elanco, a subsidiary of Eli Lilly, for more than a year, Head of Marketing, China with Novartis AH Division for one year, Senior Marketing Manager with Sanofi China for nearly three years and Marketing Manager China with GlaxoSmithKline Biologicals for three years.

John Xu joined Abpro as SVP of Strategic Alliance. He had previously been with HD Biosciences for a year as Vice president, Global Business Development, Executive Director of Business Development with Crown Bioscience for less than a year, Senior Director of Business Development, Lab Testing Division with WuXi AppTec for over two years, Director of Project Management with ShanghaiBio Corp for three years, Sr. Research Scientist with Wyeth for more than nine years, Associate Research Scientist II with BMS for over four years and Medical Resident with Shanghai Huashan Hospital for two years.

HE Yun is promoted by Chongqing University to the new position of Professor and Dean, School of Pharmaceutical Sciences. He was previously Professor and Director of Innovative Drug Research Center at the university in the past four and half years. He had previously been Board Director with The BayHelix Group for over two years and Senior Vice President and Chief Scientific Officer with Bioduro (Beijing) for more than three years, Head of Medicinal Chemistry at Roche R&D Center (China) with Roche for two years, Associate Director at Genomics Institute of the Novartis Research Foundation (GNF) with Novartis for nearly five years, Group Leader with Ionis Pharmaceuticals for nearly two years and Research Chemist with Abbott Laboratories for more than four years.

Dr. WANG Jingsong is now CEO and ***Dr. Liang Schweizer*** CSO of Harbour BioMed. Prior to co-founding the company, Dr. Wang was at Sanofi, serving as Head of China R&D and Head of Translational Medicine, Asia Pacific. Prior to Sanofi, he served at Bristol-Myers Squibb, where he held multiple roles with increasing responsibilities, including Director of Discovery Medicine and Clinical Pharmacology and Global Program Lead for multiple preclinical and clinical assets. Dr. Schweizer was previously Head of Sanofi Asia Cancer Research. Before that, she was at Bristol-Myers Squibb as a Director of Leads Discovery and Optimization.

Other News

Upcoming Events

Event: Generic International Summit Asia 2017
Dates: April 20 – 21, 2017
Venue: TBD, Shanghai, China
Weblink: www.genericsummit.com
Contacts: Luke Xia
Tel: +86 21 6053 8962
Email: luke.xia@bestmediaworld.com

Event: DCAT Week' 17
Dates: March 20 – 23, 2017
Venue: New York City, USA
Weblink: www.dcat.org/DCATWeek
Contacts: Erin Sanders
Tel: +1 800 640 3228
Email: Esanders@dcat.org

Feature Articles

IMS: Chinese Hospital Drug Sales Up 6.4% in MAT Q3/2016

The Chinese hospital drug sales was up 6.4% in the MAT Q3/2016, which was 0.2 percentage point higher than that in the MAT Q2/2016, according to *IMS Health* quoting IMS's China Hospital Pharmaceutical Audit (CHPA). The generally flat growth was attributed by IMS to be government policies for restricted use of antibiotics, hospital tender purchase, overall hospital expenditure cap, rationalized TCM use and anti-corruption in the healthcare sector.

In the third quarter of 2016, Chinese hospital drug sales reached CNY 179.0 billion, rising at 5.7% year on year.

MNCs (7.6%) led Domestic companies (6.1%) in terms of growth rate for in the third quarter of 2016. In the MAT Q3/2016, the competitive landscape is changing in different market tiers. The growth rate of MNCs was 6.3%, which is lower than that of domestics at 10.3% in Tier 1, and Tier 2 cities due to competitive landscape, while growth of MNCs at 11.8% had an upper hand than that of domestic companies at 5.8% in medium and small cities, driven by rationalization of drug consumption.

Among the top ten drug suppliers to Chinese hospitals in the third quarter of 2016, there were four MNCs and six domestic companies.

The top ten drug products by sales in Chinese hospital continued to be dominated by domestic products (7) in the third quarter of 2016 with Shen Jie taking the lead again. The only three MNC products in the pack were Plavix, Lipitor, and Sulperazon ranking No.1, No.2 and No.10 in the period.

Other drugs TC (mainly formulated TCMs) remained the top therapeutic category by drug sales in the third quarter of 2016, followed by systemic anti-infectives. However, impacted by government policies, the growth rates of both categories was flat or dropped in the quarter.

Tier 1 cities: Beijing, Shanghai, Guangzhou

Tier 2 cities: Chengdu, Shenyang, Chongqing, Tianjin, Nanjing, Hangzhou, Shenzhen, JiNan, Zhengzhou, Wuhan, Ningbo, Harbin, Suzhou, Xi'an, Changsha

Tier 3 cities: Changzhou, Taiyuan, Dalian, Qingdao, Urumqi, Wuxi, Changchun, Shijiazhuang, Guiyang, Kunming, Shaoxing, Wenzhou, Taizhou, Jinhua, Jiaxing, Yantai, Nantong, Yangzhou, Xuzhou, Nanyang

Top 10 Drug Suppliers to Chinese Hospitals Q3/2016

Rank	Company	+/- (%) Q4/2015	+/- (%) Q3/2015	+/- (%) Q2/2015	+/- (%) Q1/2016	+/- (%) Q2/2016	+/- (%) Q3/2016
1	Pfizer	+2.4	+3.2	+6.6	+4.8	+7.6	+11.1
2	AstraZeneca	+8.2	+10.3	+13.7	+10.2	+12.6	+12.6
3	Shandong Qilu	+9.5	+13.3	+15.1	+8.2	+7.1	+6.6
4	Sihuan Pharma	+15.5	+14.8	+17.1	+17.2	+16.0	+14.4
5	Yangtze River Pharma	+7.9	+10.7	+12.8	+8.4	+9.6	+11.3
6	Shanghai Fosun	+2.8	+4.7	+6.2	+3.6	+4.3	+4.4
7	Sanofi	+8.5	+9.7	+11.7	+9.2	+9.1	+9.3
8	Jiangsu Chia Tai Tianqing	+17.9	+20.2	–	+16.6	+14.3	+12.2
9	Jiangsu Hengrui	+11.8	–	–	–	+12.9	+14.4
10	Bayer	+2.3	+3.2	–	+3.6	–	+6.1

Source: IMS CHPA (>=100 patient beds)

Top 10 Drug Products by Sales in Chinese Hospitals Q3/2016

Rank	Product	Producer	+/- (%) Q2/2016	+/- (%) Q1/2016	+/- (%) Q3/2016	+/- (%) Q4/2015
1	Plavix	Sanofi	+12.5	+12.5	+12.6	+10.4
2	Lipitor	Pfizer	+15.5	+11.7	+16.6	+8.8
3	Shen Jie (Ganglioside)	Shandong Qilu	+1.4	+4.5	-1.9	+7.7
4	Dezocine	Yangtze River Pharma	+27.8	+25.1	+31.8	+23.8
5	Xue Shuan Tong	Guangxi Wuzhou Pharma	+5.0	+8.2	+0.0	+5.9
6	Bei Tong	Shandong Danhong Pharma	+13.1	+11.3	+12.6	+9.2
7	Danshen Duofensuan Yan	Shanghai GeeenValley Pharma	+1.5	-1.1	+4.4	-1.6
8	Ou Di Mei	Sihuan Pharma	+8.9	+10.5	+6.8	+11.1
9	Ao De Jin	Jingzhou Ahon Pharma	–	–	-12.8	-6.6
10	Sulperazon	Dalian Pfizer	–	–	+14.4	–

Source: IMS CHPA (>=100 patient beds)

Top 10 TCs in Chinese Hospitals Q3/2016

Rank	Therapeutic Category	+/- (%) Q4/2015	+/- (%) Q3/2015	+/- (%) Q2/2015	+/- (%) Q1/2016	+/- (%) Q2/2016	+/- (%) Q3/2016
1	Others (inc. TCMs)	+2.6	+4.9	+6.8	+2.5	+3.3	+3.3
2	Systemic Anti-infectives	+2.2	+4.2	+5.3	+3.1	+3.6	+2.6
3	Digestive System and Metabolic Drugs	+5.9	+7.7	+9.7	+5.4	+5.9	+6.2
4	Cardiovascular Drugs	+7.0	+8.2	+9.9	+7.6	+8.4	+8.6
5	Central Nervous System	+8.6	+10.3	+12.6	+5.9	+9.9	+10.8
6	Oncology and Immunomodulators	+5.9	+6.2	+8.0	+6.9	+7.8	+8.6
7	Medical Solutions	+1.7	+4.0	+5.3	+2.1	+2.6	+3.4
8	Blood and Hematopoietic System Drugs	+8.2	+9.2	+10.8	+9.4	+9.9	+11.1
9	Respiratory System Drugs	+10.6	+12.7	+13.6	+12.3	+12.9	+10.9
10	Skeletal Muscle System Drugs	+4.1	+6.6	+9.2	+3.4	+3.7	+4.8

Source: IMS CHPA (>=100 patient beds)

IMS: Chinese Retail Pharmacy Sales Up 4.2% in MAT Q3/2016

The sales of OTC drugs and health foods of Chinese retail pharmacy sector reached CNY 76.8 billion in MAT Q3/2016 (12 months ending the end of September 2016), up 4.2% , considerably lower compared with 6.3% of Q2/2016 due to slow price increases and negative volume growth, according to IMS PharmaTrend, which monitors retail pharmacies in 41 Tier 1/2 thru 4 representative Chinese cities. Growth of unit prices outpaced that of sales value in the period.

Among the total, sales of OTC drugs in the period were CNY 64.1 billion, up 4.6% year on year, with growth primarily driven by price increases and undermined by fallen volume. Formulated TCMs surged 5.5%, as a subclass of OTC drugs, accounting for over 66% of total OTC drug sales. However, growth rate of chemical drugs in the period slowed to only 2.2% in the quarter.

Domestic companies contributed 86% of the OTC drug and health food sales of retail pharmacy sector in MAT Q3/2016, suggests IMS. The strong performance of domestics had been driven by formulated TCMs, which represent at least 53% of retail pharmacy sales in the period.

The top 20 players by retail pharmacy sales of OTC and health food products represented 26.4% of the overall market. There are only five MNCs in the top 20 with a market share of 6.4%.

Guangzhou By-health was the top player in the period with down 3.6%, followed by Shandong Dong'e Ejiao and Wyeth, which led the MNC pack, with growth rates of 15.1% and 5.3%.

In terms of therapeutic classes, the category of cough, cold and other respiratory system therapeutics remained on the top in MAT Q3/2016 with a market share of 26.1%, followed by vitamins, minerals and supplements (VMS) and analgesics. The first two classes saw growth rates of 4.9% and 3.6%, while those of miscellaneous and analgesics had the highest growth of all TCs at 11.7% and 6.4% respectively in the period. The TC of urinary system drugs saw negative growth.

Among the top 20 OTC and health food products by retail pharmacy sales, 12 were formulated TCMs, six chemical drugs and four health foods. Five products were from MNCs, while the rest were from domestic players. The average growth of domestic products in the leading 20 was 11.0%, which was sharply higher than that of MNCs at only 3.1%.

41 representative cities covered by IMS PharmaTrend™ National Audit are as follow:

Tier 1 cities: Beijing, Shanghai, Guangzhou, Shenzhen

Tier 2 cities: Tianjin, Chongqing, Hangzhou, Nanjing, Shenyang, Wuhan, Chengdu, JiNan, XiAn, Harbin, Changsha

Tier 3 cities: Foshan, Dalian, Ningbo, Qingdao,

Top 20 OTC & Health Food Players in China Retail Pharmacy Market MAT Q3/2016

Rank	Company	Change +/- Q3/2016 (%)	Change +/- Q2/2016 (%)	Change +/- Q1/2016 (%)	Change +/- Q3/2015 (%)
1	By-health	-3.6	+4.5	+16.0	+25.0
2	Shandong Dong'e Ejiao	+15.1	+19.5	+22.8	+31.5
3	Wyeth Pharma	+5.3	+7.2	+6.6	+9.2
4	Yunnan Baiyao Group	-0.1	+1.8	+6.0	+9.8
5	Beijing Bayer Healthcare	-1.5	-1.1	-1.6	+0.5
6	Jiangxi Huiren	+30.2	+36.0	+53.4	+129.7
7	Xi'An Janssen Pharma	-4.1	-4.4	-3.7	-1.3
8	Hongmao Pharma	+40.2	+32.2	+33.1	+22.8
9	Jilin Xiuzhen Pharma	-0.5	+0.1	+2.5	+6.6
10	Nin Jiom Medicine	-2.0	-1.6	-1.5	-3.2
11	Shandong Fujiao Group	-4.4	+9.0	+10.7	+61.2
12	Jiangxi Jiangzhong Pharma	-7.4	-4.9	+0.5	+19.5
13	Tianjin SK&F	+3.6	+6.8	+6.2	-14.4
14	China Resources Sanjiu	-3.3	-4.6	-4.2	-5.3
15	Guangzhou Chen Li Ji	+9.5	+26.4	+46.7	+99.0
16	Beijing Tongrentang	-1.9	+0.3	+2.3	+15.5
17	Chongqing Fuling Pharma	+4.0	-2.6	+2.3	+8.4
18	Hainan Yangshengtang	+15.4	+16.9	–	–
19	Guangzhou Longli Trade	-0.9	+1.5	-0.5	-17.3
20	Henan Wanxi Pharma	+1.9	–	9.9	18.9

Source: IMS PharmaTrend™ National Audit

Top 20 OTC & Health Products in China Retail Market Q3/2016

Rank	Product	Producer	+/- (%) Q3/2016	+/- (%) Q2/2016	+/- (%) Q1/2016	+/- (%) Q3/2015
1	Ejiao	Shandong Dong'e Ejiao	+5.3	+6.1	+8.0	+28.5
2	Shen Bao	Jiangxi Huiren	+33.5	+40.0	+59.4	+145.2
3	Caltrate D 600	Wyeth Pharma	+9.1	+8.0	+3.4	+3.2
4	Hongmao Medicinal Liquor	Hongmao Pharma	+40.2	+32.2	+33.1	+22.8
5	E'jiao	Shandong Fujiao Group	-4.5	+9.0	+10.7	+61.1
6	Chuanbei Pipa Gao	Nin Jiom Medicine	-3.2	-3.0	-2.4	-2.4
7	Fufang Ejiao Jiang	Shandong Dong'e Ejiao	+63.7	+102.3	+135.0	+79.4
8	ShuJin JianYao Pills	Guangzhou Chen Li Ji	+11.8	+31.9	+57.0	+132.1
9	By-health Protein Powder	Guangzhou Baijian Bioengineering	-11.6	-6.3	+5.9	+18.9
10	Centrum Tablets	Wyeth Pharma	-7.5	-6.7	-2.1	+4.3
11	D-Cal	AZ Pharma	-3.4	-3.7	-2.0	+0.8
12	Huoxiang Zhengqi	Chongqing Fuling Pharma	+13.8	+4.1	+15.2	+27.0
13	Jianweixiaoshi Tablets	Jiangzhong Pharma	-1.1	+1.5	+4.5	+9.6
14	Bendazac Lysine Eye Drops	Zhejiang Shapuaisi Pharma	+7.4	+6.3	+8.6	+10.1
15	Yunnan Baiyao	Yunnan Baiyao Group	-5.8	-4.1	-0.7	-2.8
16	Elevit Pronatal	Bayer Healthcare	+33.5	+33.2	+20.0	–
17	999 Ganmaoling Granules	China Resources Sanjiu	-3.1	-5.5	-5.4	-7.2
18	Calcium and Zinc Gluconates	Hebei Baoding Aonuo	+2.7	-1.1	+3.3	+13.7
19	By-health Liquid Cal	Guangzhou Baijian Bioengineering	-5.0	+11.2	+17.4	+15.2
20	Lanqin Oral Liquid	Yangtze River Pharma	+39.1	+2.5	-0.1	-9.3

Source: IMS PharmaTrend™ National Audit

Wuxi, Zhengzhou, Dongguan, Taiyuan, Hefei, Nanning, Fuzhou, Nanchang, Shijiazhuang, Huhehaote, Changzhou, Xuzhou, Wenzhou, Guiyang, Yantai, Linyi, Kunming

Tier 4 cities: HuaiAn, Weifang, Taizhou, Huizhou, Yichang

SMEI: Review of Chinese Retail Pharmacy Sales 2013-2015

SMEI recently released its Chinese Retail Pharmacy Drug Terminal Competition Landscape Database (the database), which suggests that the market segment rose 9.7% in 2015 to reach CNY 445.9 billion. Among the total, offline retail pharmacy sales grew 8.2% while online pharmacy sales surged 85.1%.

Growth of Chinese Pharmacy Market 2013-2015

Year	Retail Pharmacy Sales (CNY bln)		+/- (%)	
	Online	Offline	Online	Offline
2013	4.3	361.6	–	–
2014	7.8	398.8	+82.9	+85.1
2015	14.4	431.5	+10.3	+8.2
	445.9		+9.7	

Source: SMEI

Among the total, sales of drug products accounted for 69.77% of the overall Chinese retail pharmacy sales in 2015.

Drugs Sales and Growth in Major 22 Cities 2013-2015

Region	Sale Value (CNY bln)	CAGR (%)
Shanghai	7.57	+3.1
Beijing	7.41	+8.7
Guangzhou	7.11	+0.3
Shenzhen	5.80	+2.5
Chongqing	4.09	-0.9
Tianjin	3.58	+0.1
Wuhan	3.56	+9.4
Shenyang	3.30	+2.3
Hangzhou	3.12	+8.4
Nanjing	2.92	+5.6
Changsha	2.65	+5.8
Harbin	2.64	+0.3
Xi'an	2.32	-0.7
Qingdao	2.16	+4.1
Jinan	1.94	+8.6
Changchun	1.93	+6.8
Ningbo	1.85	+5.2
Shijiazhuang	1.58	-1.9
Hefei	1.37	+1.3
Nanning	1.21	+0.6
Nanchang	0.94	+9.8
Yangzhou	0.69	+17.2

Source: SMEI

Drugs Sales and Growth of China Retail Pharmacies 2013-2015

Year	Sales Value (CNY bln)	Share (%)	+/- (%)
Online	3.2	0.72	+52.3
Offiline	307.9	69.05	+9.7
Overall Retail Pharmacy Drug Sales	311.1	69.77	+10.0

Source: SMEI

The 22 major Chinese cities monitored in focus by the SMEI account for about 40% of all urban retail pharmacy drug sales (289 prefectural level and above cities) in 2015. Generally, retail pharmacies in tier 1 and 2 cities had relatively lower growth rates compared with those in tier 3 and 4 cities.

The category of chemical drugs led all other categories with 42.6% market share in overall Chinese retail pharmacy sales and 51.08% market share in total drug sales of Chinese retail pharmacies in 2015.

The following tables provide more details on the various segmentations of the Chinese retail pharmacy market, as well as leading products and suppliers to Chinese retail pharmacies in the past three years.

Structure of Overall China Retail Pharmacy Sales 2013-2015

Sector	Share (%)		
	2013	2014	2015
Chemical Drugs	42.9	42.4	42.6
Formulated TCMs	27.5	28.0	28.8
Herbal Crude Drugs	9.2	9.8	9.0
Health Supplements	8.4	8.1	8.4
Medical Devices	5.1	5.0	4.8
Others	7.0	6.8	6.4
Total	**100.0**	**100.0**	**100.0**

Source: SMEI

Structure of Chinese Retail Pharmacy Drug Sales: Chemical Drugs vs. TCMs

Class	Sales Value (CNY bln)	Share (%)	Top 3 Share (%)	Top 3 Therapeutic Classes
Chemicals	94.2	51.08	57.90	Digestive and metabolic drugs, Cardiovascular system and Systemic Anti-infectives
TCMs	90.1	48.86	46.46	Respiratory System, Digestive System and Skeletal muscle system
Total	**184.4**	**59.90**		

Source: SMEI

Structure of Urban Retail Pharmacy Drug Sales 2015: OTC vs. Rx

Class	Share (%)
OTC Drugs	42.6
Rx Drugs	48.7
Cross-over Drugs	8.7
Total	100.0

Source: SMEI

Chemical Drug Sales of Urban Retail Pharmacies by TCs 2015

Therapeutic Categories	Share (%)
Digestive System and Metabolism	28.09
Cardiovascular System	17.17
Systemic Anti-infectives	12.64
Oncology & Immuno-Regulatory Agents	6.94
Genitourinary System and Sex Hormones Drugs	6.42
Dermatology	6.13
Nervous System	4.81
Blood & Blood-making System	4.30
Respiratory System	4.24
Muscle-skeletal System	4.07
Others	5.18
Total	100.00

Source: SMEI

Formulated TCM Sales of Urban Retail Pharmacies by TCs 2015

Therapeutic Class	Share (%)
Respiratory System	23.68
Digestive System	11.83
Musculo-Skeletal System	10.95
Blood and Qi Supplementing Drugs	9.92
Cardio- & Cerebro-vascular Diseases	9.80
Urinary System	8.61
ENT	7.24
Gynecology	5.96
Paediatrics	4.41
Nervous System	2.46
Others	5.13
Total	100.00

Source: SMEI

Top 10 Drug Products by Sale Value in Chinese Urban Retail Pharmacies 2015

Rank	Product	Class	Therapeutic Category	Type	Sale Value (CNY bln)	Share (%)
1	E-Jiao	TCM	Blood and Qi Supplementing Drugs	Blood Supplementing Drugs	5.86	3.18
2	Calcium Carbonate D3	Chemical	Digestive System and Metabolism	Vitamins	3.26	1.77
3	Atorvastatin	Chemical	Cardiovascular System	Antilipemic Agents	1.91	1.03
4	Vitamins With Minerals Tablets	Chemical	Digestive System and Metabolism	Vitamins	1.87	1.01
5	Liu Wei Di Huang Pills	TCM	Urinary System	Kidney Drugs	1.77	0.96
6	Yunnanbaiyao	TCM	Muscle-skeletal System/Others	Traumatic Injury, Hemostatic	1.75	0.95
7	Entecavir	Chemical	Systemic Anti-infectives	Systemic Antivirals	1.73	0.94
8	Amlodipine	Chemical	Cardiovascular System	Calcium Channel Blockers	1.62	0.88
9	Clopidogrel	Chemical	Blood & Blood-making System	Anti-thrombotics	1.62	0.88
10	Nifedipine	Chemical	Cardiovascular System	Calcium Channel Blockers	1.51	0.82
Subtotal Top 10					22.89	12.42

Source: SMEI

Top 20 Suppliers by Sale Value to Urban Retail Pharmacies 2015

Rank	Producer	Sale Value (CNY mln)	Share (%)
1	Pfizer & Wyeth	6,944	3.77
2	Bayer	4,754	2.58
3	Dong'e E-Jiao	4,353	2.36
4	Novartis	3,057	1.66
5	AstraZeneca	2,703	1.47
6	Sanofi	2,387	1.29
7	Novo Nordisk	2,321	1.26
8	Xi'an Janssen	2,293	1.24
9	Yunnan Baiyao Group	2,114	1.15
10	China Resources Sanjiu medicine	1,846	1.00
11	Jiangzhong Pharma	1,805	1.00
12	Squibb	1,758	0.98
13	Fu Jiao Dong'e E-Jiao	1,723	0.95
14	Tasly Pharma Group	1,525	0.93
15	MSD	1,396	0.83
16	Taiji Group Chongqing Fuling Pharma	1,379	0.76
17	Beijing Tong Ren Tang Pharma	1,359	0.75
18	Li Shizhen Pharma Group	1,359	0.74
19	Nin Jiom Medicine Mfy	1,354	0.74
20	Roche	1,310	0.73
Subtotal Top 10		**32,771**	**17.78**
Subtotal Top 20		**47,738**	**25.90**

Source: SMEI