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Written by:

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ABOUT THE AUTHOR

China Pharmaceutical Guide is authored by James J. Shen, a veteran of the Chinese healthcare industry and market, who has dedicated his entire 27-year career to pharmaceutical businesses in China.

James Shen has rich operational and senior level management experience on China's healthcare businesses in the capacities of a senior consultant to multinational pharmaceutical companies, a manager of joint venture projects and companies, a business development executive, an entrepreneur, and most recently a publisher.

James Shen started his career in the pharmaceutical industry in 1987 when he joined Beijing Ciba-Geigy Pharmaceutical Ltd. (now Beijing Novartis) as Assistant to the General Manager. While he studied MBA in England in various periods of 1980s, he worked as an editorial consultant for Scrip/PJB Publications, IMS and Financial Times Business Information on China's healthcare news.

In 1991, he founded W*i*CON International Group in the USA to provide strategic consulting and competitive intelligence to international healthcare companies in order to assist and facilitate their market entry into China. He has worked with many large and mid-size international pharmaceutical companies on a diverse range of projects including entry strategy development, strategic alliances and joint ventures, marketing and distribution agreements, product registration and clinical trials, licensing and technology transfer, API sourcing, and M&A due diligence.

As an entrepreneur, James Shen co-founded *Beijing Jicai Pharmaceutical Technologies Ltd.* in 1992, one of the first private pharmaceutical research institutions in China, and took over its management in 2001. He is also a co-founder of *Nanjing Zinox Pharmaceutical Co. Ltd.*, an emerging generic pharmaceutical company in China.

James Shen was the Managing Editor of the well-known *IMS China Update*, a monthly newsletter covering China's pharmaceutical market co-published by IMS and W*i*CON. He authored many China healthcare business publications in English throughout 1990s, including *Marketing Pharmaceuticals in China*, *Guide to Pharmaceutical Research Institutions in China*, and *Directory of Bulk Pharmaceutical Manufacturers & Products in China*.

In early 2006, following a restructure of WiCON's businesses, James Shen founded ***Pharma China***, now the highly-respected English media and business intelligence service on China's pharmaceutical industry and market which is subscribed by almost all multinational pharmaceutical companies, CROs, consulting companies and investment banking firms active in China.

James Shen was educated in China, Europe and the USA at university and postgraduate

levels, and received an MBA from the University of Exeter (UK) in 1990.

He is now based in Princeton, New Jersey with frequent visits to China and Europe. He continues to be active in strategic consulting with multinational pharmaceutical companies at headquarter and regional head office levels.

PREFACE

Despite the enormous business opportunities and growth prospects offered by China's healthcare sector, I've witnessed and experienced countless regulatory and business environmental changes, which has frequently caused painful business difficulties, frustrations and downfalls, in my past 27 years of work in the sector as a consultant, manager and entrepreneur.

The ever-changing legal and market environments in China healthcare present the single biggest challenge to companies and executives operating in the sector. Naturally, many operational level issues and problems in the country also pose significant challenges to successful businesses.

In spite of these challenges and difficulties, the Chinese pharmaceutical industry and market have achieved remarkable growth in the past two decades. The sector is generally developing towards a positive direction in the sense that it continues to grow steadily, its regulatory regime has become increasingly compatible with international standards with improving transparency, once rampant corruption is being tackled, its ongoing consolidation will eventually help establish order and stability, and the country's new healthcare reform will ultimately led to a more stable and healthier market environment.

There are success stories from all categories of players, whether they are foreign or local, large or small, newcomer or established, private or state-owned. However, to be one of the success stories require a thorough understanding of the sector, ability to face and tackle challenges, flexibility to deal with changes, and skills to maneuver through complex situations.

It has been my wish to put my experience and observations in the past 27 years of operating in almost every aspect of China's pharmaceutical business into a publication, which will serve as a one-stop reference to anyone seeking to enter or operate in the Chinese pharmaceutical market. As of our 2007 edition, we have been adding a rising number of commentaries and contributions from many other leading pharma industry executives and experts.

Packed with hard-to-find current data and the author's expert knowledge from years of hard-earned experience in the industry, its comprehensiveness, practicality, insight, reliable data and analysis, and up-to-date information, are the features which set this the guide apart from other publications with similar titles.

This Guide is written based on my past experience, interviews with relevant industry experts and government officials, articles from Pharma China, information obtained from or published by Chinese government agencies, information obtained from or published by independent pharmaceutical industry associations, reliable data and information released exclusively to WiCON for publication from various reputable market research and consulting firms, information from other trustworthy trade journals and newspapers, related information found on the internet, and a large in-house information collection by

WiCON International Group accumulated since 1991.

About China Pharmaceutical Guide 2014 (9th Edition)

The China Pharmaceutical Guide 2014 (9th Edition) has been thoroughly updated with ample latest data from many reputable sources, abundant analysis by leading industry experts, new regulations and more case studies. Its coverage was renewed and expanded significantly in the following areas:

- ☞ Hundreds of pages of new data, information, analysis and case studies.
- ☞ Thorough summaries and analysis of the latest healthcare reform, drug pricing & reimbursement and hospital tender purchase policies.
- ☞ Comprehensive industry, market and international trade data as well as health statistics are updated with the 2013 (full year) and early 2014 figures.
- ☞ Expanded coverage on the primary healthcare sector, the OTC and consumer healthcare sector, high growth market segments, key regional hospital markets, the pharmaceutical distribution sector and online retail pharmacy segment.
- ☞ Updated coverage of the Chinese biosimilar market prospects and regulatory outlook.
- ☞ Updated coverage of emerging legal issues (including latest Chinese government crackdown on corruption in healthcare, FCPA/compliance and liability issues) and drug-related IP and trademark concerns.
- ☞ Comprehensive top line data, research findings and observations from our collaborative partners such as IMS Health, Kantar Health, Nicholas Hall, ZS Associates and RDPAC, as well as other reputable sources including the Chinese Pharmaceutical Association, SMEI and Sinohealth.
- ☞ All regulatory changes in 2013/2014 are updated to present a clear and most up-to-date picture of the Chinese drug regulatory framework with summaries and analysis of all drug regulations in effect by mid-2014.
- ☞ Focused coverage of China's deepening reform of its drug registration and evaluation regime, new policies to support drug innovation and high clinical value generics, and its initiative to re-evaluate all generic drugs with bioequivalence studies.
- ☞ An updated section covering proposed new drug-related laws and regulations under drafting process with previews of the draft versions.
- ☞ Extensive review and analysis of China's drug registration applications and approvals as well as Chinese drug innovation trends in recent years.

- ☞ Comprehensive review of Sino-foreign M&A, joint venture, strategic alliance, licensing, research partnerships, co-marketing, and new drug research events in 2013 and early 2014.
- ☞ Expanded coverage on MNC strategies in China with healthcare reform in the backdrop, intellectual property/patent law amendments, data exclusivity, patent litigation, drug regulations, pharma marketing and distribution strategies, drug consumption patterns, the Chinese R&D and outsourcing sector, clinical studies/practices, healthcare reform, community healthcare sector, essential drug policy, regional drug consumption patterns, and the vaccine and API sectors.
- ☞ Numerous new case studies are added to the 2014 Edition.
- ☞ Comprehensive revision of the China operation profiles of MNCs to reflect their latest performance, business deals, legal disputes and outlook.

I would like to take the opportunity to thank all those organizations and individuals who contributed to this publication and their continued cooperation is greatly appreciated.

James J. Shen

June 30, 2014

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ADR – Adverse Drug Reaction

API – Active Pharmaceutical Ingredients

APP – Administrative Protection of Pharmaceuticals

AmCham – American Chamber of Commerce

CAGR (Compound Annual Growth Rate)
CCCIEMHP – China Chamber of

CFDA – China Food and Drug Administration (formerly State Food and Drug Administration or CFDA)

Commerce for Import & Export of Medicines and Health Products

CNCM – China National Corporation of Medicines

CAPC – China Association of Pharmaceutical Commerce

CNY – Chinese Yuan

CRO – Contract Research Organization

DRGs – Diagnosis Related Groups

ED – Erectile Dysfunction

FDI – Foreign Direct Investment

FIEs – Foreign Invested Enterprises

GCP – Good Clinical Practices

GDP – Gross Domestic Products

GLP – Good Laboratory Practices

GMP – Good Manufacturing Practices

GSP – Good Supply Practices

IFPMA – International Federation of Pharmaceutical Manufacturer Associations

JV – Joint Venture

M&A – Merger and Acquisition

MIIT – Ministry of Industry and Information Technology

MOFCOM or MOC – Ministry of Commerce

MOF – Ministry of Finance

MOH – Ministry of Health

MoHRSS – Ministry of Human Resources and Social Security

NHFPC – National Health and Family Planning Commission

MNC – Multinational pharmaceutical companies (*in the context of this guide*)

MR – Medical Representative

NBS – National Bureau of Statistics

NCGHSR - National Coordination Group for Healthcare System Reform

NDRC – National Development and Reform Commission

NHFPC – National Health and Family Planning Commission

OECD – Organization for Economic Co-operation and Development

OTC – Over the Counter

QA – Quality Assurance

QC – Quality Control

PRC –People's Republic of China

R&D – Research and Development

RDPAC - R&D-based Pharmaceutical Association Committee in China

SATCM – State Administration of Traditional Chinese Medicine

SDA – State Drug Administration

CFDA – State Food and Drug Administration of China (now China Food and Drug Administration or CFDA)

SIPO – State Intellectual Property Office

SMEI – Southern Medicine Economic Institute under the CFDA

SOE – State Owed Enterprise

SPAC – State Pharmaceutical Administration of China

STD – Sexually Transmitted Disease

TC – Therapeutic Class

TCM – Traditional Chinese Medicine
USTR – US Trade Representative
VAT – Value Added Tax
VC – Venture Capital
WM – Western medicine
WHO – World Health Organization
WTO – World Trade Organization

EXECUTIVE SUMMARY

James J. Shen

China's full-year GDP growth in 2013 came in at 7.7%, steady from 2012 and just slightly above market expectations for a 7.6% expansion and the official target of 7.5%. Well, official figures can say whatever the Chinese authorities want them to say, but there is widespread agreement among observers that the country's economy is suffering a longer-term slowdown.

Beijing has been saying it will accept slower growth as it tries to reshape the economy toward sustainable growth that is based on consumer demand, after three decades of breakneck expansion driven by exports and credit. The history of transitions from export-led models doesn't make for pretty reading. These transitions for Japan in 1973 and South Korea in 1991 led to sharp slowdowns in economic growth.

Meanwhile, a few analysts warned about the possibility of China's economy heading for a crash in 2014. Such bearish predictions are often dismissed casually, with the vast majority of economists and policymakers being sanguine about the country's economic prospects, pointing to still healthy data and confidence in recently-announced structural reforms to steer China in the right direction.

Continued slowdown of pharmaceutical sector growth last year

As predicted, the *Year of Black Water Snake (2013)* brought lots of unexpected changes, instability, and changeability to the sector, while the previous *Year of the Water Dragon (2012)* was generally more auspicious by comparison despite some anticipated turbulences. It is well known that the Chinese pharmaceutical industry, especially research-based MNCs, were overwhelmed for the most part of last year by selective government crackdown on unethical marketing practices and intensified pressure on prices of originator and premium branded drug products.

By large the Chinese pharmaceutical sector still saw double-digit growth in 2013 despite a host of challenges stemmed from slowing Chinese economy, regulatory shakeups, cost containment measures and price cuts, as well as healthcare reform turbulences. Revenue and profit growth last year inherited the down trend from 2012, although their rates were still considered robust compared with the global pharmaceutical industry and most of other Chinese industries.

Overall pharma industry and subsector performance

Total output value for the Chinese pharmaceutical industry is expected by the Southern Medicine Economic Institute (SMEI) under the CFDA to grow 20.45% for 2013, reaching a total of CNY 2,270 billion (US$372.6 billion). The predicted growth is in par with that of 2012, although official data shows that the industry's revenue growth slowed again in the second and third quarters of 2013, after rebounding marginally in the previous three quarters.

The Chinese pharmaceutical market at the retail level is estimated to reach a total of CNY 1,145.8 billion, up 17.5% year on year, according to Sinohealth Pharmaceutical Consulting Group's *Bluebook for Analysis of Six Chinese Drug Consumption Terminal Markets (2012-2013)*.

Separately, Business Monitor's newly-published *China Pharmaceuticals and Healthcare Report Q1 2014* also predicts that the Chinese pharmaceutical market size would grow 17.5% in local currency and 19.6% in US dollar terms. The company also expects the Chinese healthcare expenditures to grow from CNY 2,845.6 billion (US$451.1 billion) in 2012 to CNY 3281.6 billion (US$527.6 billion) in 2013, up 15.3% in local currency terms and 17.0% in US dollar terms.

IMS suggests that the overall Chinese pharmaceutical market rose 14.5% in 2013 and it replaced Japan as the second largest pharmaceutical market in the world, two years earlier than estimated. The Chinese hospital drug market also grew 13.4% in the same year to CNY 550.7 billion at hospital purchase prices. The market continued a growth downtrend due to restrictions on antibiotic usage, price cut and cost containment in major cities.

Sinohealth also projects the Chinese retail pharmacy market to be CNY 198.5 billion in 2013, up 10.4%. On the other hand, Data from *IMS PharmaTrend*, a retail pharmacy audit covering 288 prefecture level cities, indicates that the growth of Chinese retail pharmacy market rose to 10% in 2013 (from 6.4% in 2012), reaching a total size of CNY 101.7 billion.

Specifically on the Chinese OTC drug market, Nicholas estimates the Chinese OTC drug market (OTC drug sales in all retail channels, prescription sales of OTC-registered brands plus packaged herbal medicines (including branded TCMs) to be US$18,030 million at manufacturer-suggested price (MSP) in 2013, up 6.8% year on year. The growth last year resulted from more OTCs being prescribed via hospitals and more branded OTCs being consumed by the rural population.

2013 added more than 60 B2C retail drug sales approvals and the size of Chinese online pharmacy market should have reached CNY 4.0 to 4.5 billion in 2013, according to ZHANG Yong, Secretary General of the Chinese Online Pharmacy Society (COPS). Drug sales is estimated by Zhang to account for only 45% of Chinese online pharmacy sales and the rest 55% are made up by healthcare supplements, contraceptive products, contact lenses and home medical appliances.

Last, but not the least, the Chinese import and export trade of medicines and health products grew 10.27% in 2013 to US$89,693 million in 2013, according to the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCIEMHP). Among the total, export increased 6.84% to US$51,180 million while import rose 15.17% to US$38,513 million. Growth of both import and export slowed in 2013 and China's surplus of such trade narrowed 12% in the year to US$12,666 million. While the country's total foreign trade in the pharmaceutical industry increased, a significant portion of the uptick was due to higher domestic demand for premium quality drugs from abroad, which led to increased imports.

Government reorganization reinforces drug regulatory regime as NDRC struggles with drug price reform

In early 2013, the new Chinese leadership engineered a major reorganization of China's healthcare regulatory regime to streamline jurisdictions and processes and to improve efficiency and strengthen regulation.

Developments were across many different areas of drug regulation last year with the newly-created CFDA remaining to be preoccupied with promotion of drug quality and registration/evaluation efficiency.

On the front of drug pricing, NDRC, which was minimally affected by the government reorganization, is still overwhelmed by stakeholder disputes and has failed to make up its mind about the reform direction for another year.

Central government reorganization

Reorganization of central government agencies under the State Council began in late March with the establishment of a few new agencies. In healthcare, the National Health and Family Planning Commission (NHFPC) was officially inaugurated on March 18 to replace the Ministry of Health (MOH) and the National Population and Family Planning Commission (NPFPC). Days later, the China Food and Drug Administration (CFDA) was officially inaugurated merging the former CFDA and relevant food and drug regulatory functions under a number of other central government agencies. In order to cope with its sharply expanded jurisdictions, CFDA sought to simplify, consolidate and decentralize some of its responsibilities in phases over a few years.

While reinforced standing of CFDA in drug regulation has been rather productive, resulting in improved legal framework, higher efficiency and better enforcements last year, outcomes from boosted role of the NHFPC in healthcare reform has been rather mixed, given the agency's vested interest in and official responsibilities for the state-owned hospital sector.

Drug registration and review

CFDA, the predecessor of CFDA, kicked off last year with a new policy, "*Opinions on Deepening Drug Evaluation and Approval Reform and Further Encouraging Drug Innovation*" in February 2013. The document seeks to improve the Chinese drug registration regime, enhance the efficiency and standards of drug evaluation, and accelerate review and approval of selected innovative and generic drugs.

It also issued the *Plan for Bioequivalence Study of Generic Drugs* which mandates phased compulsory bioequivalence studies for all generic chemical drugs approved before October 1, 2007 and preliminary development of the list for reference originator drugs. Through the process, the agency hopes to raise overall level of generic drugs in China to or near "advanced international standards". This requirement would begin with selected essential drugs in 2013 and then be expanded to other generic drugs between 2015 and 2020.

Drug quality and safety

CFDA pushed hard in 2013 on implementation of the new 2010 GMP and 2013 GSP, which went into effect on June 1, 2013 and requires phased full implementation before the end of 2015. As of the beginning of this year, the 2010 edition of GMP was fully implemented for sterile drug products.

In a bid to improve clinical research quality in China, the Center for Drug Evaluation (CDE) under the CFDA announced on September 17, 2013 the completion of its Drug Clinical Trial Registration and Information Public Platform (www.chinadrugtrials.org.cn). A few days earlier, the agency issued its No.28 Announcement which requires all its approved clinical trials in China to register and publish information on the platform. Similarly, the agency released in late 2013 a series of rules and guidelines to improve quality control of vaccine clinical trials and production.

Drug pricing reform and antitrust enforcement

Instead of earlier proposals to focus regulatory efforts on drug sales margins in the distribution process, NDRC has reportedly turned to three new options for drug pricing reform since mid-2013: 1) abandoning the approach to set maximum retail prices of drugs which is now viewed by some experts as an outdated regulatory model and ineffective against irregular drug sales margins in the distribution process; 2) trials of uniform drug reimbursement guidance price system under which NDRC will put emphasis on uniform reimbursement prices of the BMI system with excess costs above such prices to be picked up by patients, thus encouraging price competition among pharmaceutical companies; and 3) the issue lingers on as to if China should maintain the existing separate pricing policy of off-patent originator drugs.

The agency's latest move in December 2013, the *Notice on Improving Price Regulation of Low-cost Drugs*, reflects to some extent its new ideas about drug regulation. The document defines low-cost drugs as "those drug products priced relatively lower among similar drugs for a given indicated disease". Government-set maximum retail prices are withdrawn for such drug products and, instead, daily average consumption limits are set. Below the limits, manufacturers are free to set their prices which should be filed with provincial level price authorities.

In a separate development, the NDRC indicated in late 2013 that it would continue to crack down on excessively high prices in six industries (including the pharmaceutical industry) through enforcement of anti-price monopoly laws and regulations.

Slow and superficial progress seen for healthcare reform in 2013

Plagued by structural flaws, inadequate government financing as well as conflict of interests among different agencies and stakeholders, China's ongoing healthcare reform remained to be bottlenecked in 2013 despite some superficial progresses.

It is understandable that the *Third Plenum of the 18th Party Congress* had little to say about the ongoing healthcare reform other than calling to deepen it. Indeed, all top-level reform plans over healthcare seem to be well-developed and it is the actual funding and execution at the local levels that have been holding things up.

The central government, nonetheless, claimed victory as usual with release of various

official data to show progress as perceived by them on different reform fronts as well as their plans forward. Let's take a look at these as follows.

National policy environment and central government funding

The State Council issued a new policy, *Certain Opinions for Promoting Development of Healthcare Services*, in October 2013. The document sets a target of boosting the gross value of China's healthcare service sector to over CNY 8 trillion (US$1.31 trillion) by 2020. Central government subsequently allocated CNY 2.22 billion (US$358.3 million) to the healthcare service sector to improve well-being and shore up growth as provided the new policy. The new policy is expected to create a more favorable environment for private capital in the sector. It also demands relevant authorities to take advantage of TCM in disease prevention and healthcare.

Earlier, the NHFPC and the Ministry of Finance (MOF) issued a joint notice calling for the elevation of per capita funding for the New Rural Cooperative Medical Scheme (NRCMS) to CNY 340 in 2013. This meant the total NRCMS funding would reach a total of over CNY 280 billion, an expansion of CNY 41.6 billion compared with 2012.

BMI and major medical coverage

A document recently released by the Ministry of Finance, *Explanatory Notes for Final Accounts of National Social Security Funds in 2012*, shows that the urban employee basic medical insurance (BMI) and the urban resident BMI programs had annual surpluses of CNY 118.3 billion and CNY 26.8 billion respectively in 2012. By the end of 2012, both programs had accumulated surpluses of CNY 668.2 billion and CNY 161.1 billion respectively, totaling CNY 829.3 billion. With such huge annual and accumulated surpluses, it seems unfounded for the Chinese government to continue preoccupying itself with healthcare cost containment. But some analysts argue that, while the BMI programs show huge surpluses nationally in the past few years, the health of local BMI funds deviate sharply across the country.

Never mind the surpluses, Ministry of Human Resources and Social Security (MOHRSS) said in late 2013 it would deepen reform of BMI payment schemes, fully implement overall BMI spending caps, conduct trials of real time BMI surveillance systems, strengthen regulation of medical services, investigate and improve provisions for out-of-territory BMI reimbursement, and push forward trials of urban and rural resident major medical insurance.

As to major medical insurance programs, MOHRSS reported in October 2013 that a total of 23 provincial level governments had introduced implementation plans for major medical insurance programs in their jurisdictions and 120 trial site cities had been selected.

Public hospital reform

In late 2013, the Chinese government reported completion of its preliminary assessment of the experiment for phasing out the 15% drug sales margin in county level public hospitals. Public hospitals in 311 national trial site counties have all removed the margin and the measure has also been fully implemented in county-level public hospitals

province-wide in Shaanxi, Anhui, Zhejiang and Qinghai provinces.

The county level public hospital reform is therefore deemed by the State Council's Healthcare Reform Office to be "successful at this stage" and it has subsequently announced its plan to initiate the second round experiment of county level public hospital reform at the end of this year and full public hospital reform implementation nationwide in 2015.

Essential drug system (EDS)

The MOH issued the 2012 Edition of *National Essential Drug List* (NEDL) which went into effect on May 1, 2013. As previously speculated, the new list contains a total of 520 drugs including 317 chemical drugs and biological products as well as 203 formulated traditional Chinese medicines. What came as a surprise is that the accompanying official notice is very low key with how the new NEDL should be implemented locally. Such an approach may weaken the role of this new NEDL and lead to substantial regional variances for future implementation.

To support implementation of the 2012 NEDL, the government plans to introduce a range of complementary policies to support its implementation. The NHFPC sought industry comments in late 2013 on a proposed new policy, *Rules for Expanding Essential Drug Consumption*, which proposes to set a minimal 40% ratio for essential drug consumption in level II and III public hospitals.

In the meantime, the central government has ordered provincial level governments to conduct thorough reviews and strictly control the number of essential drug supplements to the new 2012 NEDL repeatedly, but a string of local governments, including Jiangxi, Shanxi, Guangdong and Qinghai provinces and Chongqing, have ignored central government mandates and expanded their provincial level EDLs substantially, while other local governments such as Hunan, Jiangxi, Shaanxi and Jilin provinces as well as Shanghai have pledged not to escalate their local EDLs.

National Drug Reimbursement List (NDRL)

There are growing gossips among industry insiders that the existing NDRL will be reviewed with a new list likely to be released within 2014. Earlier rumors pointed to start of the review process in November 2013 with a new NDRL released in mid-year. It is suggested that the government will try to maintain the same number of drug products in the NDRL. There has been no response to such speculations so far.

Nonetheless, industry analysts expect the number of drug products in the new NDRL to increase and they suggest the matter to be clouded by many uncertainties and therefore it is even optimistic to expect release of the new NDRL before the end of 2014.

Factors affecting the revision of NDRL include implementation progress and results of the 2012 NEDL and provincial level essential drug supplemental lists, major medical insurance programs and low-cost drug lists at the local government levels. These reform measures need to be integrated with the new NDRL. In addition, uncertainties surrounding the central government-proposed integration of China's three BMI programs, namely the urban employee BMI program, urban resident BMI program and NRCMS, are expected to

affect the NDRL revision progress significantly.

Centralized hospital drug purchase tenders

2014 is a year when most provinces are expected to execute their respective centralized drug purchase tenders. As such, the NHFPC revealed its policy outlook for tenders in November 2013 including: 1) policy documents setting out specific ratios for essential drug consumption by all levels of hospitals are likely to be issued in December this year; 2) price cut of non-essential drugs will be in the spotlight again next year; and 3) prices of off-patent originator drugs may be targeted for further reduction.

Cost reduction of non-essential drugs will be moving to the top of government agenda in 2014, suggested relevant government officials at a NHFPC event in late 2013. They hope to achieve this objective through further price cuts and modification of tender purchase policies, such as eliminating or reducing policy preference of originator drugs at tenders.

Fighting corruptions in healthcare

In its latest attempt to crackdown on widespread corruption in the Chinese healthcare sector, the NHFPC unleashed two new measures before the end of 2013. The first is the *Notice on "Nine Prohibitions" to Strengthen Healthcare Industry Compliance* which sets out comprehensive anti-corruption requirements to be observed by hospitals and physicians, and expressly prohibits nine types of non-compliant activities, while the second is the amended *Provisions for Establishing Bad Records of Commercial Briberies in Medical & Pharmaceutical Sales & Purchase* with effect on March 1, 2014, updating a "blacklist system" on pharmaceutical and medical device companies that are convicted of commercial bribery.

MNCs remain committed to China despite wrath of government crackdown and strengthened domestic competition

The tumultuous Chinese healthcare marketplace took a breath in the first half of 2013 before the new Chinese leadership began to show their prowess with new directions, policies and actions.

As such, the year of 2013 had a good start with renewed optimisms following release of slower but still inspiring 2012 industry data, impressive annual growth reported by both domestic and MNC players, as well as proactive investment plans, pledges of ambitious expansion, and an uptick of business activities such as joint ventures, strategic alliances and licensing.

But the business climate for the pharmaceutical industry in China, took a sudden turn in late May when dramatic police investigation of GSK corruption scandal began with arrests and later public parades on TV of the company’s senior executives, consultants and related travel agents.

Chinese government targets MNCs for selective law enforcement

Government crackdown on corruption in drug sales dominated the pharmaceutical business landscape for the 2nd half of 2013 and the first half of 2014, and substantially affected performance of the Chinese pharmaceutical industry, especially MNCs. Initial

government actions obviously targeted at MNCs with the hidden agenda of pressuring them into cutting premium drug costs.

From start of the GSK investigation, the Chinese media has been filled with negative news on MNC drug giants. A growing list of multinational companies, including UCB, AstraZeneca, Sanofi, Novartis (including its Alcon division), Novo Nordisk, Baxter and Eli Lilly, reported visits and investigations by various government agencies. Some of these cases seemed planned, while many others were triggered by copycat whistleblowers or media reports.

Regardless of what the initial targets of the Chinese government were, the shock wave spilled over to domestic players as of last September as corruption allegations by insiders become almost viral. Leading Chinese companies, starting with Gan & Lee Pharma and followed by Chiatai Tianqing, EddingPharm, Shanghai Pharmaceutical Group and SinoPharm Group, were drawn into the mud pool of corruption in drug sales.

Pressures from the government have cowed a number of MNCs, in particular GSK, into pledging to lower costs of their products at least superficially to win government lenience. In reality, none of these companies have come out with concrete and voluntary price cuts and the pressure on them to do so is subsiding.

MNCs also began to fight back the Chinese government hostility through their home governments and trade associations. Examples include British Prime Minister speaking up for GSK, criticisms of EU Chamber of Commerce in China on unfair treatment of foreign companies, call by EUPIA for better transparency of corruption probes, and release of a position papers by RDPAC and PhRMA to urge drug quality improvement. At the same time, RDPAC also tried to mend fences for MNCs by letting go the membership of GSK for now and entering an agreement to implement "*Codes of Ethics for Chinese Pharmaceutical Enterprises*", which is originated from APEC's Mexico City Principles, with eight other Chinese pharmaceutical industry associations.

On the part of GSK, the company cleverly aired about its frustration through leaking internal talks of abandoning China and then denied it publicly. It also followed up with cooperative attitudes with the Chinese investigation, pledges to stay put in China and concrete steps to reform its sales practices. Most recently, Actavis made a high profile announcement to exit China because of the country's "unfriendly business climate".

These moves have softened and pressured the Chinese authorities at the same time. Through various channel, the government conveyed its continued friendliness and support to foreign investment and pharma MNCs. Apparently this may have contributed to the slow progress of the ongoing investigations and probably even indecisions as to how these cases should be wrapped up.

It is notable the NHFPC released two new anti-corruption measures in December 2013, indicating its commitment to combat corruption in healthcare. Earlier, the NHFPC and a number of other central government agencies also pledged to bolden the fight against commercial briberies in drug sales for three years beginning 2013.

Before MNCs found any relief from seemingly subdued government actions, new worries

arose from the official GSK investigation that lasted ten long months which has now culminated in the Chinese police charging the former China head of GlaxoSmithKline with bribery. Officials from the Ministry of Public Security (MPS) alleged that the executive, U.K. national Mark Reilly, ordered his sales team and other employees to bribe hospital doctors, medical institutions and other parties on "a large scale" to boost drug sales in China.

Rather than laying all the blame on individual GSK executives, the the official mouthpiece Xinhua pointed to corporate GSK for premeditation and systematic execution of various bribery practices as well as deliberate cover-ups, indicating the government's intention to hold the company responsible.

What came as a surprise to many, Xinhua centered substantial firepower on GSK's extraordinary profits in China and accused the company of moving profits overseas through transfer pricing and re-packing arrangements. By keeping huge profits off-shore, GSK was able to finance large scale commercial bribery activities in China, Xinhua alleges.

Besides, in the aftermath of GSK scandal, MNCs were also alerted by what's taken place in Hangzhou, where Roche's offices were raided by local industry and commerce officials. In addition, a number of other MNC companies including Eli Lilly, AstraZeneca and Novo Nordisk are reportedly handpicked by the local health department as primal targets for corruption investigations.

Confidence cracked but not shaken, MNCs remain committed to China

Big Pharma thought China had the cure for two conditions the global pharma industry had long endured: anemic sales growth in developed markets and revenue erosion because of competition from generics. Yet after a few boom years, the China effect has started to fade as the country’s economic began to slow and cost containment took over the center of healthcare reform in the last couple of years. In addition, U.S. and European pharma companies face a number of hurdles in their quest for greater access and faster growth in China where they are facing more intense competition from domestic players.

China is also becoming a bigger headache, McKinsey said. The business models that presented drug makers with solid growth in China are now under pressure. The risks of operating in China, such as the anti-bribery investigation and volatility caused by price cuts and tender timings, as well as protectionism, are now on the rise.

But MNCs seem ready to stay committed at least for now with its original plans of investments, business expansion and strategic alliances in China. Business activities of foreign companies only dampened shortly in the third quarter of last year and they gradually resumed towards the end of last year.

Last year, the name of China investment game for MNCs was R&D and manufacturing capacity expansion in the country to meet rising local and international demands. Many of them, including Pfizer, J&J, Boehringer Ingelheim, AstraZeneca, MSD, Merck Serono, Eli Lilly, Sanofi and GSK, proceeded with new projects and made major business maneuvers in the country.

There are no easy solutions for MNC players in China. Companies will need to boost compliance structures, reform business models, refocus China strategies, form more R&D and business partnerships with local companies, target diseases prevalent to China, leverage China's R&D and manufacturing capabilities globally, and integrate commercial investment plans with government objectives.

Improved performance of domestic drug companies

As MNCs were grilled by the government over compliance and price reduction, Chinese companies remained mostly intact last year and were in high spirits for business expansion. Many of them, especially leading domestic players, benefited from the fall of pharma giants like GSK.

By the end of 2013, 55 publicly-listed Chinese drug companies issued guidance for their 2013 performance. 42 or 76% of them predicted better results for the year, while only eight or 15% anticipated falling performance and three or 5% foresaw losses. Six companies expected more than 100% and 23 companies forecasted between 30% and 100% net earnings growth. By comparison, only 66 or 62% of the 107 listed Chinese pharmaceutical companies expected their profits to grow in the first half of last year before the GSK scandal.

Other than picking up lost grounds of MNCs, industry observers suggest that these listed companies with improving performance last year benefited significantly from earlier R&D investments into new and specialty drugs. It is hoped that downstream integration of hospital business by domestic companies would become yet another growth driver for them.

In the meantime, leading Chinese companies continued to push forward their international business expansion plans with substantial investments into regulatory compliance. By the end of July 2013, Chinese pharmaceutical companies had submitted a total of 1,532 DMF files to the USFDA and gained 463 COS certifications from EDQM, according to a recent article of *China Pharmaceutical News*. In addition, 37 Chinese finished drug producers received GMP certifications from regulatory authorities of EU, U.S. and Japan, and five were granted GMP certifications from the WHO.

Chinese players are taking more aggressive paths to expand their international business in recent years. Such endeavors include acquisitions of foreign companies, joint ventures with local companies, setting up foreign subsidiaries and research units, as well as licensing and co-development deals.

Cross-border licensing and R&D partnerships remained a hotspot in 2013

The Deals Monitor of *Pharma China* recorded a total of 48 events in the last quarter and 145 events in 2013. The leading categories of events last year were licensing deals (38) and M&A deals (38), followed by contract research/collaborative R&D (26) and joint venture/strategic alliance agreements (23).

Representing 92% all recorded licensing events last year, the number of Sino-foreign/foreign-foreign licensing deals surged 17% to 35 in 2013 compared with 30 in 2012 and only 22 in 2011.

There were also a total of 26 contract research/collaborative R&D deals recorded last year, down slightly from 29 such transactions in 2012. Among all such deals, 24 Sino-foreign contract research and collaborative R&D deals were recorded in 2013.

Chinese companies dominated heated M&A space

Domestic Chinese companies stayed on as the driving force behind the heated pharmaceutical M&A landscape in 2013. Leading state-owned conglomerates such as SinoPharm, China Resources and Shanghai Pharmaceutical continued to be active players of M&As. China and Hong Kong-listed drug companies as well as smaller players seeking IPOs also bought hard to expand business, diversify or improve product pipelines, while many overseas-listed players lost steam for M&As as they labored to exit the unfriendly foreign stock markets.

The number of major M&A deals recorded by *Pharma China* in 2013 (37) was roughly on par with 2012 (38) and 2011 (36), while the number of M&A agreements between Chinese and foreign companies last year (14) was down considerably from such deals in 2012 (18). Deals among domestic companies (23) accounted for 61% of all recorded M&A events last year.

On the other hand, there is a sustaining trend that Sino-foreign joint ventures are back in favor again in the pharmaceutical industry in the past couple of years.

Old IP issues remaiedn as China undertook drastic IP and antitrust enforcements

A wide range of Chinese policies and practices in 2013 continued to generate significant concerns among foreign companies operating in China. Major issues included China's export restraints, investment restrictions, serious problems with IP rights enforcement, indigenous innovation policies, technology transfer initiatives, government subsidization, inappropriate use of trade remedy laws, and China's slow movement toward accession to the WTO Government Procurement Agreement, according to USTR's *2013 Report to Congress on China's Compliance with WTO*.

A range of developments and concerns are highlighted by the report specifically in the pharmaceuticals sector:

- *Pharmaceutical patents* - Of particular concern is China's State Intellectual Property Office (SIPO)'s interpretation of Article 26.3 and related provisions of China's Patent Law, which govern information disclosure requirements for pharmaceutical patent applications. As a result, pharmaceutical patent applications granted by U.S. and other leading patenting authorities are denied only in China. In addition, patents granted prior to the adoption of the more restrictive standards have been vulnerable to invalidation challenges in China based on the retroactive application of those standards.
- *Data exclusivity* – Foreign companies continues to be concerned about the extent to which China provides effective protection against unfair commercial use of, and unauthorized disclosure of, undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. However, Chinese law does not

include an appropriate definition of the term "new chemical entity" for purposes of identifying new pharmaceutical products entitled to protection;

- ☞ *Regulation of bulk substances for APIs* – China is urged to adopt comprehensive reforms to ensure that all Chinese producers of bulk chemical and biological substances capable of being used as APIs for medicinal products be subject to CFDA's registration requirements and operate in compliance with GMP;
- ☞ China committed to allow foreign suppliers to distribute pharmaceuticals by December 11, 2004. Despite overall progress in this area, many restrictions affecting the pharmaceuticals sector continue to make it difficult for foreign pharmaceutical companies to realize the full benefits of China's commitments;
- ☞ *Price control* - In its WTO accession agreement, China agreed that it would not use price controls to restrict the level of imports of goods or services. China agreed that it would try to reduce the number of products and services on this list. In 2013, China continued to maintain price controls on several products and services including pharmaceuticals; and
- ☞ *Counterfeit Drugs* - Despite repeated anti-piracy campaigns in China and an increasing number of civil IPR cases in Chinese courts, overall piracy and counterfeiting levels in China remained unacceptably high in 2012. IPR infringement continued to affect products, brands and technologies from a wide range of industries including, among many others, pharmaceuticals.

In the fields of IP and antimonopoly law enforcement, 2013 saw two drastic actions by China intellectual property enforcement which are likely to have far reaching impacts and provide hints on future directions for such issues.

First and foremost, the SIPO’s Patent Reexamination Board has declared the entire patent of Gilead Sciences's HIV/AIDS and hepatitis B drug Viread (tenofovir) invalid, after a challenge brought by a local Chinese firm Aurisco, which pointed to deficiencies in the drug's patent on novelty grounds.

SIPO announced a change to China's IP laws in 2012 permitting compulsory licensing, when sources indicated Viread as one of the government's targets. Gilead Sciences reportedly responded to the threat by offering substantial donations of Viread if purchasing levels were maintained, but this evidently was not enough. Rather than demanding a compulsory license for Viread, China chose to revoke Gilead's patent on the drug altogether.

In a separate development, A Shanghai court ordered two Chinese Johnson & Johnson subsidiaries to pay a pharmaceutical distributor CNY 530,000 (US$85,800) in compensation for monopolistic pricing practices in August 2013.

The contract signed between Rainbow Medical and the Johnson & Johnson subsidiaries was a typical vertical monopoly agreement, said HUANG Yong, a consultant for the country's anti-monopoly committee and a professor at the University of International Business and Economics.

"China has begun to refer to the legal practices of the United States and the European Union and punish vertical monopoly practices," said Huang. "This will protect price competition and not hinder commercial choices of enterprises."

2013 also saw stream of antitrust investigations by Chinese regulators which sought to toughen enforcement of the country's anti-monopoly law enacted in 2008. In particular, authorities are paying attention to whether manufacturers are forcing retailers to set minimum prices for products.

Other IP developments include introduction of the third amendment to the trademark law which will come into force on May 1, 2014. The amended trademark law is praised by many experts to be a significant improvement on the past version of the trademark law.

Guarded outlook for 2013 with lots of uncertainties ahead

Even with the new Chinese leadership and the communist party recently reinstating its pledge to continue broad economic and healthcare reforms, the near future remains clouded by uncertainties and challenges ahead, which are underlined by the unrelenting Chinese economic slowdown.

The ongoing healthcare reform is ambitious but inadequately funded by the government from the start and it is further complicated by an imbalance of financial responsibilities between local and central governments. Excessive financial burdens on local governments compel them to rely excessively on cost containment to finance healthcare reform and lead to premature failures as well as uneven regional implementation of many reform measures across the country.

Despite turbulences and growth rate fallbacks in recent years, most experts continue to agree that China is set to become the second-largest pharmaceutical market by 2020, and ultimately, the largest one in the world.