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China Pharmaceutical Guide

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Written by:

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Unrivaled China Healthcare Intelligenece Since 1991

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China Pharmaceutical Guide is authored, edited and published by James J. Shen, a veteran of the Chinese healthcare industry and market, who has dedicated his entire 30-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 **W*i*CON | *Pharma China***, 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 Beijing with frequent visits to the U.S., Europe and Japan. He continues to be active in strategic consulting with multinational pharmaceutical companies at headquarter and regional head office levels, as well as selective entrepreneurial and VC/PE investment projects in the Chinese healthcare sector.

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 30 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 29 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 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 2017 (12th Edition)*

The *China Pharmaceutical Guide 2017 (12th Edition)* is organized into the following four volumes:

Volume I – *Overview of the Chinese Pharmaceutical & Healthcare Sectors* (covering update of China's business environment, history and structure of the Chinese pharmaceutical industry, Chinese health sector structure and statistics, health insurance sector structure and data, as well as disease and drug consumuption patterns);

Volume II – *Chinese Pharmaceutical IP and Regulatory Guide* (covering the Chinese drug regulatory system overview, summaries of major healthcare/pharmaceutical related laws and regulations, government agencies and industry associations and pharma IP strategies & legal issues);

Volume III – *Annual Review, Trends, Opportunities and Strategic Considerations* (including a complete review of latest data, business trends, regulatory & IP/legal developments and healthcare reform progress of the Chinese pharmaceutical industry and market in 2016/1H2017, and a large collection of feature articles from industry experts relating to competemporary trends, issues and strategic considerations as well as promising opportunities of the present and future); and

Volume IV – *Sales & Marketing, Entry Strategies and Case Studies* (covering orientation, models and strategies of pharmaceutical sales, marketing and distribution in China, marketing entry strategies and execution, case studies featuring success stories of MNCs and domestic players, R&D and outsourcing, human resource management and legal/IP issues), as well as appendices with full texts of important healthcare/pharmaceutical related policies, laws and regulations.

It is 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 foreign trade data as well as health statistics are updated with the 2016 (full year) and available figures for the first half of 2017.
- ☞ Expanded coverage on e-commerce and digital marketing opportunities, the primary healthcare sector, OTC and consumer healthcare sector, high growth market segments, regional hospital markets, and the pharma distribution sector,
- ☞ Updated coverage of the Chinese biosimilars/biologics 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, Rubicon Strategy Group and RDPAC, as well as other reputable sources including the Chinese Pharmaceutical Association, SMEI and Sinohealth.
- ☞ All regulatory changes in 2016/H12017 are updated to present a clear and most up-to-date picture of the Chinese drug regulatory framework with summaries and analysis of all pharmaceutical related regulations in effect by mid-2017.
- ☞ Focused coverage of China's ongoing efforts to revamp its drug regulatory regime through amendments of the *Drug Administration Law*, its latest proposal and preparations to overhaul the drug pricing mechanism, 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 selective 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 2016 and H1/2017.
- ☞ 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.

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

July 30, 2017

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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 Commerce for Import & Export of Medicines and Health Products

CAPC – China Association of Pharmaceutical Commerce

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

ChP – Chinese Pharmacopoeia

CMH – China Monitor Health

CNCM – China National Corporation of Medicines

CNY – Chinese Yuan

CPIIC – China Pharmaceutical Industry Information Center

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

MNCs – 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

SFDA – 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

2016 was a turbulent year for the broad Chinese economy. For the year ahead, China's Central Economic Work Conference has made "seeking progress while maintaining stability" the main theme for economic work, pledging to push for substantial progress in supply-side structural reform. The forecasting department at the State Information Center (SIC) predicts that the country's economic growth could slow to 6.5% this year from about 6.7% in 2016.

Meanwhile, things between Washington and Beijing have been on the rope since Trump won the presidential election. There will be broad impacts of Trump Presidency on the pharmaceutical industry and related China business. Trump slammed the U.S. pharmaceutical industry for producing drugs overseas even before taking office. Pharmaceutical factories in India and China, in particular, may be tempting targets, given that they've repeatedly been called out for safety and quality violations, from lying to inspectors to leaving bird droppings and black mold on the factory floor.

Trump also has a tough stance toward trade with China, which is well founded although it could be a double-edged sword for pharma MNCs. A tougher U.S. trade policy will help improve Chinese market access and IP protection of big pharma companies in general, but an all-out trade war between the two countries may result in Chinese retaliations which could very well negatively affect pharma MNC business there.

Each year there are more uncertainties surrounding China healthcare and 2017 is no exception. The pharmaceutical industry in China is facing an overhaul of its business model, fast changing marketplace and repeated assaults of its bottomlines. Indeed, there will be no more middle road for anyone, as the *Fengshui* masters say about the Chinese New Year of Rooster. Those unfit will be wiped out and those surviving will embrace a turbulent new world, which is for sure much bigger but not necessarily as profitable. What will be the name of new game? Volume over margin, perhaps?

The Chinese pharmaceutical industry revenue growth rebounded slightly in 2016 to above 10% despite shadows of numerous challenges stemmed from the troubled Chinese economy, regulatory shakeups, cost containment measures and healthcare reform turbulences, according to the *China Pharmaceutical Guide 2017 (12th Edition)* quoting official data.

The industry's core revenues and net profits are estimated to have risen 10.3% and 15.6% respectively in 2016, suggests a recent presentation by Minli Lu, Chief Consultant of China National Pharmaceutical Industry Information Center (CPIIC).

On the other hand, SMEI data shows the size of the Chinese drug market to be CNY 1,497.4 billion in 2016 at retail price level, up 8.28% year on year. The pace of growth has been falling consecutively in recent years affected by stringent drug cost containment measures, according to LIN Jianning, President of Southern Medicine Economic Institute under the CFDA (SMEI). Among the total, the size of hospital drug market, retail pharmacy drug market and primary healthcare drug market are projected to be CNY

1,024.0 billion (+7.60%), CNY 337.5 billion (+8.49%) and CNY 135.9 billion (+13.16%) respectively.

The Chinese drug market had just exceeded CNY 1 trillion in 2016, according to QuintilesIMS. Rx Western medicines dominated the hospital drug market with nearly 80% market share, while TCM market share was quite significant in the retail and the third terminal drug markets. The Chinese hospital drug sales were up 8.1% in the same year, reaching CNY 698 billion.

Ethical and OTC Western medicines as well as formulated TCMs witnessed high growth in the third terminal drug market in the year as a result of tiered medical system reform. The growth of Rx TCMs was particularly fast.

The growth of retail drug sales slowed in 2016, said QuintilesIMS, which predicts major changes with the Chinese retail drug market landscape in 2017. In retail pharmacies, Rx drug products of large MNCs experienced strong performance in 2016. 44% of retail pharmacy sales came from Rx drugs in 2016.

The sales of OTC drugs and health foods of Chinese retail pharmacy sector reached CNY 77.4 billion in 2016, up only 2.8%, continuing a slowing growth trend due to slower price rise and negative volume growth, according to IMS PharmaTrend, which monitors retail pharmacies in 41 Tier 1/2 thru 4 representative Chinese cities. Price surges remained main driver of growth with sales volume down persistently.

Among the total, sales of OTC drugs in the period were CNY 64.7 billion in 2016, up 3.7% year on year. Formulated TCMs as a subclass of OTC drugs surged 4.2%, accounting for over 66% of total OTC drug sales. However, growth rate of chemical drugs and health foods in the period were slowed to only 2.0%.

Most notably for pharmaceutical retail sales, according to SMEI, the Chinese online pharmacy drug market surged 50% to CNY 4.8 billion in 2016. The growth of this market is expected to see more explosive growth as the Chinese government liberalize its regulation.

CFDA makes marked advances with drug regulatory system reform as uncertainties continue with drug pricing reform

First and foremost, the State Council issued its #666 order in March 2016 to amend a number of administrative regulations including *the Implementation Regulation of the Drug Administration Law of PRC*. The amendment is necessary to facilitate the earlier amendment of the *Drug Administration Law of PRC* in April 2015. Meanwhile, the CFDA continues to prepare another amendment of the law to facilitate its ongoing drug regulatory reform.

Later in the year, the agency issued a new document, *Implementation Opinions for Fully Strengthening Legal Infrastructural Building for Food and Drug Regulation*, on August 16. Under the document, the CFDA pledged to complete development of the framework of laws and regulations for foods, drugs, medical devices and cosmetics before 2020. Specifically, the agency said it plans to submit a draft amendment of the *Drug Administration Law of PRC* to the State Council before the end of 2016. Nonetheless,

the pledge had not materialized by the end of January 2017.

The *PRC Law on Traditional Chinese Medicine* also found its way through China's top legislature, the Standing Committee National People's Congress, in late 2016 and it will become effective in July 2017 to give traditional Chinese medicine (TCM) a bigger role in the healthcare system.

Meanwhile, following a year of drug evaluation and approval system reform, the CFDA said at the *2017 National Food and Drug Regulatory Working Conference* in January that it has successfully established the drug evaluation project managing system, clinical value-oriented team review system, reviewer and applicant communication system, expert consultation committee system, open validation system for major disputes among reviewers and applicants, review and approval information publication system and priority review system.

The drug application backlog has been reduced to 8,863 at the end of 2016 from 22,000 at the peak in 2015, the agency disclosed. The review for clinical trial of chemical drugs and vaccines, as well as all types of applications for TCM and minority medicine registration are now under processing subject to regular official timeline requirements. Priority review status has been granted to 146 innovative drugs, drugs under urgent clinical needs, off-patent generic drugs and first-to-copy generic drugs.

On the front of drug pricing, the NDRC returned to the drug pricing theme in 2016 under a different flag. There are signs that the government is beginning to back-paddle for at least some renewed control over drug prices through antitrust enforcements.

As to the proposed uniform BMI drug payment standards, the MOHRSS has submitted its final draft for "*Guiding Opinions for Basic Medical Insurance Drug Payment Standard Development Rules (Interim)"* in November 2016 to the State Council for approval. The initial draft for comments was also not publicized, but Chinese reporters gained access to the document and reported the following components of it: 1) an essential principle of the document is to rationalize drug use, improve drug consumption behaviors and motivate designated medical institutions on the basis of securing medical service quality; 2) for drugs not passing quality equivalence appraisals and those with large quality gaps, differentiated BMI drug payment standards can be set for the same drugs produced by different manufacturers; 3) medical institutions are allowed to sell drugs at prices above the uniform BMI drug payment standards; 4) If the actual drug prices of medical institutions are lower than their respective uniform BMI payment standards, they will continue to be paid by the BMI in accordance with payment standards, while co-pay of BMI participants will still be calculated on the basis of actual prices; and 5) the uniform BMI drug payment standards are set on the basis of generic drug names in principle.

Healthcare reform stumbles on amid a matrix of government policies

By early 2017, the NHFPC claimed victories for deepening healthcare reform, elevating healthcare service quality and public satisfaction, boosting capability for public health and healthcare emergency response, and implementing the national two-child policy in

2016.

Information from the agency shows that more than 1,560 urban public hospitals have already removed drug sales margins and eliminated the model of compensating medical services with drug sales profits. It said the income structure of public hospitals continued to optimize in 2016 and medical expenditure growth was effectively controlled.

Compared with 2013, the shares of government and social funding went up by 0.8 and 3.1 percentage points while that of personal out-of-pocket funding was down by 3.9 percentage points in 2015, according to the latest information release by the NHFPC. As China's commercial health insurance sector is still tiny, it is fair to conclude that the Chinese BMI system has absorbed most of the healthcare expenditure growth and a significant drop of personal out-of-pocket share. Without sharply increased government subsidies and personal premium contributions, the question remains with the sustainability of Chinese BMI system under fast rising healthcare expenditures? Will the last straw of relentless cost cutting be enough to save the day?

On a more positive note, the share of healthcare spending in Chinese GDP rose to 6.0% in 2015 from 5.6% in 2013. Even though this figure is still very low compared with developed countries which are much less populated, progress in this direction is encouraging and the endpoint is about funding to meet the true demands of China's 1.4 billion people for good quality healthcare services.

Though China has achieved a number of milestones in healthcare advancement over the past three decades, further reforms are urgently needed, said a new report by WHO, the World Bank and the Chinese government. Escalating health care costs are set to place an unsustainable burden on citizens, underlining the need for drastic reforms, according to the study. "China needs to deepen its health reform to avoid the risk of creating a high-cost-low-value health system as observed in some high-income countries," the report underlines. "Business as usual, without reform, would result in growth of total health expenditure from 5.6% of GDP in 2015 to 9.1% in 2035, an average increase of 8.4% per year in real terms."

Meanwhile, China's healthcare reform may have a new direction under the direct leadership of President Xi Jingping in the wake of a top-level national health conference and approval of a new blueprint *Healthy China 2030* in July. Xi's Central Leaders Group for Comprehensively Deepening Reform mapped a new blueprint of healthcare reform and he put the "tiered medical service system" (TMS) on top of the five essential healthcare systems which are to become the foundation of Chinese healthcare reform. In the spirit of this new blueprint, the NHFPC held press release conferences in September 2016 to showcase healthcare reform experiences of various local governments, citing in particular their reform efforts to build the TMS, restrict excessive growth of big hospitals and elevate service capacity of primary healthcare facilities.

To begin the New Year on a high note, the State Council introduced China's *13th Five Year Plan for Healthcare Reform (2016-2020)* in early 2017, outlining the reform path forward in the next five years. The essential principles of this plan are laid out as follows: 1) Putting the health of people in the center as priority for development. The ultimate

goals are to ensure fair access, public benefits and welfare nature of basic medical services; 2) Securing basic and primary healthcare with solid infrastructure. Basic healthcare system should be provided to all residents as a public product; 3) Combining the leadership role of government and the role of market forces; 4) Persisting on supply side reform to separate government from institutions, ownership from management, medical services from drug sales, as well as for-profit from non-profit healthcare institutions; 5) Sticking to coordinated reform of medical service, health insurance and pharmaceutical sectors; and 6) Spotlighting key reforms, demonstrating reform trial outcomes and proceeding the reform orderly.

Pharma industry in the process of revamping its business model to fit in new business environment

Despite superficial slogans and touted ambitions of the Chinese government, the healthcare reform has been hijacked by cost containment and gone astray from the pledged path of improving efficiency and fixing structural flaws.

With tax and other revenues drying up and under increasing threat of BMI system deficit amid a slowing Chinese economy, local governments are pressured by both the central government and the public to do more for healthcare with less financial resources. As local governments assaulted the pharma industry above the table with wave after wave of cost containment measures, public hospitals also squeezed drug companies under the table for funds through a variety of schemes.

Pushed to the corner, the Chinese pharmaceutical industry is now at the brink of business bottomlines. Under pressures of escalating anti-corruption campaigns, increasingly sophisticated cost containment measures as well as policy shifts in drug pricing and reimbursements, both domestic and multinational drug companies had no choice but to recalibrate their strategies and business models in order to meet the challenges of the Chinese healthcare business today.

The Chinese economy and the reform of its healthcare system are once again at crossroads. Pharma companies, local or foreign, must change to remain competitive and fit with the market.

Nonetheless, many drug company executives are still bullish about China's long-term growth prospects. As the government improves access to healthcare, the country’s pharmaceutical market is projected by QuintilesIMS to maintain growth at slower single-digit rate. But the short-term picture is proving difficult, with reforms in the hospital sector affecting physician prescriptions and price pressures growing for most drugs.

Old IP flaws remained as new issues spring up amid regulatory reform and antimonopoly enforcements

The U.S. Trade Representative (USTR) recently issued its *2016 Report to Congress on China's Compliance with WTO*, which comprehensively reviews the magnitude of China’s continuing compliance problems related to intellectual property rights, including such issues related to the pharmaceutical sector, after 15 years of WTO accession.

Our case for the following contemporary IP concerns in relation to the Chinese pharmaceutical sector is built on the basis of this report.

IP and market access related issues

- Patent protection is an area of serious concern of foreign pharmaceutical stakeholders. In particular, SIPO examination guidelines governing information disclosure requirements for pharmaceutical patent applications have been revised through a series of amendments making these guidelines more restrictive.
- *Data exclusivity* - There has been persistent concern over 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 test or other data entitled to protection.
- *Delay in new drug approvals and drug regulatory reform* - This additional area of concern in the pharmaceuticals sector involves the long delays in China's review of applications for permission to market new and innovative pharmaceutical products in China and for these products to be placed on approved reimbursement lists. While China is committed to take several specific steps to streamline and speed up its regulatory review and approval systems, there are growing concerns that some of the steps contemplated by China to implement reforms to address the regulatory delays would serve to promote domestic Chinese enterprises at the expense of foreign enterprises and foreign-invested enterprises in China.
- *Drug distribution* - Despite overall progress in this area, many other restrictions affecting the pharmaceuticals sector continue to make it difficult for foreign pharmaceutical companies to realize the full benefits of China's WTO distribution commitments.
- *Price control* - China continued to maintain price controls in 2016 on several products and services including pharmaceuticals.
- *Counterfeit drugs and API/bulk drug regulation* - Although rights holders report increased enforcement efforts by Chinese government authorities, counterfeiting in China remains widespread. Despite sustained engagement by the United States, China still needs to improve its regulation of the manufacture of APIs to prevent their use in counterfeit and substandard medications..
- *Anti-monopoly Law enforcement* - The implementation of China's Anti-monopoly Law by Chinese regulatory authorities poses multiple challenges. One key concern relates to how the Anti-monopoly Law will be applied to state-owned enterprises. Another concern relates to the procedural fairness of Anti-monopoly Law investigations. U.S. industry has expressed concern about insufficient predictability, fairness and transparency in the investigative processes of the NDRC, including the agency's pressure to "cooperate" in the face of

unspecified allegations.

More Challenges in the New Year, Despite Unchanged Long Term Prospects

Unfortunately Chinese pharma inherited in 2016 most old devils overshadowing the sector in prior years with no new fixes found and new challenges kept pouring in. It is almost certain that the industry will face an even more challenging time in 2017.

The trend of irrational cost containment is expected to intensify further this year, with the central government upholding the radical healthcare reform experiment in Sanming City of Fujian Province as a model for national replication. The Sanming experiment, which is set in the background of local BMI system in heavy deficits, is known for its ruthless cost containment measures, excessive emphasis on drug prices and harsh hospital reform moves. It is also the first local BMI system paying suppliers of originator drugs and local generics at uniform low prices. Besides, three more cut-throat cost containment policies, namely 1,001 additional clinical pathways, disease group-based fee standards and two-invoice system for public hospital drug procurement, were mandated for implementation in public hospitals in 2017.

Local governments are set to put more cost containment pressure on pharmaceutical companies, as they try to keep the public and central government happy and the books of BMI programs balanced in a time of fiscal crisis amid a slowing economy. On the other hand, the pharmaceutical industry will continue to be confronted by a host of other challenges including continued uncertainties of the broad Chinese economy, non-stop drug regulatory and healthcare reform turbulences, more stringent compliance requirements, and risks associated with constantly changing pharmaceutical business environment.

Chinese pharmaceutical industry experts have summed up 11 emerging trends for the Chinese pharmaceutical market in 2017 as follows:

- ☞ Further consolidation of the Chinese pharmaceutical market is expected following implementation of the two-invoice policy. Industry consolidation in both pharmaceutical manufacturing and distribution subsectors will intensify further as profit margin of prescription drugs narrow. Many pharmaceutical companies will turn to the OTC drug market for better opportunities.
- ☞ Ex-hospital pharmaceutical market will become the new battleground of pharma companies with intensive competition, as hospital drug sales become increasingly restrictive under deepening healthcare reform which is set to uphold the cost containment centered-Sanming model as template.
- ☞ Sales outsourcing or contract sales organizations (CSOs) will become more and more popular to the pharmaceutical industry. Although the model is favored more by smaller companies, even larger players may utilize it for some of their non-core products.
- ☞ More major OTC companies with dedicated sales force may diversify into consumer healthcare business.

- ☞ Pharmaceutical companies will continue penetration of the primary healthcare drug market as the reform of tiered medical service system picks up speed.
- ☞ Backed by a string of recent government policies supporting development of TCM and China's adoption of the TCM Law, clinical applications of TCM appropriate technologies will grow substantially.
- ☞ TCM clinics and hospitals will become increasingly popular as medicine sales outlets on government policy support and they will quickly emerge into the fourth terminal market for drug products, a new opportunity land for those well prepared to take advantage of it.
- ☞ Retail pharmacy chains are expected to attract by venture capitalists and private equity investors, given the rising prospects of pharmaceutical retail market under the new healthcare business environment.
- ☞ The business of contract hospital pharmacy management will become more attractive to brand name drug companies as healthcare reform deepens and social capital participation in select public hospitals increases.
- ☞ Retail pharmacies are expected to diversify into supermarket styled retailing of consumer healthcare and daily commodities in order to boost revenues and profitability.
- ☞ Pharma e-Commerce, especially B2C online pharmacy market segment, is set to see explosive growth following latest regulatory liberalization to withdraw Type B and C licenses for B2B and B2C online drug sales.

The short and intermediate term outlook of Chinese pharmaceutical market is going to be tough and blurred, but long term prospects remain hopeful for and warrant patience of those with sustaining power. Conversely, let's also remember that most Chinese pharma industry observers still agree that the Chinese healthcare market will keep on growing in the foreseeable future, albeit at a slower rate and with lower profitability.

China is projected to maintain its place as the second largest pharmaceutical market, trailing only the United States. The U.S. is projected to account for 53% of forecasted growth over the next five years (through 2021) while China will continue as the second largest market, a position it has held since 2012, contributing 12% of growth, according to a recent QuintilesIMS study. Growth of drug spending in developed markets will be driven by original brands while pharmerging markets will continue to be fueled by non-original products (i.e. generics) that make up an average 91% of volume and 78% of spending.

The study suggests that overall lower economic growth is triggering slower expansion for medicine use in pharmerging markets, including China. Leading pharmerging markets have seen real growth in GDP slow 1 to 4 percentage points over the past decade, according to the study, which has corresponded to a reduction in medicine volume growth, from an average of 7% annually over the past five years (2011–2016) to a 4% forecast through 2021. China, in particular, will see a decline in annual volume growth from 17% to 4% over the same period. Overall, volume growth continues to be

driven by non-original products that account for 91% of the volume in pharmerging markets. The outlook for spending growth across these pharmerging markets is expected to moderate from the 10% CAGR seen over the past five years (2011–2016) to 6% to 9% through 2021.

China is the largest pharmerging market. In 2016, China's pharmaceutical market was valued at nearly $117 billion and is projected to reach approximately between $140 billion and $170 billion by 2021, according to QuintilesIMS. CAGR growth (as measured in constant US dollars) in China's pharmaceutical market in the period of 2011–2016 was approximately 12.4% but is projected to slow to 5% to 8% in the period of 2016–2021.