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China Pharmaceutical Guide

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Third Edition (2008)

Written by:

James J. Shen, MBA

Unrivaled China Healthcare Intelligence Since 1991

Published by W*i*CON International Group

W*i*CON International Group

407 Wickes Road, Bushkill, PA 18324, USA

Tel: (570) 588-3854   Fax: (702) 995-3905

E-mail: info@pharmachinaonline.com   Internet: www.pharmachinaonline.com

China Office

Suite 17D, Building B, Oriental Kenzo Plaza

48 Dongzhimenwai Dajie, Dongcheng District, Beijing 100027, China

Tel: +86 10 84476010/11   Fax: +86 10 84476110

E-mail: info@pharmachinaonline.com

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 20-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 Ltd. 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. His clients include *Pfizer*, *GD Searle*, *IVAX*, *Glaxo-SmithKline*, *Novartis*, *Sanofi-Synthelabo*, *TEVA*, *Taro*, *Ajinomoto*, *AL Pharma*, *IMS*, *Medical Economics/PDR*, *Mylan Pharmaceuticals*, *Polichem*, and *Merrill Lynch*.

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 his businesses, James Shen founded ***Pharma China***, now the most influential English media on China's pharmaceutical industry and market which is subscribed by most 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 the USA near New York City, New Jersey, Philadelphia and Washington DC, with frequent visits to China, Singapore and Europe. He continues to be active in strategic consulting with multinational pharmaceutical companies at the 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 20 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 dangers to successful businesses.

Despite 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 contribute 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 observation in the past 20 years 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 operating in the Chinese pharmaceutical market. ***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 sets 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 1986.

About China Pharmaceutical Guide 2008 (3rd Edition)

In this Guide, we will take our readers through some historical backgrounds, and the reform and development path that China's pharmaceutical sector has undergone since 1978. We will then discuss the varying estimates on the size of China's pharmaceutical markets (both ethical and OTC), and its different market segments, as well as drug consumption patterns in terms of therapeutic applications, regional differences, market shares between local and foreign companies, and more.

Contemporary challenges facing the pharmaceutical industry and market in China are reviewed, and potential opportunities are explored in the Guide. Understanding these challenges and opportunities will help foreign companies face the realities of China up close, be prepared for any turbulence ahead, and grasp the opportunities as they arise.

At present, 27 of the world's leading 30 multinational pharmaceutical companies have manufacturing and sales operations in China, and many of them have multiple operations. The Guide will review the current state of foreign investment in the Chinese pharmaceutical industry, and discuss the contemporary challenges facing international pharmaceutical companies in China.

The Guide also covers the healthcare provision and financing structure of the Chinese healthcare system, gives an overview of the Chinese pharmaceutical regulatory framework with briefings on each of the relevant important regulations, and offers introductions on each relevant government agencies with administrative and regulatory duties over the pharmaceutical industry.

Finally, the Guide includes a chapter that focuses on exploring pros and cons of various strategic approaches for market entry into China's burgeoning pharmaceutical market.

The size of the 2008 Edition of China Pharmaceutical Guide increased to over 850 pages from previously 700 pages, and its coverage was expanded significantly in the following areas:

- Most industry, market and health sector data are updated with the 2007 (full year) and early 2008 figures
- All regulatory changes in 2007/2008 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
- An additional 100 pages of new data, information and case studies
- New and expanded coverage on international regulatory cooperation, the Chinese R&D and outsourcing sector, clinical studies and practices, healthcare reform, community healthcare sector, essential drug policy, regional drug consumption patterns, and the vaccine sector.
- Nine new case studies are added in the 2008 Edition. A total of 21 mini case studies in six important areas including market entry, R&D outsourcing, human

resource management, market size/information sources, legal/IPR battles and local success stories.

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.

While every effort has been made to ensure that information in this publication is correct, no liability can be accepted for any loss incurred in any way whatsoever by any company or individual relying on the information herein. To the best of our knowledge the information given is accurate at the date of publication.

James J. Shen

June 8, 2007

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ADR – Adverse Drug Reaction

API – Active Pharmaceutical Ingredients

APP – Administrative Protection of Pharmaceuticals

AmCham – American Chamber of Commerce

CNCM – China National Corporation of Medicines

CNAPC – China National Association of Pharmaceutical Commerce

CNY – Chinese Yuan

CRO – Contract Research Organization

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 Sales Practices

IFPMA – International Federation of Pharmaceutical Manufacturer Associations

JV – Joint Venture

M&A – Merger and Acquisition

MOH – Ministry of Health

MOLSS – Ministry of Labor and Social Security

MPC – Multinational Pharmaceutical Company

MR – Medical Representative

NBS – National Bureau of Statistics

NCGHSR - National Coordination Group for Healthcare System Reform

NDRC – National Development and Reform Commission

NPFPC – National Population and Family Planning Commission

OECD – Organization for Economic Co-operation and Development

OTC – Over The Counter

QA – Quality Assurance

PRC –People's Republic of China

R&D – Research and Development

RDPAC - R&D-based Pharmaceutical Association Committee

SATCM – State Administration of Traditional Chinese Medicine and Medicines

SDA – State Drug Administration

SFDA – State Food and Drug Administration

SIPO – State Intellectual Property Office

SMEI – Southern Medicine Economic Institute

SOE – State Owed Enterprise

SPAC – State Pharmaceutical Administration of China

STD – Sexually Transmitted Disease

TCM – Traditional Chinese Medicine

USFDA – US Food and Drug Administration

VAT – Value Added Tax

WM – Western Medicine

WHO – World Health Organization

WTO – World Trade Organization

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EXECUTIVE SUMMARY

James J. Shen

Continuous double-digit growth in the past two decades has convinced even the most conservative industry analysts to offer optimistic views about the future of the Chinese pharmaceutical market. Flashy news titles such as “China Seen as Fifth Biggest Drug Market by 2010”, “China to Become the Second Largest Pharmaceutical Market by 2020” and “China Could Overtake the United States as the Top Drug Market by 2050” are frequently seen in well-known papers and journals in recent years.

Indeed, these daring predictions are not unfounded and are supported by various broad economic evidences. Nevertheless, when taking a closer look at today’s reality of the pharmaceutical industry in China, one will see the mounting challenges ahead for such rosy pictures to materialize. In fact, some challenges facing the pharmaceutical industry in China threaten to derail it from the development fast track depicted by many observers.

Recap of Chinese pharma industry and market in recent years

Official statistics suggest that the total revenue of China’s pharmaceutical industry in 2006 was around CNY 500 billion (US$64 billion) with a total net profit of CNY 40.2 billion (US$5.2 billion), up by 17% and 10% respectively compared with the same figures in 2005. In 2007, the total output value and sales of the Chinese pharmaceutical industry surged over 20% again, reaching over CNY 680 billion and over CNY 640 billion respectively.

Despite its continued rise, the growth rate of the Chinese pharmaceutical industry slowed significantly in 2006 due to the country’s regulatory corrections, and its profit margin also fell by nearly 50%. 25.6% of the Chinese pharmaceutical companies made losses in 2006 and their total losses rose 26.2% compared with the same figure in 2005.

With impetuous regulatory corrections of the Chinese pharmaceutical sector gradually winding down in 2007, all the market growth potential depressed in 2006 found its way back. Large companies, especially R&D-based multinationals, experienced phenomenal growth last year after regulatory cleanup of the market drove out many small and irregular competitors.

WiCON’s estimate on the overall Chinese drug market (including finished Western medicines, biochemical drugs, formulated traditional Chinese medicines and herbal drugs) in 2007 was about US$50 billion at ex-manufacturer prices, up 19.0% from US$42 billion in 2006.

Rising global importance

With sharp growth and advancements on many fronts in 2007 as backdrop, the global importance and influence of the pharmaceutical industry in China is beginning to emerge, and therefore, it is now a good time for me to initiate this topic.

The following landmarks serve as good indicators for the rising importance of China in the global pharmaceutical sector.

Rapid growth of the Chinese pharmaceutical market – Regardless of the wide ranging estimates made by different information sources on its size, China is now one of the largest drug markets, and by 2020 is likely to be the second largest market in the world.

For many MNCs, such as Eli Lilly, China is becoming a leading overseas market and will probably become their largest overseas market within a decade;

MNCs are increasingly relocating their R&D operations to China, and some, such as GSK, are moving some of their core and integrated research functions to the country;

MNCs and foreign companies are outsourcing an increasing volume of R&D and manufacturing projects from China;

China is now the dominant supplier of active pharmaceutical ingredients and intermediates to the world;

Chinese companies are investing heavily in the past year to gear up their preparations to become a major supplier of generic formulation drug products to the world;

More and more Chinese pharmaceutical companies have become listed in overseas stock markets, in particular the United States, and the resulting financial strength of these companies will help facilitate their rapid growth in China and internationally; and

Chinese companies are beginning to acquire foreign companies for fast growth and market penetration, as shown by Wuxi PharmaTech's acquisition of AppTec.

China strives to build up an innovative drug industry as its long term goal

I have been a long time observer of the different paths of pharmaceutical industry development adopted by China and India. The Chinese government has always stated that it wants to have an innovative pharmaceutical industry led by large and research-based companies. At the same time, it has consistently welcomed foreign investment and encouraged integration of the local industry with international companies.

To achieve its goal, the Chinese government has adopted industrial and regulatory policies that favor research-based multinationals and large domestic enterprises, and at the same time, it has improved market access for foreign companies, strengthened IP environment to foster innovation and, most recently, cleaned up the country's marketplace to ensure success of larger and innovative companies.

Because of this, China has won increasing trust and confidence from foreign companies, most notably from R&D-based multinationals, who are boosting their investments in the country not only to expand manufacturing and marketing operations, but also to move some of their critical business operations and to transfer core technologies to the country.

Today, China is well on its way to develop its pharmaceutical industry side by side with the research-based multinational pharmaceutical companies. With the ongoing restructure of the global pharmaceutical industry in the backdrop, the fate of the Chinese pharmaceutical industry and those of R&D-based MNCs are increasingly linked together. As this bond grows stronger and deeper, it becomes a path of no return for both sides.

It is my observation that China will be, as its long term policy, committed to supporting new drug innovation as well as growth and development of research-based multinational companies in the country, while, at the same time, attempting to foster the rise of its own large and innovative companies at the same time.

On the other hand, China faces the daunting challenge of securing the essential healthcare needs of its entire people. As the country's economy continues to grow, the need for new medicines and high quality healthcare will also rise. While large domestic companies are best-positioned to fulfill the essential healthcare needs of the nation in the short- and medium-term, innovative MNCs are certainly better -suited for the task of satisfying higher level demands.

Despite short term regulatory corrections, administrative changes or healthcare reform uncertainties, the long term direction and present development path for China's pharmaceutical sector are unlikely to be altered in any significant way.

Improving and expanding business prospects for R&D-based multinationals

In spite of the turbulent market and regulatory environment, innovative multinational pharmaceutical companies (MPCs) have managed to establish a solid foothold and accumulated their business strength in China in the past few years.

During the period, MPCs have consolidated their bases and organizations in the country, gained absolute control in their joint ventures, expanded sales and marketing networks, improved on IPR awareness and enforcement, quietly increased their influence over the Chinese government and its policies, and most importantly, successfully fostered an industrial and market environment that is now relatively more friendly to them.

While most large and mid-sized pharmaceutical companies in China would confirm that they fared much better in 2007 compared with the previous year, the executives of R&D-based multinational companies are reporting, unofficially, sharp growth of their performance in the year, largely benefiting from government policies which are generally more favorable for MPCs.

In response to such positive market environments and mounting opportunities, MPCs are boosting their positions in China through strengthening their sales and marketing network, expanding manufacturing facilities, and accelerating R&D relocations.

In late 2007, Bayer and Novartis announced ambitious plans to expand their OTC business in China, Wyeth decided to expand its Suzhou facility, Sandoz (part of Novartis) acquired a new manufacturing facility in Zhongshan, and Sanofi Aventis began construction of a new vaccine plant in Shenzhen.

Many multinational pharmaceutical companies such as Eli Lilly and GSK poured more investments into expanding their R&D operations in China in 2007, while other MNCs such as Sanofi Aventis, Merck KGaA and Novo Nordisk entered into major research deals with Chinese research institutions. It is on the rising trend for major MNCs to relocate some of their key R&D functions to China as represented by the bold move of GSK to relocate its entire R&D on neurodegenerative diseases to China.

R&D outsourcing market grows at breakneck speed

Phenomenon growth for R&D outsourcing business was observed in the past few years. According to a recent research, the Chinese pharmaceutical R&D outsourcing market is estimated to be around CNY 4 billion annually at present with 100% growth potential in the next few years.

Leading companies in this sector have typically recorded triple-digit growth and are expanding in both their sales and business scope at astounding speed in the past few years. Strong financial support from venture capitalists, investors and the stock market will lead to fast expansion of the major players and the sector as a whole.

Despite its huge potential, the further growth of the Chinese pharmaceutical R&D outsourcing market may be limited by three factors: 1) Shortage of highly-skilled talents, 2) High upfront investment for startup companies, and 3) Relatively low IPR awareness and weakness in the IP security of local CROs.

Challenges Clouding the Future …

Despite all the positive forecasts and encouraging trends, the pharmaceutical industry in China, including both local firms and multinationals, is facing serious challenges that may potentially jeopardize the future prospects of the pharmaceutical market in the country.

Contradictions in Government Policies - There is no doubt that the Chinese government’s economic policies and systemic reform spurred the rise of the Chinese pharmaceutical industry and market. However, many structural problems in China’s healthcare system and pharmaceutical sector remained in the past 25 years in exchange for faster short-term growth.

On the one hand, the Chinese government wants the pharmaceutical industry to develop into an internationally competitive industry with strong new drug R&D capabilities, advanced technologies, and high quality standards; but on the other hand, it has cut back state investments in the pharmaceutical industry, repeatedly slashed prices of drug products and squeezed profit margins of the pharmaceutical industry through various cost containment measures.

The government has also cut its healthcare spending sharply, forcing the medical industry to rely on profits from drug sales, hence making the pharmaceutical industry a major source of healthcare financing, and leading to many structural flaws in the healthcare system. Evidently the share of government healthcare spending in the country’s total healthcare expenditures fell to 17.1% in 2004 from 36.2% in 1980. Meanwhile, the self-paid healthcare expenditures of urban Chinese residents rose 9.6 times between 1993 and 2005.

Healthcare expenditures as a percentage of China's GDP had been falling since 2003 and it was down to 4.82% in 2007 from 5.7% in 2004. The growth of healthcare consumption obviously lags behind that of the country's GDP.

Changing Directions of Healthcare Reform - A survey carried out by China Youth Daily in August 2005 found over 90% of the people in China were dissatisfied with the reform to the country's healthcare system in the previous 10 years. A survey by the National Bureau of Statistics (NBS) released on January 2008 showed again that rising medical costs have become the top concern of Chinese people. A heated discussion about China's healthcare reform began in May 2005 following the publication of a report by the Development Research Center under the State Council that concludes China's healthcare reform in the past two decades was largely unsuccessful.

Consequently, the future direction of China's healthcare reform has now become a subject of heated public debate involving ordinary people, government officials, representatives of the National People's Congress and the media. As a result, the Chinese government formed an inter-agency group to develop a new healthcare reform plan for the country. Unable to settle disputes among various government agencies within the group, the Chinese government contracted nine external organizations to help develop healthcare reform plans in 2007.

However, the government agencies and experts so far have failed to reach an agreement over the country's healthcare reform model, although some principles of the reform were announced just before the end of 2007. What will happen next is likely to be based on the late paramount Chinese leader Deng Xiaoping's famous doctrine, "crossing the river by touching the stones", meaning that many experiments will be launched to test different paths before a final agreement is reached.

The changing direction of the healthcare reform will have overwhelming and comprehensive impacts on the pharmaceutical industry, and is likely to trigger another round of restructuring of the industry. Deng's doctrine may be a pragmatic and effective way to settle differences between government agencies for the time being, the final outcome is hard to predict and may come at high costs.

Cost-containment Measures - In its desperate attempts to control the rapidly rising healthcare expenditures, the Chinese government has introduced a matrix of cost-containment measures at national and local levels. These measures, including 23 rounds of price cuts on drug products by the central government, have seriously disturbed the normal operation and profit margin, causing sharp increases in administrative costs and resources, and substantially narrowing the profit margins of pharmaceutical companies, both local and foreign.

Intensive Competition and Industry Consolidation - The Chinese pharmaceutical industry, which was once dominated by large state-owned enterprises, slowly disintegrated in the past 25 years into a large number of small enterprises with similar product portfolios. By 1985 there were only 1,377 pharmaceutical manufacturing companies in the country, but the number rose to over 5,000 in 2007 in spite of ongoing consolidation and compulsory GMP implementation.

This has led to intensive competition and to the rise of unethical and illegal practices in pharmaceutical sales and marketing. Cut-throat competition among local generic drug manufacturers has also resulted in shortening product life spans for generic drug products. Most local pharmaceutical companies are trapped in a vicious circle of low R&D investment, poor innovativeness and product differentiation, price competition and low profitability. Compounded by the effect of government price control and cuts, many pharmaceutical companies are suffering from heavy losses, and most small companies are expected to be out of business in the near future.

The government's strategy to *"support the big, and let go of the small"* in recent years has not produced the desired result. Many large state-owned enterprises have simply became bigger and fatter in size, rather than stronger, more competitive and more profitable. Valuable capital and resources drawn from the government and the stock market have been largely under-utilized without delivering expected performance.

Rising Conflicts between Local and Multinational Companies - In the 1980s and early 1990s, local Chinese and multinational pharmaceutical companies had focused on the collaborative parts of their mutual relationships. The honeymoon period was over in the past decade, however, with both sides growing stronger in their own ways and beginning to concentrate more on the competitive parts of their relationships, leading to rising conflicts of interests between the two sides, especially in the area of IPR.

Rampant Counterfeit Drugs - AmCham China estimated that between 10% and 15% of drugs sold through the retail channel in China are counterfeits. Not only do counterfeit and fake drugs pose serious public health problems for China, but also the country is now one of the biggest exporters of such products. In the past, drug counterfeiters in China developed poor quality fakes, but today they are producing high quality counterfeit drugs.

Outlook for the future – cautiously optimistic

Despite variances in market size estimates among different sources, one thing everyone agrees on is the growth of the Chinese pharmaceutical market. Most forecasts predict the market to grow at between 13% and 18% annually between 2006 and 2010.

These growth predictions are supported by an official estimate by the Development Research Center of China's State Council that based on current trends, health spending in the country is set to rise to 7-8% of GDP by 2010 from 5.7% in 2004, thus spurring further pharmaceutical market growth.

2007 was a good year in general for the Chinese pharmaceutical industry which was reshuffling and repositioning itself to adapt to market environmental changes. Many positive developments last year will continue to benefit research-based multinationals and larger local companies in 2008. We are likely to see more growth this year, but companies need to remain prudent because many structural problems in China's healthcare sector remain to be tackled with and the direction and implementation of the healthcare reform may simply change overnight the ways business is being done today.

SMEI forecasted that the total output value of the Chinese pharmaceutical industry in 2008 will grow by 19% to 20% to reach CNY 740 billion to CNY 760 billion (US$99 billion to US$101 billion).

On the other hand, IMS projected that the combined market of China, Brazil, Mexico, South Korea, India, Turkey and Russia was expected to grow by 12% to 13% in 2007 to $85 billion to $90 billion. Prescription drug sales in China, Brazil, Mexico, Turkey and other emerging economies will account for 25% of the global market in 2008.

The three biggest drivers for future drug consumption growth are: 1) sharp increase of government funding in healthcare, 2) continued expansion of the rural, suburban and urban community healthcare markets, and 3) favorable government policies and cleanup of the urban pharmaceutical market by recent regulatory corrections offer lucrative expansion opportunities to well-positioned larger and innovative companies.

Despite anticipated growth, we believe that the future outlook of the Chinese pharmaceutical industry in 2008 will continue to be heavily influenced by new government policies in areas such as healthcare reform, drug pricing, drug registration, basic medical insurance and healthcare administration.

As the importance of China's pharmaceutical industry grows and its bond with the world fortifies, its future fate will no longer be isolated but instead, will insert wide-ranging impacts on the global pharmaceutical industry and market.

In conclusion, I would borrow a fairly recent Chinese proverb to describe the challenges and future outlook facing the pharmaceutical industry in China: "*while the future is bright, the path to it is twisty with zigzags*".