

China Pharmaceutical Guide

中国医药市场指南

6th Edition (2011)

Written by:

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Unrivaled China Healthcare Intelligence Since 1991

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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 24-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 WiCON 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. 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 WiCON. 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 most influential English media 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 24 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 24 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 1986.

About China Pharmaceutical Guide 2011 (6th Edition)

The China Pharmaceutical Guide 2011 (6th 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 2010 (full year) and early 2011 figures.
- ☞ A new section on high growth market segments and expanded coverage of the Chinese contract manufacturing (CMO) sector, licensing and R&D partnerships, and emerging legal issues.
- ☞ Comprehensive top line data and research findings from our collaborative partners such as IMS Health, Synovate Healthcare, Nicholas Hall, ZS Associates and RDPAC.
- ☞ All regulatory changes in 2010/2011 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 June 30, 2011.
- ☞ New and 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 2011 Edition.
- ☞ Comprehensive revision of MNC companies profiles 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, 2011

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TABLE OF ABBREVIATIONS

ADR – Adverse Drug Reaction	MNC – Multinational pharmaceutical companies (<i>in the context of this guide</i>)
API – Active Pharmaceutical Ingredients	MR – Medical Representative
APP – Administrative Protection of Pharmaceuticals	NBS – National Bureau of Statistics
AmCham – American Chamber of Commerce	NCGHSR - National Coordination Group for Healthcare System Reform
CAGR (Compound Annual Growth Rate)	NDRC – National Development and Reform Commission
CCCIEMHP – China Chamber of Commerce for Import & Export of Medicines and Health Products	OECD – Organization for Economic Co-operation and Development
CNCM – China National Corporation of Medicines	OTC – Over The Counter
CAPC – China Association of Pharmaceutical Commerce	QA – Quality Assurance
CNY – Chinese Yuan	PRC –People’s Republic of China
CRO – Contract Research Organization	R&D – Research and Development
DRGs – Diagnosis Related Groups	RDPAC - R&D-based Pharmaceutical Association Committee in China
ED – Erectile Dysfunction	SATCM – State Administration of Traditional Chinese Medicine
FDI – Foreign Direct Investment	SDA – State Drug Administration
FIEs – Foreign Invested Enterprises	SFDA – State Food and Drug Administration of China
GCP – Good Clinical Practices	SIPO – State Intellectual Property Office
GDP – Gross Domestic Products	SMEI – Southern Medicine Economic Institute
GLP – Good Laboratory Practices	SOE – State Owed Enterprise
GMP – Good Manufacturing Practices	SPAC – State Pharmaceutical Administration of China
GSP – Good Supply Practices	STD – Sexually Transmitted Disease
IFPMA – International Federation of Pharmaceutical Manufacturer Associations	TC – Therapeutic Class
JV – Joint Venture	TCM – Traditional Chinese Medicine
M&A – Merger and Acquisition	USTR – US Trade Representative
MIIT – Ministry of Industry and Information Technology	VAT – Value Added Tax
MOFCOM – Ministry of Commerce	VC – Venture Capital
MOF – Ministry of Finance	WM – Western medicine
MOH – Ministry of Health	WHO – World Health Organization
MoHRSS – Ministry of Human Resources and Social Security	WTO – World Trade Organization

EXECUTIVE SUMMARY

James J. Shen

China's economy already surpassed Japan in 2010 as the second largest in the world and its GDP, which is expected to grow between 7-9% per annum in the next three years, may exceed the U.S. in 2012.

Sustained economic development is foundational to growing healthcare expenditures which are estimated to surge to 20% CAGR (2006-2011) in China. Rising levels of disposable income are laying the groundwork for higher out-of-pocket expenditures for healthcare and pharmaceutical products.

As the nation moves forward with its universal healthcare coverage plan, McKinsey & Co. said, the size of China's healthcare market could exceed US\$600 billion within 10 years from currently at US\$240 billion. On the other hand, the Chinese pharmaceutical market is projected to grow much faster than Chinese GDP at a CAGR rate of 24% between 2009 and 2013.

Another high performance year despite turbulences

Notwithstanding the challenges, the Chinese pharmaceutical industry and market managed to post higher growth again in 2010.

Pharmaceutical industry and market performance

The Southern Medicine Economic Institute (SMEI) under the SFDA estimates the overall output value of the Chinese pharmaceutical industry to reach CNY 1,256 billion in 2010, up 25% year on year (compared with 21% in 2009) and accounting for no less than 7% of the Chinese GDP.

The Chinese drug market size in 2010, on the other hand, is expected to reach CNY 755.6 billion at the retail price level, up 22% year on year (up from 21% growth in 2009). Among the total, the hospital, retail pharmacy and third terminal (community + rural) market segments are estimated to be CNY 452.0 billion (+22.5%), CNY 173.9 billion (+17.0%) and CNY 129.7 billion (+27.9%) with market shares at 59.8%, 23.0% and 17.2% respectively.

Separately, Business Monitor International (BMI), the pharmaceuticals market in China was \$56.7 billion in 2010. The sales of patented drugs in China witnessed an increase, from \$4.51 billion in 2009, to \$5.41 billion in 2010.

On the other hand, IMS Health reported that the Chinese hospital drug market rose 22% to reach CNY 312,894 million last year. However, the Chinese Pharmaceutical Association (CPA), which audits drug purchases by representative hospitals in 22 major Chinese cities, said that hospital market growth slowed to 19.2% in 2010, which was three percentage points lower than the previous year.

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\$12,260.5 million in 2010, up 9.2% year on year in US\$ terms, according to Nicholas Hall & Co. The growth rate of the Chinese OTC drug market fell slightly last year from 9.8% in 2009.

Import and export

With recovery of global market demands and revival of China's export incentive policies, the Chinese import and export of medicines and health products swelled 24.57% in 2010 to US\$60,197 million, according to data from the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCIEMHP). Among the total, export surged 24.87% to US\$39,733 million last year, while import grew 23.98% to US\$20,464 million.

China's drug formulation export jumped 31.19% in 2010 and it was led by such export to emerging markets like ASEAN, India, Brazil and Russia with growth rates at 44.88%, 72.96%, 61.73% and 65.27% respectively. Boosted by growing manufacturing activities of multinational pharmaceutical companies in China, such exports to EU and U.S.A. also rose 34.32% and 25.49% in the past year.

The Chinese API export was US\$20,301 million in 2010, up 26.19% year on year and accounting for 51.09% of total medicine and health product exports. The average export price of API also grew 2.27% in the period. The recovery of Chinese API export last year was attributed to three major factors including 1) rising demand from India as it moves further downstream to drug formulations; 2) continued penetration into EU and north American markets; and 3) growing demands from emerging countries as their pharmaceutical industries develop.

Despite renewed growth in 2010 and expected continuation of export incentive schemes, CCCIEMHP warned that the growth of foreign trade for medicines and health products this year may slow down due to sluggish global economy recovery, rising production costs and anticipated Chinese currency appreciation. Additionally, intensive competition among Chinese producers is expected to generate significant pressures on prices and lead to various uncertainties. But improved manufacturing technologies, R&D capabilities and upgraded product pipelines of the Chinese pharmaceutical industry will help elevate its overall global competitiveness in the coming years.

Foreign investment

RDPAC's 37 member companies invested a total of CNY 20 billion in China in the 11th Five-Year Plan period (2006-2010) and one third of the total went into infrastructure building for R&D centers, said the association recently.

70% of RDPAC's members have manufacturing operations in China and they own a total of 49 production facilities in China and 15 of its members had established a total of 19 R&D centers in the country by the end of last year.

At the same time, latest data from the Ministry of Commerce (MOFCOM) shows that foreign-invested enterprises (including HK, Macao & Taiwan-invested enterprises) accounted for 30% of all pharmaceutical companies and their revenues represented 26%-27% of the Chinese pharmaceutical industry sales.

Pharma business landscape becomes more dynamic

The Chinese pharmaceutical sector become increasingly dynamic in the course of last year as MNCs diversified their China businesses/investments and local conglomerates sought to challenge their foreign counterparts through domestic consolidation and international expansion.

Domestic industry consolidates and expands vigorously

Chinese pharmaceutical industry went through another year of forceful industry consolidation. Backed with CNY billions raised from the stock market, the leading state-owned or state-controlled conglomerates such as SinoPharm, China Resources and Shanghai Pharma dominated the domestic M&A landscape with a large number of big and small acquisitions nationwide throughout the year. The intensive acquisitions were aimed at establishing national pharmaceutical distribution networks, boosting business domination, and expanding market shares.

Besides, many leading Chinese companies are making substantial progresses with their international business expansion plans and a few of them were successful in securing GMP certifications and generic drug registrations from EU and U.S. authorities last year. These firms are also increasingly keen on utilizing acquisitions as a means for faster expansion.

MNCs open floodgate of M&As as they diversify

MNC pharma giants had not been active at the Chinese pharma M&A scene until the last quarter of 2010 when a flurry of deals took place. With a price tag of US\$135 million, Bayer's acquisition of the cough & cold business of Topsun in 2006 had been hailed as the biggest acquisition deal in China by a MNC big pharma until recently when a transaction almost four times as big took place. Sanofi agreed in last November to acquire BMP Sunstone, a leading pediatric OTC player, for US\$520.6 million. Just a few days after, Nycomed bought 51% of Guangdong Techpool for US\$210 million which was again much larger than the Bayer-Topsun deal.

A month after, more MNC acquisition deals followed. Cardinal Health took over Zuellig Pharma China entirely for US\$470 million, GSK acquired 100% of Nanjing Meirui Pharma for US\$70 million and Sumitomo bought 29% of C&O Pharma in the last month of 2010.

Alliance Boots is also believed to be fishing a big deal. Its Executive Chairman Stefano Pessina visited China late last year with British Prime Minister David Cameron and was busy talking to potential acquisition candidates on the sideline. It was later learnt that the company joined in the competition for reorganization of Nanjing Pharmaceutical Group (NPG), the fourth largest pharmaceutical distributor in China. Three other contenders are the big three Chinese players mentioned earlier.

Many other MNCs are also ready to jumpstart their acquisition drive in China by putting together dedicated teams searching for potential candidates. The latest deals with higher-than-expected valuations might be a wake-up call for CEOs of those big pharma companies which are still holding out for bargains. Alas, thrifty deals are hard to come

by in a market with blazing growth and few desirable companies for sale.

Separately, MNCs are pursuing a range of other options to accelerate growth in the country. More companies elevated the corporate status of their Chinese subsidiaries last year to ensure organizational efficiency/management attention; some reformed their Chinese organizational structures to cope with new market dynamics and business growth. Many MNCs such as Novo Nordisk, Eli Lilly, Roche, Pfizer and Novartis continued to pour more money into expanding R&D operations in China last year to expedite new product launches and improve product pipeline. Many of them are also boosting sales forces in China to facilitate business and geographic expansion.

Aside from M&As and new investments, many MNCs and Chinese pharma companies are stepping up their Chinese OTC and consumer healthcare business.

Cross-border licensing and R&D partnerships rise

With draining new drug pipeline of domestic companies, cross-border licensing in China blossomed last year and *Pharma China* recorded a total of 31 global licensing and 20 contract research/collaborative R&D deals and most of them were between Chinese and foreign companies. Among the licensing deals, seven involved technology transfer/co-development of new drugs, while the rest 24 were for exclusive marketing rights in China.

The following trends are rising: 1) licensing and co-development agreements between Chinese companies and smaller foreign research companies such as the latest deal between Ligand and Hainan Kaihua for two hepatitis drug candidates; 2) research partnerships between MNCs and leading Chinese companies such as the co-development of two oncology compounds by BMS and Simcere; 3) co-marketing agreements among foreign companies such as the alliance of Pfizer and Takeda for Actos; and 5) co-marketing agreements between MNCs and leading Chinese distributors such as the deal between MSD and SinoPharm for vaccines.

Increased short term risks and contemporary challenges

China is currently going through one of its toughest times, both politically and economically, during its four decades of economic reform. On the one hand, China's continued stability is currently under threat with most of its population, who have benefited inadequately from the country's existing prosperity, demanding a re-engineering of wealth distribution through better pay, more welfare entitlements, increased political liberalizations and their wish list goes on. On the other hand, the Chinese government is facing broad economic challenges ranging from insufficient domestic consumption, structural issues with housing, healthcare and education sectors, blazing inflation, unmanageable foreign exchange reserve, global economic downturn & trade imbalance, and international currency & financial issues.

On top of the macro-economic challenges, there are signs recently showing increased short term risks which are specific to the pharmaceutical industry in China, especially to MNCs.

Government policy contradictions

Despite its commonly perceived fat margins, the pharmaceutical industry in China is actually quite volatile to inflation and rising costs as the sector is under rigid government price control and manufacturer/distributor drug sales margins are generally at a low level after repeated government price cuts.

New measures of the SFDA, which aim to raise the quality and manufacturing standards of drug products sharply in response to surging drug safety incidents (i.e. the new 2010 edition of China Pharmacopoeia and the upcoming new cGMP regulation), will lead to fast growth of costs and significant upfront investments in a time of prevailing inflation. The current drug pricing regime is unfortunately not well-established to cope with such regulatory upgrades and dynamic economic conditions, thus creating short term turbulences, falling profits, working capital shortage and various other sustainability issues for the pharmaceutical industry.

Drug pricing issues for MNCs

Before widespread inflation, which centered mostly on popular food products, hit China in the last quarter of 2010, there had been signs that the proposed drug price cuts would be delayed given many disputes surrounding it.

The wind changed suddenly in late November as raging inflation panicked both the public and the government. The Chinese leadership decided quickly to combat inflation through government intervention, but such moves have not been particularly effective with agricultural products as the government does not control their prices any longer, thus prompting it to act on slashing drug prices abruptly.

Products which were individual-priced, most of them off patent originator drugs from MNCs, made the most convenient target as their prices are much higher than those of local drugs and the public has been pressuring the NDRC to slash them for years.

RDPAC argues that the average Chinese ex-manufacturer prices for generic drugs are far too low by average international standards to serve as the basis for resetting prices of originator drugs. Aligning prices of originator drugs to such a basis will "undermine pharma industry investments into the quality control and is harmful to the healthy development of the Chinese pharmaceutical market and industry", RDPAC warns.

NDRC said in late 2010 that it was hoping to release its new drug pricing regulation soon and we hear from sources that the agency has already completed the second draft of this important document. It is almost certain that the NDRC will remove the drug pricing bracket of and provisions for off-patent "originator drugs" (or "innovative category drugs"). Although there may be provisions for quality-based price differentiations, the NDRC is expected to gradually reduce the existing large price gaps between off-patent originator drugs and their local generics over a four-year transition period.

If the price differentiation on quality basis is not as generous as MNCs hope, as seen in the ongoing trials in Guangdong province (as little as 5%), foreign companies will also be exposed to serious challenges for continued viability of their off-patent originator

drugs.

Besides, the upcoming "*Provisions for Drug Prices*" calls for drug price reviews at two-three-year intervals. Specifically, it wants the prices of patent or patent equivalent drugs to be reviewed every three years with 6% minimum reduction during patent protection and 15% minimum reduction when such protection expires. This provision threatens to undermine the profitability of innovative drug products substantially.

Most recently in early 2011, NDRC launched across-the-board price review and price cuts with emphasis on patented, off-patent originator and generic drugs under the National Drug Reimbursement List (NDRL), especially those drugs deemed to have high daily costs.

The agency also developed a new proposal for reference pricing scheme which will be experimented on drug products newly listed in the 2009 NDRL. Introduction of the reference pricing scheme is believed to be a mandatory task set by the State Council and is likely to become the new future direction for drug pricing. The concept of China's reference pricing scheme is similar to that of Germany's. It seeks to set reimbursement prices based on generic prices for all drugs within the same group, while patients will pay out of personal pocket for the difference between the reimbursement prices and the actual retail prices.

Essential drugs and the primary healthcare sector – *pie in the sky for MNCs*

There is also discouraging news for foreign companies eyeing the potential of essential drug business. An important domestic industrial policy recently-released by the Ministry of Industry and Information Technology (MIIT), the Ministry of Health (MOH) and the SFDA, *Guidelines for Accelerating Restructure of the Pharmaceutical Industry*, seeks to expedite domestic pharma industry consolidation and to foster large local groups with significant market dominance. It openly sets the goal of having the top 20 domestic manufacturers of essential drugs control at least 80% of the Chinese market for such drugs. It is apparent that the government wants the largest Chinese conglomerates, especially state-owned or state-controlled companies (although this is not spelled out), to be the main players in the arena of essential drugs.

In a related development, RDPAC said recently that its member companies may be excluded from the essential drug tenders nationwide and will subsequently be forced to exit the community healthcare sector in many regions as most of them will fail to comply with government-set maximum prices for essential drugs due to their higher cost structures for premium quality and services.

The Chinese third-terminal market, which is composed of urban community healthcare and township hospital sectors, grew 27.9% last year reaching CNY 130 billion. The market is expected to be even more lucrative in future given the rising government investments and higher-than-average growth. MNCs had high hopes for the market as one of their potential growth engines in China and losing it will dampen the entire prospect of the Chinese pharmaceutical market for MNCs.

Regulatory developments last year

Various agencies of the Chinese central government issued a total of 26 laws, polices and regulations which have significant impacts on the pharmaceutical sector in the country, according to *Pharma China's Regulatory Monitor*.

Summary of new regulations introduced last year

At the national law level, the *Tort Liability Law of People's Republic of China* became effective on July 1 2010 after eight years of drafting and evaluation.

Besides *the Implementation Regulation of the Third Amendment of the Patent Law*, three new policies were adopted by the State Council last year centered on healthcare reform, essential drugs and hospital drug purchase tender system.

The Ministry of Health issued numerous new rules and regulations last year but only a few have substantial impacts on the pharma sector targeting mainly hospital drug prescription practices and centralized hospital drug purchases.

The SFDA issued a total of 11 regulations, guidelines and notices last year covering areas including drug quality, controlled substances, drug registration, R&D, electronic regulation and pharmaceutical export. In particular, the agency issued three documents on electronic regulation of drug products in 2010.

More recently in 2011, SFDA introduced a new GMP regulation for pharmaceutical products with effect from March 1, 2011. The new rule significantly raises the country's pharmaceutical manufacturing quality control and management requirements.

As elevated standards under the new GMP mean higher manufacturing costs for drug companies, it will benefit big drug companies with resources, particularly those who have already adopted higher GMP standards, whereas many smaller companies will likely be eliminated.

Newly established drug manufacturing units, and renovations or expansions of manufacturing facilities by existing drug manufacturing sites will have to comply with the new GMP immediately. However, existing manufacturing facilities have a transition period of five years to come into compliance.

Other central government agencies also released four new regulations which affect the pharmaceutical industry significantly. Among them, China's new industrial policy for domestic pharma industry development, *Guidelines for Accelerating Restructure of the Pharmaceutical Industry* issued by the Ministry of Industry and Information Technology (MIIT), the MOH and the SFDA last October, is of particular importance.

Also of great importance is the Ministry of Commerce (MOFCOM)'s *Notice on Implementing Industry Administration of the Pharmaceutical Distribution Sector* which marks the beginning of the MOFCOM's rein over the Chinese pharmaceutical distribution sector.

In the meantime, the NDRC failed to achieve its goal for introducing the proposed drug pricing regulation, *Provisions for Drug Prices*, before the end of 2010, but the agency

managed to finish the second draft of the regulation and launched a comprehensive price cut on 174 individually-priced drugs late last year.

The latest draft does not contain the drug pricing bracket of and provisions for originator drugs and the individual pricing mechanism as the NDRC is expected to gradually reduce the existing price gaps between originator drugs and their local generics during a four-year transition period.

Proposed regulations on the horizon

The following regulations are planned for introduction in 2011 by various central government agencies:

- The *Provisions for Drug Prices*;
- The *Quality Control Standards for Drug Distribution (GSP)*;
- The *Provisions for Adverse Drug Reaction Reporting and Surveillance*;
- The *Provisions for Supervision of Drug Clinical Research*; and
- The *Provisions for Drug Standards*.

Healthcare reform powers forward on all fronts

Steady progresses were made as planned on all following five major healthcare reform fronts last year, the State Council's Office for Reform of Pharmaceutical and Health Systems. Let's take a look at the advances and issues in these areas reported.

Universal basic medical insurance (BMI) coverage and expansion

The urban Basic Medical Insurance Program (BMI) now covers 424 million or about 68% of urban residents and the new rural cooperative medical scheme (NRCMS) covers 835 million or at least 96% of its rural residents at the end of March 2011, so the Chinese government is expected to achieve universal BMI coverage ahead of its plan. Government subsidies of urban BMI programs and NRCMS have been raised to CNY 120 per capita, the hospitalization reimbursement rate has been elevated to 60% in most areas, and outpatient reimbursement has been introduced in more than 50% of the areas.

Implementation of essential drug system

The essential drug system (EDS) and the zero drug sales margin policy were implemented in around 50% of the public primary medical institutions nationwide and the prices of essential drugs were reduced by an average of around 30% last year.

However, various independent researches on EDS implementation all reported mounting difficulties and problems. The slow progress on this front left the reform objective of introducing the EDS in at least 60% of all public primary medical institutions nationwide by the end of 2010 behind schedule. Subsequently the State Council had to introduce a new measure mandating government subsidy of EDS-compliant primary medical institutions which suffer from policy losses. In the first quarter of 2011, EDS implement made substantial progress and it was implemented in 82.6% of all public primary

medical institutions at the end of March.

Another major issue, widespread overemphasis of drug prices in essential drug purchase tenders, was also highlighted. In this respect, the State Council responded with a new policy in late 2010 to resolve emerging issues in pricing, purchase and distribution of essential drugs.

Primary healthcare infrastructure

In its 12th Five-Year Plan (2011-2015), the Chinese government wants to focus on improving community healthcare services as its healthcare reforms gather pace. New health-care resources will be channeled to rural and urban communities, and medical workers, especially generic practitioners (GPs), are encouraged to serve in grassroots medical institutions.

The central government of China invested a total of CNY 55,840 million into building nearly 50,000 new medical institutions, most of which were primary medical facilities, in the 11th five-year plan period (2006-2010). During the period, over 1,100 urban level III hospitals established mutual support and cooperation link with 2,139 county level hospitals, thus improving the medical service standards of primary medical institutions.

Public health services

China's priority in the public health sector was on prevention and control of communicable diseases last year but it will shift to treating chronic diseases in the next five years, according to the MOH.

Public health objectives in the country's 12th Five-Year Plan include 1) stepping up prevention efforts of major diseases to control health risks; 2) gradually increasing the government funding and scope of basic public health services; and 3) emphasizing the public health administration role of the government at all levels.

Hospital reform

China made substantial progresses last year in deploying and initiating its public hospital reform, the core component of the entire Chinese healthcare reform plan. Reform on this front is expected to accelerate this year.

The State Council issued *Guiding Opinions for Public Hospital Reform Experiment*, on February 2, 2010 as the official plan for public hospital reform experiments. Subsequently 16 cities were selected by the central government last February as national level sites while the other 31 cities were later selected by provincial governments as provincial level trial sites.

Reform tasks commonly initiated by all trial sites last year centered on 1) improving regional healthcare planning and medical institution distribution, expediting development of county level hospitals, and establishing service division and cooperation mechanisms between public hospitals and primary medical facilities; 2) strengthening internal management of public hospitals, securing medical quality, raising efficiency and controlling costs; and 3) pushing forward standardized training of resident physicians to prepare healthcare talents for urban and rural medical institutions.

At the same time, the public hospital reform experiment also began to explore complex healthcare reform issues including public hospital financing, management model and administrative system, according to the MOH.

The agency also plans to expand public hospital reform experiments to 300 county level public hospitals with relatively higher population coverage and better infrastructure in 2011.

In the meantime, the Ministry of Finance released in early 2011 five new standards covering finance, accounting and auditing of Chinese hospitals and primary medical institutions with effect from July 1, 2011.

Apart from the five major healthcare reform fronts above, progresses in a number of complementary reform areas are also notable:

Centralized hospital drug purchase

The Chinese government issued three major policies/regulations in this area last year to streamline the systems of centralized purchase of essential and non-essential drugs by public medical institutions.

Under the regulations, centralized medical institution drug purchase systems should be established at the provincial level under leadership and management by administrative agencies organized by the provincial level governments. The regulations modify the existing standards and processes of centralized hospital drug purchase tender and establish standard practices of tender management agencies, medical institutions and pharmaceutical manufacturers & distributors in the tender process.

In December 2010, the State Council issued *Guidelines for Establishing and Streamlining the Mechanisms of Essential Drug Purchase by Government-owned Primary Medical Institutions* in an attempt to resolve emerging issues in pricing, purchase and distribution of essential drugs and improve regulation of the sector.

Although the actual language of the new policy is poorly written with scattered coverage of many details, it does contain a number of groundbreaking new approaches to the subject and many specific operational guidelines.

Medical payment reform, DRGs and clinical pathway

The MOH has been developing various rules and policies to complement the ongoing hospital reform experiment including policies on clinical pathways/diagnosis related groups (DRGs) and disease-based payment schemes.

The ministry issued numerous clinical pathways throughout last year and is piloting them and disease-based payment scheme for 50 single diseases in 110 hospitals of 23 provinces.

Meanwhile, debates over DRGs in China began to heat up. Some officials with the MOH believed that China is now ready for the medical payment system reform along with the introduction of DRG schemes, while other leading health policy experts question the maturity for and feasibility of the DRG scheme in China.

Regardless of the arguments, China has already initiated reform experiments of various new medical payment mechanisms under which healthcare institutions are reimbursed at standard rates for given diseases (disease-based reimbursement) or by lump sum prepayment for common diseases on the basis of patient numbers (headcount-based reimbursement) as an integral part of the country's public hospital reform trial.

Negotiation mechanism under the NDRL

Progress on this front was slow in 2010 with little transparency, although the first round negotiation for inclusion of selected expensive drug products into the National Drug Reimbursement List (NDRL) was reported last August. Details of the relevant rules for the negotiation mechanism were not made public.

It was leaked that the MoHRSS will establish three classes (A, B and C) of reimbursement for drug products included through the negotiation mechanism. The reimbursement levels will be 80% for A class, 50% for B class and 30% for C class.

Future outlook remains rosy despite problems

All leading healthcare industry observers agree that the Chinese pharma will continue to grow strongly in the next few years although their data basis, perspectives and emphasis often differ.

Assuming the Chinese government fulfilling as planned its commitment for an additional CNY 850 billion investment into the healthcare sector and the world economy does not dip into the bottom again, SMEI believes that the total output value of the Chinese pharmaceutical sector will see another 23% growth in 2011, reaching CNY 1,545 billion. SMEI also predicts the cumulative annual growth rate (CAGR) of the Chinese pharmaceutical sector in the next decade to be 20% with its output value reaching CNY 4,018.8 billion in 2019.

Combined sales of prescription drugs and OTC medicines are forecasted to increase from US\$56.7 billion in 2010 to US\$69.9 billion in 2011 (+21.9%), according to Business Monitor International (BMI). Key drivers of market expansion are the CNY 850 billion (US\$125 billion) healthcare reform plan, the expansion of China's essential drug list, the growing demand for medicines in rural areas and the increasing adoption of tender systems for pharmaceutical procurement.

IMS predicted that China's hospital drug sales will grow 25% to 27% to more than US\$50 billion in 2011 and the country is set to overtake Japan as the world's second-biggest pharmaceuticals market in 2015.

In the interim, China's annual healthcare spending is projected by PwC to grow by 166% between 2010 and 2020, while McKinsey predicted a jump of the same to US\$600 billion in 2020 from US\$240 billion at present.

On the other hand, JZMed predicts the Chinese preclinical and toxicology outsourcing industry to grow at a CAGR of 27% in the next five years and its market size will likely reach more than US\$760 million by 2015.

Vision for the future

As market prospects have been covered extensively by other authoritative sources, the following observations will focus more on leading contemporary issues.

Firstly, the healthcare reform turbulences endured by the pharma industry in recent years are largely temporary growing pains before we eventually reach the “land of milk and honey”. Although it is still far from the end of the long tunnel of reform, significant progresses are being made on many reform fronts along with some pitfalls and mistakes, and mostly things are moving towards the planned direction.

Secondly, MNCs are reminded not to over-emphasize potential revenues from state-funded BMI programs or build their China ambitions on this basis entirely. Companies need to be aware that the Chinese government does not have a huge healthcare budget allocation to the essential drug system and the basic medical insurance programs by international standards despite its recent pledges to boost investments.

Sustained Chinese economic growth and development of a national healthcare insurance system, which is comprised of both the state basic medical insurance system as the basic security blanket and a mature commercial health insurance sector for higher level healthcare needs, will therefore offer far better assurances for healthy development of the Chinese pharmaceutical market in future.

A few major positive developments in this territory took place last year including the introduction of new government policies to open up medical service and health insurance sectors to private and foreign capital and participation of more global leaders in Chinese healthcare IT infrastructure building. Progresses like these will facilitate faster transformation of the Chinese healthcare system towards the “land of milk and honey” for all stakeholders.

Thirdly, ultimately MNCs need to come to terms with the reality that it is simply unsustainable to continue building their China business plans on the shaky ground of off-patent originated drugs at their existing price levels. The ongoing healthcare reform seeks to control healthcare expenditures and is therefore set to benefit the Chinese companies more in the generic drug arena, while MNCs are most likely to be the winner for the high-end drug market segments. Besides, MNCs may fare better in the OTC/consumer healthcare sector and enjoy improved access to the biologic market. If MNCs wish to succeed also in the Chinese generic drug sector, they need to reshape their tools (strategy, business model, corporate culture, cost structure and management team) for this arena.

Fourthly, RDPAC has been emphasizing the importance of drug safety and quality which is shared by the Chinese government and the public. MNCs are likely to benefit from the broad trend as they are already manufacturing at higher standards.

The upcoming Chinese GMP standards are expected to raise the costs of pharmaceutical products sharply, thus leveling the ground for cost structures of Chinese and MNC companies to some extent and subsequently narrowing the price gaps between them.

The new GMP also promises to phase out a large number of small and irregular

pharmaceutical manufacturers, therefore making more room for large domestic and foreign companies.

Last but not the least, it must not be forgotten that the leading Chinese pharmaceutical companies are making huge advances on almost every front, be it high standard manufacturing, innovative R&D or lobbying. Backed by their growing financial muscles, government support, cost advantage and strength in pharma distribution, they will make formidable competitors to MNCs.

How do foreign pharma companies compete with them? The core competitiveness of MNCs will continue to lie in drug innovation, so their existing drives to boost R&D capabilities and expedite new product launches in China are in the right direction.

In conclusion ...

Despite the anticipated growth, the future outlook of the Chinese pharmaceutical industry in the near future 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.

In the next few years, varying regional policies, local protectionism and characteristic experiments will almost certainly result in a more fragmented and chaotic healthcare marketplace. Pharmaceutical companies need to be vigilant, prudent and flexible to navigate through troubled waters.

Also, 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 will instead be increasingly intertwined with the global pharmaceutical marketplace.