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China Pharmaceutical Guide

中国医药市场指南

Written by: James J. Shen, MBA

2012 (7th Edition)

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Written by:

James J. Shen, MBA

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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 25-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.

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 highly-respected English media and business intelligence service on China's pharmaceutical industry and market which is subscribed by almost all multinational pharmaceutical companies, CROs, consulting companies and investment banking firms active in China.

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

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

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

PREFACE

Despite the enormous business opportunities and growth prospects offered by China's healthcare sector, I've witnessed and experienced countless regulatory and business environmental changes, which has frequently caused painful business difficulties, frustrations and downfalls, in my past 25 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 25 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 2012 (7th Edition)

The China Pharmaceutical Guide 2012 (7th 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 2011 (full year) and early 2012 figures.
- ☞ A new chapter on “*Social Media Strategies and Opportunities for Pharma Companies*” and new data on Chinese online drug sales.
- ☞ Expanded coverage high growth market segments including oncology, diabetes, cardiovascular diseases and hepatitis, and added coverage of regional markets, especially those in Yangtze River vicinity.
- ☞ Updated coverage of emerging legal issues (including FCPA/compliance issues) and drug-related IP concerns, as well as new commentaries on recommended approaches for government affairs in China’s healthcare sector.
- ☞ Comprehensive top line data and research findings from our collaborative partners such as IMS Health, Kantar Health, Nicholas Hall, ZS Associates and RDPAC.
- ☞ All regulatory changes in 2011/2012 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, 2012.
- ☞ An updated section covering proposed new drug-related laws and regulations under drafting process with previews of the draft versions.
- ☞ Overview of China’s 12th Five-Year Plans for the pharmaceutical and related industries, as well as other long term industrial planning documents and foreign investment guidelines of the government.
- ☞ 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 2011 and early 2012.

- ☞ 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 2012 Edition.
- ☞ Comprehensive revision of the China operation profiles of MNCs to reflect their latest performance, business deals, legal disputes and outlook.

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

James J. Shen

June 30, 2012

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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 or MOC – 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

The world had a terrible year in 2011 with horrendous natural disasters, raging political uprisings and unstoppable global economic meltdown. Even China's economy began to show signs of slowdown.

The outlook for 2012 is by no means less gloomy. Many of the themes of 2011 will be carried over to 2012. The sovereign-debt crisis in Europe, the US budget deficit and the continuing debate over the sustainability of China's economic growth will still weigh on us this year.

Broad Chinese economy shows signs of weakness

"The march of the Chinese dragon is relentless. However, it is not immune to the economic morass of its major trading partners and is experiencing a slowdown in growth rate that is more rapid than anticipated," said Zacks Investment Research in a recent article.

Yet for all its successes, there are several imbalances in China's model of a mixed economy, the article went on to suggest. The government's search for a Goldilocks economy - not too hot, not too cold - may have backfired somewhat. Latest statistics indicate that overall export growth was sharply lower on a month-over-month basis, although the composite growth rate at 15.9% was still respectable, partly on account of buoyancy in Latin American markets.

There are other telltale signs of a cooling Chinese economy. The economy grew at 8.9% year over year in the fourth quarter of 2011, which represents the slowest growth rate in the past couple of years.

That took 2011's growth to 9.2% year-on-year, compared with 10.4% for 2010. Analysts said the figures suggested the economy was broadly on course, given the government's long-running attempts to curb inflation and property prices. But they warned the coming months are likely to see a more significant fall in growth.

The Chinese government has reacted to the challenges, although it does not want to signal a sharp policy shift in the open. It has cut the cash reserve ratio to infuse liquidity and announced in low profile an initiative to pour CNY 10 trillion into seven so-called "strategic sectors" (including biopharmaceuticals) over the coming five years. Among other measures, a politburo member has asked local officials to enhance their social management skills in order to curb social unrest and labor strikes.

The Chinese economic slowdown or any forms of financial system trouble are bound to affect the country's healthcare sector deeply from the perspectives of government investments, BMI funding and private consumption in healthcare.

The Chinese healthcare space is likely to be more challenging in 2012 with the

healthcare reform stalled with growing uncertainties, the wild government cost containment drive undercutting quality and supply, and the pharmaceutical industry in total disarray with disappearing profits. Little progress or improvements are expected before the upcoming 18th CPC Congress in November when the new Chinese government is installed. While Chinese healthcare demands continue to surge and business confidence remains high for long term prospects of the sector, there is widening gaps between near term goals of MNC headquarters and market realities projected by executives in the field.

Review of Chinese pharmaceutical sector performance in 2011

Healthcare demands in China remained robust last year. Matching this observation, the Chinese pharmaceutical industry performance in 2011 can be characterized as sustained high revenue growth at lower profit margins in the backdrop of intensified government cost containment.

Revenue growth and profitability are found to be imbalanced across subsectors and company categories. Smaller and flexible private companies continued strong growth, while large players, both state-owned and MNCs, lost ground with sharply falling growth. Subsector-wise, formulation traditional Chinese medicines and crude drugs fared much better than pharmaceuticals and biological products.

Sustained pharma industry revenue growth at lower profits

According to data released by the National Bureau of Statistics (NBS), the revenues of the Chinese pharmaceutical manufacturing sector grew 29.37% reaching CNY 1,452.2 billion. Meanwhile, growth of the sector's net profits slowed to 23.50% with a total of CNY 149.4 billion.

The sub-sector of crude drugs and formulated traditional Chinese medicines had the highest revenue growth at 56.11% and 34.76% last year, while those of pharmaceutical formulations and APIs fell far behind at 24.02% and 22.59%, which are well below average industry growth of 29.37%.

Hospital market

According to IMS Health, Chinese hospital drug market rose 17.1% in 2011, reaching CNY 366,101 million (US\$58,111 million). The growth rate was down nearly five percentage points when compared to the 21.9% growth rate in 2010, continuing a falling growth trend which started in 2008.

A look at quarterly growth rates reveals that domestic companies surpassed MNCs for the first time in Q4 with a growth of 17.4% versus 16.1% for MNCs. Over the course of 2011 MNCs and Domestic companies have grown at nearly the same rate with a difference of only 0.1 point in MAT growth rate, at 17% and 17.1%, respectively.

International trade

According to data from the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCIEMHP), the Chinese foreign trade of medicines and health products grew 39.09% reaching US\$73,284 million in 2011. Among the total,

import rose 46.12% to US\$28,768 million, while export surged 34.90% to US\$44,516 million.

On the import side, the growth trend is particularly strong with import of pharmaceutical formulations. Meanwhile, the Chinese export growth of medicines and health products in 2011 was driven by three trends: 1) increased sourcing of specialty APIs from China by the global pharmaceutical industry; 2) continuous global market expansion of China's conventional APIs; and 3) rising Chinese export sales of high-end medical devices.

Large pharma companies positions for the future as industry consolidation continues

Despite policy turbulences, pricing pressures and a host of other challenges, the pharmaceutical industry in China had shown unusual resilience last year. In the face of less desirable performance last year, large pharmaceutical companies, represented by state-controlled companies and MNCs, continued to reposition themselves through M&As, diversification drives, alliances and partnerships, and capacity building for both manufacturing and R&D. Against convention wisdom, smaller private companies actually did quite well last year on the back of disappointing performance of large companies.

Domestic pharma industry continues the trend of vigorous consolidation

Chinese pharmaceutical industry had another year of intensive industry consolidation in the face of all challenges. Armed with CNY billions raised from the stock market, the leading state-owned or state-controlled conglomerates led by SinoPharm, China Resources and Shanghai Pharma continued to dominate the domestic M&A landscape with a large number of big and small acquisitions nationwide throughout the year. As in the previous year, the intensive acquisitions were aimed at establishing national pharmaceutical distribution networks, boosting business scale and domination, and expanding market shares.

On the other hand, leading private and publicly-listed Chinese companies are putting more efforts into and making substantial progresses with their international business expansion plans. More of them secured GMP certifications and generic drug registrations from EU and U.S. authorities last year. Many of them, such as Simcere Pharma and Hengrui Medicine, have been investing heavily into development of innovative new drugs and me-too products. A few including Hisun and Simcere also began to forge partnership or joint ventures with MNCs for branded generics and R&D of new products.

MNCs continue to raise their bets on China

Multinational pharmaceutical companies pursued China expansion at full speed last year and were active across all spectrums including M&As, joint ventures, research partnerships, geographic and horizontal diversification, new and expanded research operations, manufacturing facility expansions, and internal restructures.

Besides a rising number of M&A, joint venture and alliance deals, MNCs are committing significantly more investments into their Chinese R&D operations. Moreover, MNCs were also keen on expanding their manufacturing capacities in China

last year to prepare for rising domestic demands and integration of Chinese manufacturing with their global supply chain.

Big multinational pharma companies also made multiple moves to break into lower tier markets in the past year through sales force expansion, sales channel realignments, alliances, joint ventures and acquisitions. Pfizer is particularly busy last year with such moves and it has formed joint ventures and close alliances with leading local distributors like Jointown and Shanghai Pharma. In addition, many MNCs are also working to expand horizontally into new areas like generic drugs and consumer healthcare. Companies like Pfizer, GSK, Merck and AstraZeneca formed joint ventures or acquired local companies last year to gain entry into the Chinese generic drug business.

In the vaccine sector, a number of MNCs are already well positioned for the sector's opportunities and they worked hard to bypass various policy restrictions on foreign companies through partnerships with Chinese players, as they introduced a rising number of new products in 2011. However, there are some complications with M&As in this area which we will get into some details later.

M&A space keeps heating up

Pharma China recorded 36 major M&A deals in 2011 including 15 between Chinese and foreign companies. Mergers and acquisitions among domestic companies accounted for 58% of all such deals recorded. At the same time, the number of joint venture/strategic alliance agreements rose to 54 compared with only 37 in 2010, a 46% jump year on year. Among the 54 joint venture/strategic alliance events, 31 were strategic alliance agreements and 23 joint venture deals.

The large state-controlled conglomerates continued to be the driving force for domestic pharma M&A in 2011. Shanghai Pharma kick off the M&A war among big players last year in February with its CNY 2.33B acquisition of China Health System, probably the largest pharma M&A deal in 2011. It then bought more companies including Wuxi Shanhe Pharma for CNY 344M and is believed to be exploring overseas acquisitions. SinoPharm's acquisition pace slowed somewhat last year, as China Resources Group (CRG) became Shanghai Pharma's acquisition archrival with multiple deals including CNY 1.5B reorganization deal of Shanxi Kangxingyuan Pharma, CNY 500M+ acquisition of Beijing Purenhong Pharma, and CNY 1B joint venture with Zhangzhou Piantzhuang Pharma.

Conversely, MNCs have become increasingly interested in acquisitions as a way to grow faster in China, although a few companies like Novo Nordisk have ruled out the option. The real challenge, nevertheless, is not only finding good candidates at acceptable prices, but also the quality of due diligence work and the ability to integrate the acquired Chinese business. MNCs made a flurry of new deals last year to acquire or form joint ventures with Chinese companies in order to facilitate faster expansion.

The biggest motivation of MNC acquisitions and joint ventures last year was probably about access to China's vast low-cost generic drug market. Most recently, AstraZeneca bought privately-held Guangdong Beikang Pharma, a Chinese maker of generic

injectable antibiotics, for an undisclosed amount. Merck formed a joint venture with Sincere Pharma for branded generics in major therapeutic areas, while Pfizer signed a MOU with Zhejiang Hisun Pharma to establish a joint venture in the branded generics arena and launched a joint venture for animal vaccines. Besides, Lonza Group and Shanghai Fosun Pharma also announced a JV for high-end generic drugs.

Cross-border licensing and R&D partnerships continues to uptick

The trend of co-development, alliance and joint venture deals last year among major Chinese players and smaller foreign research companies continued last year with rising number of deals. Pharma China recorded a total of 24 Sino-foreign licensing deals in 2011.

While more deals still focused on development and commercialization of drugs not yet marketed in China, a growing number of deals are for R&D of experimental drugs such as those between Chiva Pharma and Ligand, as well as among the two institutes under the CAMS and Agenix Limited, to name just a few. Most of the Sino-foreign licensing deals are usually for China rights of new drugs with a few exceptions where expanded territories and global rights are involved.

There were also a few out-licensing deals where Chinese companies form joint ventures with foreign research companies for global development of their innovative products such as the deals between SemBioSys Genetics and Tasly Pharma as well as Jiangsu Kanion Pharma and NewGen Therapeutics.

More drug regulations came on stream in 2011

The various agencies of the Chinese central government issued a total of 32 polices and regulations which have significant impacts on the pharmaceutical sector in the country, according to *Pharma China's* Regulatory Monitor.

The SFDA remained the main force for issuing new drug regulations last year, followed by and the Ministry of Health (MOH), which is becoming increasingly active in the drug regulatory theme, not to mention the agency also oversees the SFDA.

Among the total in 2011, 20 were issued by the SFDA, five from the MOH and the rest 7 from the National Development and Reform Commission (NDRC), the Ministry of Commerce (MOFCOM) and the State Council. New regulatory introductions by the SFDA doubled last year mostly because of the restructure of CDE's drug registration review framework.

Drug quality and safety remained the top regulatory priority last year for the SFDA. Following five years of drafting and comment seeking, the agency, in association with the MOH, issued the 2010 Revised Edition of *Good Manufacturing Practice for Pharmaceutical Products* (GMP), with effect from March 1, 2011.

Meanwhile, the NDRC continued to struggle with its much-delayed revision of the Chinese drug pricing regulation, it managed to issue in the past year two important regulations, namely the *Rules for Ex-manufacturer Drug Price Survey (Interim)* which seeks to streamline practices and processes of ex-manufacturer drug price surveys of the

agency and the "*Rules for Differential and Relative Pricing of Drug Products*" which targets price manipulation by irregular drug producers through changes of dosage forms, specifications and packaging.

Healthcare reform in stalemate with little visibility ahead

2011 is the last year in the first phase of the Chinese healthcare reform (2009-2011) and, by the end of it, all stakeholders, including the public, the pharma industry, the medical community and the government agencies, have shown substantial disappointment and frustration with the reform progress and achievements, with the exception of only a few brighter spots. Everyone endured wild turbulences of the reform but none has seen light at the end of the tunnel.

Although the healthcare reform is relatively more successful in expanding its enrollment to over 95% of the Chinese population and implementing the essential drug system in all primary medical institutions, it has made little or no progress on the part of core reform objective - revamping the flawed hospital finance model which draws blood from drug sales profits.

“Separating medicine from drug sales”, once a key task of the reform, failed before any meaningful attempts by the government, which apparently was stunned by unyielding demands of public medical institutions for sharply-increased state funding and requests from hospital directors for startling pay raises reportedly in the range of CNY millions annually.

The public hospital reform experiments in the past three years was only scratching on superficial issues such as measures to improve patient access and infrastructure building for hospital IT systems. One of the very few areas of some visible progress is on the reform of BMI’s medical payment/reimbursement system with different models like DRGs, lump-sum advanced payment and headcount-based payment tested at reform sites and introduction of over 100 clinical pathways by the MOH. The ministry has hence been trying to re-engineer the objective of “separating medicine from drug sales” to BMI’s medical payment system reform.

Failures to move reform forward in urban public hospitals in the past three years, despite experiments at 17 national trial cities and 37 provincial trial sites, has forced the Chinese government to refocus the public hospital reform on county level medical institutions in 2012, hoping to jumpstart reform from the bottom.

The deadlock with reform of the Chinese healthcare financing mechanism and public hospital is also blocking progresses in other areas. Although the national essential drug system and the zero drug sales margin policy are now in place at the primary level, local government funding failures and shortages have crippled many primary medical institutions. Urban public hospitals, in the meantime, resisted attempts of the government to impose essential drug inventory and consumption quota on them as they need the profits from premium drug products to keep going.

On the other hand, over-emphasis on price bidding by local governments has become a critical issue for provincial-level drug purchase tenders, especially those for essential

drugs, as a result of central government support of the “Anhui model” which focuses on price almost exclusively. The aftermath is alarming with drug quality falling drastically and shortage of low-cost medicines surging. Besides, reputable large companies, both state-owned and foreign, are losing grounds to smaller and often irregular players on a considerable scale.

Drug pricing reform is also stuck, because the urban public hospitals live on the high profit margins of drug products and they, along with their allies in the pharma industry and local governments, made sure that the NDRC is sufficiently confused with and eventually misses its targets. Under mounting public pressure, the agency had to initiate more sweeping price cuts, as disputes among stakeholders and government agencies continue to prevent it from coming up with a well-defined drug pricing reform framework, not to mention the much anticipated revision of the outdated *Provisions for Drug Price Control* which was issued in 2000 and has not been enforced for years.

Despite wide-ranging problems, the Chinese government did manage to raise its healthcare funding for both BMI programs. As a result, China's healthcare expenditure composition is also undergoing major changes with falling shares of personal out-of-pocket expenditures (35.5% in 2010 from 60.0% in 2001) and rising shares of government expenditures (28.6% in 2010) and socialized expenditures (35.9% in 2010). 2011 data is not available yet, but expected to be consistent with the trend. Besides, China also boosted state funding for infrastructure building in primary healthcare institutions. However, shortage of qualified healthcare talents remains a dire challenge in primary healthcare despite comprehensive facility upgrades.

With a new Chinese government set to take over after the 18th CPC Congress this November, all things at the government have slowed down for this reason and it is therefore unlikely the healthcare reform will see any major breakthroughs this year. Executive Vice Premier Li Keqiang, who has been in charge of healthcare reform, is presumed to take over Premier Wen Jiabao, so the overall direction of Chinese healthcare reform is expected to stay on course.

Before the end of 2011, Li acknowledged at a meeting of the State Council the healthcare reform progress in the past three years and demanded consolidation of the reform achievements and completion of the *Plan for Deepening Pharmaceutical and Health System Reform during the 12th Five-Year Period (2012-2015)*. The plan is under development by healthcare policy experts, academic institutions and government agencies, who will review experiences and lessons in the past three years and propose a revised roadmap of healthcare reform.

Li upheld the core reform principles of 1) healthcare as a public welfare item; 2) essential and universal coverage of the BMI system; and 3) restructure of healthcare mechanisms with emphasis on prevention, rural healthcare and co-existence of traditional Chinese and Western medicines.

He said the objectives in the next phase of healthcare reform will move from "expanding coverage" to "raising its quality" of the BMI system, from "strengthening" to "full development" of primary healthcare, from "conducting trials" to "full implementation"

of the public hospital reform, and from "upgrading hardware" to "centering on service improvements" of the healthcare system.

Li also called for increased government subsidies of the BMI system along with its continuous coverage expansion, exploration of a major medical coverage mechanism, actively development of commercial health insurance, expansion of the national essential drug system to village clinics and non-public primary healthcare institutions, establishment of a new order for pharmaceutical production and distribution, and streamlining of drug pricing mechanisms.

Long term positive outlook unchanged with possibility of a slowdown this year

Pharma industry experts continue to maintain a long term positive view of the Chinese pharmaceutical market. A number of forecasts were released by well-established sources throughout last year.

Assuming the Chinese economy continues its steady growth at an annual rate of 8% GDP increase and the global economy will not dip further to hurt exports, SMEI predicts that the Chinese pharmaceutical industry (seven subsectors) will grow 21.5% in 2012 to a new high of CNY 1,850 billion. In addition, it projects that the Chinese drug market will continue to rise at 18% this year to CNY 1,074.9 billion.

In the meantime, a new report by Visiongain also forecasts sustained double-digit growth in the Chinese pharmaceutical market from 2011. Overall pharma revenues gained in China will rise to US\$116.8 billion in 2015, the report says. At the same time, a new study of RNCOS anticipates the pharmaceutical market in China to reach US\$87.2 Billion by 2014, growing at an impressive CAGR of around 20% during 2011-2014, while research of RNCOS suggests that the growth of the Chinese pharmaceutical industry will be driven by the high population base, healthcare spending, and high prevalence of chronic diseases. The pharmaceutical market in China is likely to reach US\$87.2 Billion by 2014, growing at an impressive CAGR of around 20% during 2011-2014.

However, in the short term, Barclays Capital predicted in its latest report, *China Healthcare & Pharmaceuticals: Finding Gain in the Pain*, that the downside will prevail in 2012 for most publicly-listed China healthcare and pharmaceutical companies. Broadly, Barclays expect continued policy focus on providing basic healthcare across China at the lowest possible price, at least through 3Q12. The company forecasts that drug prices will continue to decline through 3Q12 and it anticipates more centralized tenders, more cuts and limits in the drug and stent sectors, at least through 3Q12.

Credit Suisse also sees a slowdown of the Chinese pharmaceutical industry growth in 2012. The company expects the industry's revenue growth mildly falling to between 15%-20% in 2012, compared with around 30% growth in the past five years. The high Chinese pharma growth rate in the past was brought by expanding basic medical insurance (BMI) coverage, it points out. With universal coverage of the BMI near completion now, future growth is anticipated to slow down as the rise of BMI funding from premium contribution increases will be limited. Additionally, Credit Suisse

believes that government is likely to cut drug prices routinely in future, not to mention that centralized drug purchase tenders will drive drug prices down further.

Deloitte seems to agree with the above two estimates. Its report, *The Next Phase: Opportunities in China's Pharmaceuticals Market*, expects continued strong but modest growth for Chinese pharma between 2011 and 2015 at around 15%. But the report predicts the CAGR of patented drug sales in China to sustain at 25% in the next five years.

As opposed to the short term unenthusiastic view of Barclays Capital and Credit Suisse, analysts of Shenyin & Wanguo Securities offer a more positive outlook and it expects profitability of the Chinese pharma industry to grow 25% in 2012. The prediction is backed by other Chinese experts who believe in steady healthcare demand growth in China from rising desires for better healthcare, aging of the Chinese population, surging prevalence of chronic diseases, and elevated funding of the BMI from both premium contribution growth and boosted government subsidies. Nonetheless, analysts generally agree that sub-sectors including medical devices, healthcare services, consumer healthcare products and formulated traditional Chinese medicines will do better than pharmaceuticals in the foreseeable future.

On the vaccine front, the outlook is quite bright with much better visibility despite challenges in the overall pharma space. Although China has the largest vaccine manufacturing capacity in the world, the local vaccine industry fail to meet the domestic demands for some essential vaccines and it has weak R&D capabilities. The Chinese government therefore hopes to accelerate the development of the Chinese vaccine industry in the 12th Five-Year Plan period (2011-2015) through a number of measures including 1) elevating the government's role in vaccine R&D; 2) adopting new vaccine R&D strategies; and 3) introducing differentiated vaccine pricing policies.

Another bright spot of Chinese pharma is new drug R&D. The Chinese government plans to muster a total of CNY 40 billion into funding for major new drug R&D projects in the 12th Five-Year Plan (2011-2015) period, doubling the same figure for the 11th Five-Year Plan. The financial support for R&D of new biological products is expected to be stepped up in particular.

Most significantly, the Chinese government recently unveiled a plan to pour CNY 10 trillion (US\$1.7 trillion) over five years to support the development of seven emerging industries of strategic importance including the biopharmaceutical industry.

Besides government support, the infrastructure of pharmaceutical R&D in China is quickly maturing with MNCs accelerating their R&D relocations to China last year, growth of the Chinese drug R&D outsourcing sector, sharply increased presence of pharma related service providers, and rising research investments of leading Chinese pharmaceutical companies. As the global drug R&D paradigm continues to shift east, China is almost set to become a global drug research hotspot in the near future.

Switching to the OTC drug market, China Non-prescription Medicine Association released a new blue book last year on development of the Chinese non-prescription

medicine sector suggesting that the Chinese OTC drug market had grown five times between 2000 and 2009 and is estimated to reach CNY 192 billion by 2014.

In conclusion - Future remains rosy for MNC players despite interim challenges

On the bright side, the Chinese government remains committed to drug innovation at the macro policy level and is making growing moves at both the central and local levels to provide funding and policy support to drug innovation. Besides, the government generally stands by large pharmaceutical companies in consideration of better regulation and quality control. As China's economy continues to grow, the government will be able to invest more into healthcare and people will be able to afford higher quality healthcare.

The ongoing Chinese pharmaceutical industry consolidation, which is encouraged by the government, also benefits MNCs as small irregular players are forced out of business and the order of healthcare marketplace returns.

Undeniably, however, MNCs face many serious challenges along the process of the Chinese healthcare reform. While all pharmaceutical companies in China are caught in the reform process, irrational cost containment measures, especially uneven price control moves and unpredictable policy swings, probably hurt MNCs the most.

As margins of off-patent originator drugs narrow, MNCs face the test of not being able to replenish their innovative pipeline in time, which are often attributable to the slow approval process of innovative drugs by the SFDA.

There are also a few other issues which cloud the long term prospects of MNCs in China healthcare. In particular, the healthcare reform has the tendency of preferring low-cost generic drugs, and hence premium products of MNCs are frequently beyond the reach of China's BMI system, which is designed to provide essential but universal healthcare coverage.

The long term prospects of premium healthcare products lie with the development of a sound commercial health insurance system, without which China's healthcare expenditures can be expected to remain at around 5% of GDP and most of it will be consumed on low-cost generic drug products.

The building of a commercial health insurance system is supported by Chinese policies and some initial groundwork has been carried out. But the sector's development is largely tied with the healthcare reform progress and its outlook is still blurry. The MNCs are therefore advised to provide meaningful support to the development of this sector.

