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China Pharmaceutical Guide

中国医药市场指南

Written by: James J. Shen, MBA

2013 (8th Edition)
Volume 1

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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 26-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 26 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 26 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 2013 (8th Edition)

The China Pharmaceutical Guide 2013 (8th 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 2012 (full year) and early 2013 figures.
- ☞ Expanded coverage on the primary healthcare sector, the OTC and consumer healthcare sector, high growth market segments, key regional hospital markets, the pharmaceutical distribution sector and online retail pharmacy segment.
- ☞ Added coverage of the Chinese biosimilar market prospects and regulatory outlook.
- ☞ Updated coverage of emerging legal issues (including FCPA/compliance and liability issues) and drug-related IP and trademark concerns.
- ☞ Comprehensive top line data, research findings and observations from our collaborative partners such as IMS Health, Kantar Health, Nicholas Hall, ZS Associates and RDPAC.
- ☞ All regulatory changes in 2012/2013 are updated to present a clear and most up-to-date picture of the Chinese drug regulatory framework with summaries and analysis of all drug regulations in effect by mid-2013.
- ☞ Focused coverage of China's deepening reform of its drug registration and evaluation regime, new policies to support drug innovation and high clinical value generics, and its initiative to re-evaluate all generic drugs with bioequivalence studies.
- ☞ An updated section covering proposed new drug-related laws and regulations under drafting process with previews of the draft versions.
- ☞ Extensive review and analysis of China's drug registration applications and approvals as well as Chinese drug innovation trends in recent years.
- ☞ Comprehensive review of Sino-foreign M&A, joint venture, strategic alliance, licensing, research partnerships, co-marketing, and new drug research events in 2012 and early 2013.

- ☞ 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 2013 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, 2013

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TABLE OF ABBREVIATIONS

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

TCM – Traditional Chinese Medicine

WHO – World Health Organization

USTR – US Trade Representative

WTO – World Trade Organization

VAT – Value Added Tax

VC – Venture Capital

WM – Western medicine

EXECUTIVE SUMMARY

James J. Shen

The Chinese pharmaceutical industry and market in 2012 was characterized by slowing growth, falling profitability, mixed regulatory developments setting higher industry standards to improve drug safety and boosting drug review efficiency, renewed price cutting initiatives disregarding higher costs and expenditures of the industry, superficial healthcare reform progress driven primarily by cost containment measures, fallen healthcare quality & growing drug safety incidents, worsening patient-physician relations, and non-stop repositioning of the pharma industry adapting to new realities.

Overview of China's pharmaceutical industry and market performance in 2012

National Development and Reform Commission (NDRC) announced on March 1, 2013 that the total output value and core business revenue of the Chinese pharmaceutical industry grew 21.7% and 20.1% reaching CNY 1,825.5 billion and 1,795.0 billion respective, while the industry's net profit rose 20.4% to CNY 183.3 billion. Annual output and revenue growth rates fell by multiple percentage points in 2012. Subsectors of crude drugs and chemical drug formulations grew above average core business revenue growth at 27.5% and 25.3% respectively, while the growth of the rest three subsectors of APIs, formulated TCMs and biological/biochemical products slowed to 15.9%, 16.9% and 14.3% respectively.

Given the present market environment, it is generally anticipated that pharmaceutical industry growth in the near future would no longer match the high rates seen in 2010 and 2011. Industry profit growth continued to fall behind output value and revenues, although the speed of its freefall slowed somewhat compared with 2011. In the interim, the pharmaceutical formulation, formulated TCM and crude drug subsectors are holding out better in terms of output value and revenues, while profit erosion is less acute in the pharmaceutical formulation and crude drug subsectors.

On a positive note, IMS estimates that China's hospital market (≥ 100 beds) reached CNY 442 Billion in 2012 with MAT growth rate of 20.9%. This upward trend (compared to a growth rate of 17% in 2011) is forecasted to continue in the coming years, driven by increased government focus on healthcare reform, as well as the launch of premium-priced innovative medicines.

Looking at specific treatments or therapy areas, Systemic Antibacterials have decreased in recent years, but rebounded in 2012 following new market-wide policy adoptions. Meanwhile, other therapy areas (mainly TCM) continued on a growth trajectory, each recording up to a 36.3% growth rate. TCM, Diabetes and Cardiac drove market growth, with TCM contributing most to the overall MAT 4Q12 growth rate. Cardiac has become a new star in the local market while Oncologics, Anti-Asthma & COPD products, Anti-thrombotic agents and Anti-virals are the main growing points for MNC's.

It was a very eventful year for China's OTC market in 2012 with several developments

contributing to a slowdown in growth compared to 2011. The Chinese OTC drug sales growth slowed to 7.4%, according to Nicholas Hall's DB6 sales for 2012. Key contributors to this slowdown are the gelatin capsules scandal, stricter controls on OTCs containing pseudoephedrine and increased availability of zero-margin Rx and OTC generics in hospitals.

Chinese online B2C drug market outshined all other sectors with its explosive growth. The Chinese B2C online drug sales reached CNY 1,665 million in 2012, more than three times of such sales in 2011 (CNY 400 million), according to data from the China Online Pharmacy Society (COPS).

China's international trade of medicines and health products (MHPs) grew 10.5% in 2012, reaching US\$80,950 million in total, according to the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCIAMHP). Among the total, export rose 6.9% to US\$47,600 million while import grew faster at 15.9% to US\$33,350 million in the year. Growth of MHP import and export slowed sharply last year compared with 2011 and was at their lowest point in at least the past five years.

Western medicines (WMs) accounted for 60% of all Chinese import of MHPs in 2012, while import of traditional Chinese medicines (TCMs) saw higher growth of 22%. Meanwhile, WM formulation subsector saw the highest export growth last year at 18% in value and 16% in volume, as export of biochemical drugs dropped in both value and volume and API export growth grew only 3% in both value and volume.

Drug regulation emphasized on pricing, drug quality & safety, cGMP, OTC sector and registration efficiency last year

Central government agencies including SFDA, Ministry of Health (MOH) and National Development and Reform Commission (NDRC), had been leading the efforts of strengthening pharmaceutical regulation, while other agencies such as the Ministry of Commerce (MOFCOM) and the Ministry of Industry and Information Technology (MIIT) stepped up their industrial management role of the pharmaceutical industry through new policies and regulations which are designed to boost and protect interests of the pharmaceutical manufacturing and distribution sectors.

Price control

The NDRC sought to deepen drug pricing reform last year through a number of new measures including 1) strengthening price survey and surveillance; 2) pricing experiments of selected drug products using pharmaco-economic and international reference pricing approaches; 3) more price cuts targeting foreign originator drugs; 4) streamlining drug pricing in the pharmaceutical distribution process; 5) establishing a dynamic review mechanism for drug prices; and 6) researching on drug pricing policies which will encourage innovation.

It continued its new round of price reduction initiative which started in 2011. The NDRC had slashed drug prices of eight other therapeutic categories, including antibiotics, circulatory system, nervous system, hormonal, digestive system, oncology, immunology and blood drugs, since 2011. Most recently, the NDRC issued a notice to slash prices of

over 400 drugs by an average of 15% with effect from February 1, 2013. These products come from 20 therapeutic classes including respiratory system drugs, antipyretics and analgesics, and special drugs used by various medical specialties. The latest cut completes this round of price revision on all chemical drugs. The agency said it will move on to the prices of formulated traditional Chinese medicines thereafter.

Chinese analysts believe the cuts on maximum retail prices in 2012/2013 have limited negative impacts on the pharmaceutical industry as the actual tender purchase prices are mostly much lower than such prices. However, as the prices of more expensive MNC branded products are cut deeper this time and such products are usually less discounted at the centralized hospital drug purchase tenders, foreign companies are bound to be the hardest hit this time.

Drug quality and safety/cGMP implementation

First of all, the State Council issued at the beginning of 2012 the *12th Five-Year Plan for Drug Safety (2011-2015)* which sets the tone and direction of China's drug quality and safety regulation in the next five years.

As required by the plan, the SFDA released its "*Plan for Bioequivalence Study of Generic Drugs*" in February 2013. It calls for re-evaluation of all approved generic drugs through phased bioequivalence studies by 2020. Also mandated by the plan, the MOH issued the long anticipated *Provisions for Clinical Application of Antibacterial Drugs* (MOH Order #84) with effect from August 1, 2012.

To boost supervision of drug quality, the SFDA issued the "*Guiding Opinions for Electronic Supervision of Drug Products*" last October. The agency also introduced *Relevant Requirements on Strengthening Supervision and Management of Pharmaceutical Excipients* to strengthen regulation of pharmaceutical excipients with effect from February 1, 2013.

Most recently, four central government agencies including the SFDA, the NDRC, the MIIT and the MOH issued in January 2013 a joint notice containing seven new measures, including enhanced registration process, premium pricing and preferential tender treatments for cGMP compliant products, which are designed to push forward implementation of the 2010 GMP and eliminate outdated production capacities.

Drug evaluation/approval system efficiency

The SFDA will undertake four measures to improve drug registration efficiency through 1) delegation of certain responsibilities to local drug administrative agencies, 2) simplify procedures, 3) increase of human resources for drug evaluation, and 4) rebalancing the relationship between drug evaluators and registration applicants.

To facilitate these goals, the SFDA issued the "*Opinions on Deepening Reform of Drug Evaluation & Approval and Encouragement of Drug Innovation*", which is promulgated to deepen reform of drug regulatory regime, further strengthen the administration of drug registration, enhance the efficiency and standards of drug evaluation, and accelerate the evaluation and approval of innovative drugs and generic drugs with clinical value, in February 2013.

In addition, the Chinese government may finally move to expand the personnel force of the SFDA in order to relieve its mounting workload and expedite drug review and approval, according to Chinese press reports quoting an official of the SFDA.

OTC drug regulation

SFDA announced in late 2012 a set of six technical guidelines for switching prescription drugs to OTC drugs. It continued its drive to switch some prescription drugs to OTC status last year. For example, it approved OTC conversion of 36 drugs, including nine chemical drugs and 27 formulation traditional Chinese medicines, in last November.

But the agency also made a decision in December 2012 to switch six ephedrine-containing OTC drugs, back to prescription drug status. The agency wants the industry to revise relevant package inserts and packaging accordingly.

Meanwhile, a proposal of the SFDA to ban advertising of OTC drugs on mass media through a revision of the *Provisions for Evaluation of Drug Advertisements* overshadowed the OTC drug sector. Faced with the unprecedented fury from the pharma industry, SFDA sought to calm participants that the revision is still under evaluation and nothing is final yet.

Drug regulatory direction in the new year

The SFDA reported its plan for reform of the Chinese drug regulatory regime at the latest National Food and Drug Regulatory Conference in early 2013. The planned moves by the SFDA include:

Revision of the Drug Administration Law – This work will be initiated this year to improve various regulatory systems including those for technology transfer, contract manufacturer, certifications and exit mechanisms. Reportedly the SFDA has established a new office to revise the law and it is expected to be a comprehensive amendment;

Promoting 2010 GMP compliance and upgrading - cGMP certification of blood product, vaccine and injection manufacturers will be completed this year. The SFDA also issued a joint notice with three other central government agencies recently to push forward implementation of the 2010 GMP and to eliminate outdated production capacities;

Raising standards of drug products – The agency will begin efforts to raise 1,500 national drug standards and publish the second addendum of the Chinese Pharmacopoeia. It will also initiate bioequivalence studies of more than 50 generic drugs this year. Those passing such studies will be offered preferential treatments including premium pricing. Essential drugs will be the center of above work; and

Reform of the drug evaluation and approval system – The effort is emphasized on elevating the role of local drug administrative agencies to improve drug evaluation efficiency and encourage new drug innovation and pediatric drug development in China. Relevant procedures will be simplified and certain authorities/responsibilities will be delegated to local agencies. The move began experiment last December in Guangdong.

Reorganization of China's healthcare agencies

China announced the reorganization plan of central government agencies under the State Council in March 2013. Specifically related to the healthcare sector, the National Health and Family Planning Commission (NHFPC) would be established combining the Ministry of Health (MOH) and the National Family Planning Commission (NFPC). The existing functions of the NFPC for population-related strategic development, planning and policies would be moved to the National Development and Reform Commission.

The State Administration of Traditional Chinese Medicine would be under the administration of the new NHFPC, while the State Food and Drug Administration (SFDA), which was under the MOH, would be expanded into an independent and full cabinet level agency, China Food and Drug General Administration (CFDA), which would be responsible for overall and uniform regulation of food and drug quality, safety and efficacy in the country.

Little progress on the front of healthcare reform in 2012

As predicted, China's ongoing healthcare reform last year was limited by structural flaws, lack of central government will to finance reform, failures to coordinate agendas of different agencies and balance conflicting interest of stakeholders, fiscal challenges of local governments, and belated reform of the medical service industry.

Review of healthcare reform progress in 2012

In reality, the Chinese government at the central and local levels did step up their healthcare investment somewhat, but it is far from enough to finance the reform goals, especially the calling to move away from the existing hospital financing model of "funding medical services with drug sales revenues". In fact, the government dependence on cost containment to finance reform became more acute in the backdrop of slowing Chinese economy and central government move to reduce local government reliance on land sales and the real estate sector.

Major reform areas of notable progress last year are laid out as follows:

BMI and major medical coverage – Six central government agencies headed by the NDRC issued a new healthcare reform policy, *Guidelines for Urban and Rural Resident Major Medical Insurance*, in August 2012. The policy seeks to provide major medical coverage, "a systematic arrangement to further protect against extraordinary medical expenditures of major diseases beyond existing coverage of the BMI system", to participants of the urban resident BMI program and the NRCMS. The policy sets the tone for the execution approach of the urban and rural major medical coverage - purchasing such policies for its participants from commercial insurance companies through tenders.

Essential drug system (EDS) - It was implemented in 74.6% of all village clinics and public primary healthcare institutions last year. Along with the EDS implementation, the policy of zero margins on essential drug sales was enforced in most areas. Besides, MIIT, NDRC, MOH and SFDA jointly issued the *Notice on Initiating Trials of Designated Production of Essential Drugs with Low Consumption but Clinical Demands* in a move to secure supply and quality of such drugs. In the initial phase, five to ten chemical essential drugs with low consumption and clinical demands will be selected for designated

production trials soon.

Overall public hospital reform – The experiment was launched in more than 1,000 county level hospitals of over 600 counties as well as selected urban hospitals in 17 trial site cities last year. The State Council issued the "*Opinions for County Level Public Hospital Overall Reform Trials*" on in June 2012. Primary requirements include: 1) separation of medical institutions from drug sales as in previous policies, but leaving it open for local governments to find their own ways; 2) BMI's role in cost containment is emphasized highlighting the requirements for budgetary control and overall spending caps; 3) lower drug prices and introduction of BMI payment reform especially the disease-group-based payment scheme; 4) nothing new on the centralized hospital drug purchase tender policy but the link between volume & price and the integration of tender and purchase are stressed; 5) linking the outcomes of performance evaluation over cost containment, healthcare quality and service efficiency with hospital director employment and remuneration as well as government financial subsidies and overall salary level of hospitals; and 6) BMI supervision, motivation and punishment of hospitals and physicians are strengthened.

Cost containment/BMI payment system reform - A recent MOH report claims partial success of cost containment in the past through optimizing healthcare resource allocation, centralized drug purchase tenders, overall cap of hospital expenditures and improving internal hospital management.

In a related development, three central government agencies, MOHRSS, MOF and MOH have jointly issued a new policy, *Opinions for Implementing Overall Expenditure Control of BMI Payments*, which aims to "rationalize budgeting, contain BMI expenditure outlay and allow reasonable growth". The policy requires the measure of overall control of BMI expenditures to be implemented nationwide within two years, and standards of such control will be developed using relevant data in the previous three years.

Planned reform initiatives and outlook in 2013 and beyond

The much anticipated "*Plan and Implementation Scheme for Deepening Healthcare System Reform in the 12th Five Year Plan Period*" was released by the State Council in March 2012. The document reinstated many healthcare reform directions in previous policies, but with fresh objectives for the *12th Five-Year Plan* (FYP) period (2011-2015).

During the period, the government will continue the infrastructure building of the basic healthcare system, restructure the medical service provision system with a multi-layered medical insurance system and diversified funding sources, improve EDS, deepen public hospital reform starting from the county level, strengthen drug safety through streamlining distribution process and rationalizing pricing, control healthcare expenditures while enhancing access, and raise government healthcare investments faster than government budget growth.

Highlighted among others are the importance of the BMI payment/reimbursement reform, development of the commercial health insurance sector, EDS implementation/NEDL expansion/essential drug purchase mechanism enhancement, public hospital reform at the

county level and revamp of the hospital financial model, emphasized BMI's role in containment of healthcare expenditure growth, and reform of the drug price formation mechanism.

Pharma industry on the defensive amid challenges as MNCs face wrath of cost containment

The pharmaceutical industry in China continued to outperform other industries last year in spite of a fresh array of policy turbulences, pricing pressures, intensified cost containment, slowing economy and a host of other challenges, and it managed to grow at around 20%.

Faced with unprecedented challenges, 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.

MNCs remain committed despite recent setbacks in business environment

Many originator drugs were affected by the last few price cuts in 2012 and early 2013, as MNCs are increasingly targeted for cost containment efforts of the Chinese government.

Chinese analysts believe the cuts on maximum retail prices in 2012/2013 have limited negative impacts on the pharmaceutical industry as the actual tender purchase prices are mostly much lower than such prices. However, as the prices of more expensive MNC branded products are cut deeper in recent price initiatives and such products are usually less discounted at the centralized hospital drug purchase tenders, foreign companies are bound to be the hardest hit.

Meanwhile, big pharma companies engaged in a variety of strategies, including strengthening local R&D and product launch; business diversification into vaccines, generic drugs and consumer healthcare; geographic expansion into lower tier markets; restructure of their business organizations; co-marketing and M&As in order to maintain high growth in China.

Joint venture continues to be a preferred route to diversification. Many new deals along this line had been reached last year including those between Merck and Simcere, Pfizer and Hisun, Guangdong Techpool and Nycomed, Fresenius and Wuhan Lishizhen Pharma, to name just a few. In the meantime, a new breed of joint venture, which aims to develop and commercialize new drugs in China, also began to emerge recently. The case in point is the venture between AstraZeneca's MedImmune and WuXi AppTec for development and commercialization of MEDI5117, a novel biologic for autoimmune and inflammatory diseases.

On the hospital drug market, local companies took a more aggressive approach, and experienced a growth rate of 21.8%, versus 18.2% for MNCs in 2012. Four of top 10 leading companies are Domestic, their 2012 growth rate ranged from 19.3% (JS Yangzijiang) to 34.3% (Shandong Qilu). Growth rates for their MNC counterparts on the other hand ranged from 15.4% (Astrazeneca) to 24.7% (Roche).

But Pfizer still held the top position based on the 2012 revenue of CNY 10 Billion and a

growth rate of 24.4%. The second ranked company is Astrazeneca Group with a 2012 sales value of CNY 7.8 Billion.

Industry consolidation supported with heated M&A space

The Chinese government continued to push forward its never-ending dream of "industrial giants", which are expected to rival MNCs on a global scale eventually, with various proposed new policies to promote consolidation in and reorganization in the pharmaceutical industry.

The number of major pharma M&A deals recorded by *Pharma China* for 2012 (38) was roughly on par with 2011 (36) but much lower than 2010 (46), while the number of M&A agreements between Chinese and foreign companies last year (18) was up slightly from 15 such deals in 2011. Mergers and acquisitions among domestic companies accounted for 53% of all such deals recorded.

Conversely, JV/strategic alliance agreements dropped dramatically to 33 last year compared with 54 in 2011 and 37 in 2010, a 39% down year on year. Among the 33 JV/strategic alliance events, 13 were strategic alliance agreements and 20 were JV deals.

Multinational drug companies are spending record amounts on acquisitions in emerging markets, with China the most attractive target nation, according Thomson Reuters data. Overall expenditure by both overseas and domestic pharmaceutical companies in emerging markets has reached US\$20 billion so far this year, up two-thirds on the 2011 total. An analysis of year-to-date deals by law firm Freshfields Bruckhaus Deringer, published on December 12, showed China accounted for US\$6.8 billion of the total.

A new trend is also taking shape slowly where Chinese pharmaceutical companies are buying up or acquiring a stake in foreign drug firms for international market access or as a part of R&D partnerships.

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

MNCs increasingly utilize licensing and co-marketing to bring in additional revenues. Data from *Pharma China* shows the number of Sino-foreign and foreign-foreign licensing deals rose to 30 last year compared with only 22 in 2011, a jump 36% year on year. 12 of such transactions was recorded in the second quarter.

Despite the hurdles, PhRMA expects R&D cooperation between its member companies and Chinese counterparts to increase in the coming years. Indeed, many big pharma companies made plans for or executed R&D expansion projects or reached major partnership deals last year.

There were also a total of 29 contract research/collaborative R&D deals recorded last year, up slightly from 23 such transactions in 2011. Among the total, 25 were between domestic Chinese and foreign companies. The deals that took place in the first and fourth quarters of last year represented 69% of the annual total.

Old IP issues remain ...

China has put in place a framework of laws and regulations aimed at protecting the IPR as

required by the TRIPS Agreement, according to USTR's 2012 Report to Congress on China's Compliance with WTO. However, some critical changes to China's legal framework are still needed in a few areas and effective enforcement of China's IPR laws and regulations remains a significant challenge, it says.

Specifically in the pharmaceuticals sector, the report highlights a range of concerns as follows: 1) China committed to allow foreign suppliers to distribute pharmaceuticals by December 11, 2004. However, many other restrictions continue to make it difficult for foreign pharmaceutical companies to realize the full benefits of China's distribution commitments; 2) China has continued to maintain price controls on some products and services including pharmaceuticals; 3) China is encouraged to provide an effective system to expeditiously address patent issues in connection with applications to market drug products; 4) the extent to which China provides effective protection against unfair commercial use of, and unauthorized disclosure of, undisclosed test or other data generated to obtain marketing approval for pharmaceutical products is of concern; and 5) despite repeated anti-piracy campaigns in China and an increasing number of civil IPR cases in Chinese courts, overall piracy and counterfeiting levels in China, including the pharma industry, remained unacceptably high in 2012.

Guarded outlook for 2013 despite signs of stability

Broad pharma industry and market

SMEI expects the Chinese pharmaceutical industry and market performance to bottom out in 2013, but suggests the growth rate may not be able to match the well-above-20% level seen between 2009 and 2011.

The size of the Chinese drug market at retail price level is estimated by SMEI to grow 18.7% in 2013 to CNY 1,275.9 billion and 19.3% CAGR in the following two years to reach CNY 1,815.8 billion in 2015.

Overall output value of the industry is expected to grow 20.45% in 2013, reaching CNY 2,270 billion, it forecasts. SMEI anticipates the Chinese hospital drug market to stabilize and the retail pharmacy market to grow steadily this year. However, drug prices are predicted to continue a benign falling trend and profitability of pharmaceutical companies will remain under pressure. Besides, the outlook of pharmaceutical export by China is challenging.

SMEI predicts the Chinese pharmaceutical industry to rebound and achieve its 2013 forecasts under the following conditions: 1) Chinese GDP growth will not fall below 7.5%; 2) the government healthcare investment does not drop below the level of 2012; 3) pharmaceutical export will not go into negative growth due to global economic slowdown; and 4) the measure of eliminating 15% hospital drug sales margin will not be implemented in urban hospitals on a large scale.

Recent surveys of MNC pharma executives indicate revenue growth optimism for the global pharmaceutical industry in 2013. Despite some recent setbacks with China's healthcare business environment, executives continue to identify the country as the most important region for pharmaceutical industry growth this year. Presence of huge and aging

population, economic development, growing public expenditure towards healthcare, government support, increasing awareness about health and fitness in public are deemed as key drivers for the growth of the pharmaceutical market in China.

While there are many enticing reasons to be optimistic this year, executives should watch out for potential turmoil from another round of large scale government reorganization which tends to result in widespread and sometimes dramatic policy adjustments.

The broad Chinese economy, which is facing many challenges and uncertainties, will also weigh on the healthcare sector. Should the Chinese government fail to appropriately support its healthcare reform ambitions financially, cost containment may get way out of hand at the local levels to cause falling quality of medical care, diminishing pharma industry margins and broad healthcare system instabilities.

Besides, a report from Frost & Sullivan suggests that the Chinese pharmaceutical market earned revenue of US\$131.63 billion in 2012 and this will more than double to US\$280.30 billion in 2016.

Hospital drug market

The calming Chinese hospital drug market outlook presented by SMEI is shared by IMS Health which projects the Chinese drug market (comprising of mostly the hospital drug market) to grow by 15% to 18% annually to between US\$155 billion and US\$165 billion by 2016, making it the world's second-largest market after the United States.

Community and rural healthcare market

On the other hand, Boston Consulting Group (BCG) predicts in its latest report, *Pharma's Next Billion Patients: The Impact of Health Care Reform in China 2009-2011*, that while China's urban hospitals will continue to be the most important battleground for pharma companies, two other channels, county hospitals and community health-care centers, will be increasingly attractive for multinational and local companies alike. BCG estimates the drug market for county level hospitals to reach CNY 280 billion by 2015.

Online B2C drug market

Similarly, the Chinese online B2C drug market is forecasted to reach CNY 15.0 billion in 2015, up from an estimated of only CNY 1.7 billion in 2012, according to conservative estimates from the COPS, which anticipates an explosion of such business in 2014 or 2015.

Retail Pharmacy/OTC/Consumer healthcare market

McKinsey, however, has its eyes on another sector which it sees opportunities equally explosive. McKinsey forecasts that China will become world's largest growth opportunity for suppliers of consumer healthcare products and its second-largest consumer market by 2020 in its report, *Pills, Potions and Potential: The Consumer Healthcare Opportunity in China*.

IMS Health data on the same sector lends support to McKinsey predictions. It projects the Chinese retail pharmacy sales in 287 prefecture level and above cities in 2012 to reach

CNY 93.5 billion. It predicts 15% or above growth rate for this market in the next few years.

Similarly, SMEI projects Chinese retail drug sales to grow 15.2% in 2013, but with an estimated falling market share of 20.8% in the backdrop of anticipated faster hospital drug sales growth.

Besides, there could be bleak news on the way for the Chinese OTC sector if a proposed ban on consumer advertising for OTC medicines is approved.

Healthcare expenditures

Despite economic uncertainties, the Chinese healthcare sector can still be anticipated to continue its current expansion, though probably at a lesser speed. A recent MOH document, *Health China 2020 Strategic Research Report*, includes a strategic objective to raise the share of health expenditures in China's GDP to 6.5%-7.0% by 2020 from 5.1% in 2011.

But Swiss Re-insurance Company painted a much less optimistic picture with a new study report which suggests that China's health protection gap could hit US\$12.2 billion in 2014 and may further widen to US\$73 billion in 2020.

In conclusion ... creative solutions required to succeed

There is no doubt the healthcare reform will go on with unchanged slogans including promise of increased government investments. In reality, both central and local governments will be more financially strapped this year to achieve original reform objectives and they will be forced to rely on cost containments even more. The aftermath of excessive cost containment will be fallen quality of healthcare, increased safety incidents and reduced overall healthcare efficiency, potentially leading to social unrests in a period of political sensitivity.

The central government leadership in healthcare reform is shaky, mainly because it has unloaded most financial burdens on local governments, which have less tax revenues, more financial responsibilities and shrinking income from land sales. Under pressure, local governments will be forced to employ cost containment as the primary driver for moving the reform forward.

But don't be discouraged prematurely. The upcoming *Year of Snake* in 2013 is also meant for steady progress and achievement for those with creativity, focus and discipline, according to Chinese Zodiac readings.

Roche serves as a case in point. The company recently came out with a powerful and extremely creative solution to expand customer base of its expensive cancer drugs – by promoting insurance to its potential customers first through a partnership with commercial health insurance players.

While Roche's experiment is a good starting point and the government is beginning to act on integrating insurance providers with BMI's major medical programs at a local level, we are still far away from any serious progress in the area.

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"EDS" stands for "Electronic Data Storage" and means any automated mode of storing accessible data whether or not digital, including computer hard drives, PDFs, ROM files, tapes, CDs, diskettes, DVDs or any other means of storage of information excluding physically printed data

"One-off Purchase" means the purchase of any Materials by the Client other than on a Subscription basis

"Online Services" online Materials available on the websites operated by or for WiCON

"Personnel" means any employee of or contractor engaged by the Client

"Product" any combination of Data published, supplied or distributed by WiCON in whatever medium now known or developed in the future

"Services" any services described in the Order Form which are associated with and/or form part of the Materials purchased or subscribed for by the Client

"Subscription Period" means the period for which the Client has obtained the agreement of WiCON to provide or make any particular Materials and/or Products available to Users (provided that such period has not been terminated under any other provision of the Terms) and Subscription has a corresponding meaning. Unless WiCON agrees otherwise, a Subscription Period begins only when full payment has been received by WiCON

"User" means any member of Personnel who has been included in the agreed total number of Users set out in the Order Form and who is authorized by both WiCON and the Client to have access to or otherwise be supplied with the Materials and/or Products purchased or subscribed for by the Client

References to the singular include the plural, and references to one gender include all other genders. The expression "our website" means a website operated by or for WiCON.

3. Terms applicable to all Materials and Products

3.1 We warrant that:

- (a) we have a right to license the Materials and Products to you;
- (b) we will provide the Materials and Products with reasonable skill and care;
- (c) we will provide the Materials and Products to you for the subscription period; and
- (d) if we are unable to provide the Materials and Products to you for parts of or the entire subscription period, we will refund the relevant unexpired parts of or entire subscription fees to the client (see 5.4 for details).

(e) you have the right to cancel the subscription of *Pharma China Journal Edition* and *Pharma China Web Edition* at any time, no reason needed. A full refund (minus bank charges if payment was made by credit card or wire) will be issued if you choose to cancel within 15 days of order. After the 15 day grace period, a partial refund will be issued for the unexpired subscription period on a prorated basis.

3.2 WiCON grants you a non-exclusive, non-transferable licence to use and/or to access the Materials and/or the Products to which you have subscribed or purchased but only in accordance with the permitted use terms and restrictions applicable to the type of licence you have purchased. You undertake to comply with the permitted use terms and restrictions applicable to the type of licence you have purchased and to procure that all Users and/or members of your Personnel do likewise.

3.3 The licence granted to you is granted on these Terms and on any Additional Conditions applicable to particular Materials and/or Products as set out on the Order Form.

3.4 The Order Form will indicate the particular Materials and/or Products purchased by you or to which you have subscribed and which type of licence you have purchased, the different licence options being classified as follows:

- (a) Single User Licence (please see Part 5 for permitted use terms and restrictions); or
- (b) Multi-User Licence (please see Part 5 for permitted use terms and restrictions); or
- (c) Site Licence (please see Part 5 for permitted use terms and restrictions); or
- (d) Multi-Site Licence (please see Part 5 for permitted use terms and restrictions).

3.5 We have used our reasonable endeavors to ensure that all Materials, Products and Online Services comply with US laws. However, we make no representations that the Materials, Products and/or Online Services are appropriate or available for use in locations outside USA. Those who visit our website from other locations do so on their own initiative and are responsible for compliance with all applicable laws. You accept that if you are resident outside the United States, you must satisfy yourself that you are lawfully able to use and purchase or subscribe to the Materials, Products and/or Online Services and, to the extent permitted by applicable law, WiCON accepts no liability for any costs, losses or damages in this regard.

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circumstances where you suffer loss or damage arising out of or in connection with the viewing, use or performance of Online Services, Materials or any Product, we accept no liability for this loss or damage whether due to inaccuracy, error, omission or any other cause and whether on the part of WiCON or our servants, agents or any other person or entity.

3.9 You may not assign, transfer or sub-licence any of your rights under these Terms and/or the Order Form.

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3.11 These Terms and your use of our websites are governed by laws and regulations of the United States and you submit to the exclusive jurisdiction of the US courts.

3.12 Except in respect of a payment obligation, neither you nor WiCON will be held liable for any failure to perform any obligation to the other due to causes beyond your or WiCON's respective reasonable control.

3.13 Failure or delay by either party in enforcing an obligation or exercising a right under these Terms does not constitute a waiver of that right or remedy.

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3.17 For the avoidance of doubt, we will not be bound to supply or permit access to any of the Materials unless and until EITHER:-

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- (b) If (in our absolute discretion) we agree to accept payment after the start of the Subscription Period, you will pay us the amount due within 30 days after the date of our invoice to you for the Materials (unless otherwise agreed).

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4.1 You are solely responsible in all respects for all use of and for protecting the confidentiality of any username, e-mail verification and password that may be given to you (or to your authorized Users) or selected by you (or by your authorized Users) for access to Online Services. You may not share these with or transfer them to any third parties and you will procure that your authorized Users do not share these with or transfer them to any third parties. You must notify WiCON immediately of any unauthorized use of them or any other breach of security regarding our website that comes to your attention.

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(c) temporarily to suspend your access to Materials and/or Products to which you have subscribed through the Online Services (and/or to the Online Services generally) for the purposes of maintenance or upgrade (but we will use our reasonable endeavors to minimize the period of suspension).

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5.1 WiCON will supply and/or grant you access to the Materials and/or Products to which you have subscribed for the Subscription Period as set out on the Order Form.

5.2 WiCON may terminate or suspend your Subscription at any time if you are found in breach of any of these Terms or of the Additional Conditions. In these circumstances you will not be entitled to any refund.

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- (c) at any time to withdraw any of the Materials or any Product (or any part of the Materials or of any Product) to which you have subscribed if WiCON ceases to publish or ceases to have the right to publish the relevant Materials or Product or if the same are the subject of a libel or copyright or other third party right infringement allegation and WiCON considers that withdrawal is advisable in the circumstances.

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6. Licence Types

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- (iii) use limited and insubstantial extracts from the Data for external purposes provided that WiCON's copyright notice is included in the document and (expressly and with reasonable prominence and otherwise in a form approved by WiCON), WiCON is acknowledged as the source of the Data so used and where extracts of the Data are contained in documents which are to be included in press releases and/or otherwise made publicly available, such extracts of the Data shall (unless otherwise agreed with WiCON) not be released unless either a proof, copy or relevant section of the document is supplied to WiCON for release authorization during US office hours and WiCON gives such authorization in writing - WiCON will not unreasonably withhold or delay such authorization;
- (iv) print one copy of such Materials and/or Products; and
- (v) save only as expressly permitted in accordance with sub-paragraph (iii) above, use such Materials and/or Products solely for the internal business purposes of the Client.

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- (viii) modify, alter or create derivative works from such Materials, Products and/or Data nor may you create a database in electronic or structured manual form by systematically downloading and storing any of the content from such Materials, Products and/or Data; or
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- (ii) download and store no more than one copy per named and authorized User of such Materials and/or Products in machine readable form;
- (iii) use limited and insubstantial extracts from the Data for external purposes provided that WiCON's copyright notice is included in the document and (expressly and with reasonable prominence and otherwise in a form approved by WiCON), WiCON is acknowledged as the source of the Data so used and where extracts of the Data are contained in documents which are to be included in press releases and/or otherwise made publicly available, such extracts of the Data shall (unless otherwise agreed with WiCON) not be released unless either a proof, copy or relevant section of the document is supplied to

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(ii) download and store no more than one copy per named and authorized User of such Materials and/or Products in machine readable form;

(iii) use limited and insubstantial extracts from the Data for external purposes provided that WiCON's copyright notice is included in the document and (expressly and with reasonable prominence and otherwise in a form approved by WiCON), WiCON is acknowledged as the source of the Data so used and where extracts of the Data are contained in documents which are to be included in press releases and/or otherwise made publicly available, such extracts of the Data shall (unless otherwise agreed with WiCON) not be released unless either a proof, copy or relevant section of the document is supplied to WiCON for release authorization during US office hours and WiCON gives such authorization in writing - WiCON will not unreasonably withhold or delay such authorization;

(iv) print no more than one copy per named and authorized User of such Materials and/or Products; and

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- (v) use the Materials, Products and/or Data in any manner, (or transfer or export the Materials, Products and/or Data or any copies thereof into any country), other than in compliance with applicable laws;
- (vi) allow any person to use and/or gain access to the Materials, Products and/or Data other than in accordance with these Terms;
- (vii) allow any person who is not a User to use and/or gain access to the Materials, Products and/or Data;
- (viii) modify, alter or create derivative works from such Materials, Products and/or Data nor may you create a database in electronic or structured manual form by systematically downloading and storing any of the content from such Materials, Products and/or Data; or
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Laws and regulations are also categorized by type (eg. law, regulations, rule or notice), issuance agency and regulatory areas. The database can be searched by keywords, type, issuance agency and regulatory area.

New Drug R&D Monitor

The database contains information on new drug products under development in China and monitors latest Chinese R&D developments reported globally. The database can be searched by keywords, therapeutic class, product type and regulatory status, and contains additional information including developer names and a summary of research and regulatory status.

Note: this product is intended as an added value product for existing subscribers of Pharma China products, and is not sold separately.

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