



China Pharmaceutical Guide

中国医药市场指南

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Written by:

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Unrivaled China Healthcare Intelligence Since 1991

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ABOUT THE AUTHOR / PUBLISHER

China Pharmaceutical Guide is authored, edited and published by James J. Shen, a veteran of the Chinese healthcare industry and market, who has dedicated his entire 29-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 Beijing with frequent visits to the U.S., Europe and Japan. He continues to be active in strategic consulting with multinational pharmaceutical companies at headquarter and regional head office levels, as well as selective entrepreneurial and VC/PE investment projects in the Chinese healthcare sector.

PREFACE

Despite the enormous business opportunities and growth prospects offered by China's healthcare sector, I've witnessed and experienced countless regulatory and business environmental changes, which has frequently caused painful business difficulties, frustrations and downfalls, in my past 29 years of work in the sector as a consultant, manager and entrepreneur.

The ever-changing legal and market environments in China healthcare present the single biggest challenge to companies and executives operating in the sector. Naturally, many operational level issues and problems in the country also pose significant challenges to successful businesses.

In spite of these challenges and difficulties, the Chinese pharmaceutical industry and market have achieved remarkable growth in the past two decades. The sector is generally developing towards a positive direction in the sense that it continues to grow steadily, its regulatory regime has become increasingly compatible with international standards with improving transparency, once rampant corruption is being tackled, its ongoing consolidation will eventually help establish order and stability, and the country's new healthcare reform will ultimately led to a more stable and healthier market environment.

There are success stories from all categories of players, whether they are foreign or local, large or small, newcomer or established, private or state-owned. However, to be one of the success stories require a thorough understanding of the sector, ability to face and tackle challenges, flexibility to deal with changes, and skills to maneuver through complex situations.

It has been my wish to put my experience and observations in the past 29 years of operating in almost every aspect of China's pharmaceutical business into a publication, which will serve as a one-stop reference to anyone seeking to enter or operate in the Chinese pharmaceutical market. As of our 2007 edition, we have been adding a rising number of commentaries and contributions from many other leading pharma industry executives and experts.

Packed with hard-to-find current data and the author's expert knowledge from years of hard-earned experience in the industry, its comprehensiveness, practicality, insight, reliable data and analysis, and up-to-date information, are the features which set this the guide apart from other publications with similar titles.

This Guide is written based on my past experience, interviews with relevant industry experts and government officials, articles from Pharma China, information obtained from or published by Chinese government agencies, information obtained from or published by independent pharmaceutical industry associations, reliable data and released exclusively to WiCON for publication from various reputable market research and consulting firms, information from other trustworthy trade journals and newspapers, related information

found on the internet, and a large in-house information collection by WiCON International Group accumulated since 1991.

About *China Pharmaceutical Guide 2016 (11th Edition)*

The *China Pharmaceutical Guide 2016 (11th Edition)* has been completely reorganized into four volumes:

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

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

Volume III – *Annual Review, Trends, Opportunities and Strategic Considerations* (including a complete review of latest data, business trends, regulatory & IP/legal developments and healthcare reform progress of the Chinese pharmaceutical industry and market in 2015/1H2016, and a large collection of feature articles from industry experts relating to contemporary trends, issues and strategic considerations as well as promising opportunities of the present and future); and

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

It is thoroughly updated with ample latest data from many reputable sources, abundant analysis by leading industry experts, new regulations and more case studies. Its coverage was renewed and expanded significantly in the following areas:

- ☞ Hundreds of pages of new data, information, analysis and case studies.
- ☞ Thorough summaries and analysis of the latest healthcare reform, drug pricing & reimbursement and hospital tender purchase policies.
- ☞ Comprehensive industry, market and foreign trade data as well as health statistics are updated with the 2015 (full year) and available figures for the first half of 2016.
- ☞ Expanded coverage on e-commerce and digital marketing opportunities, the primary healthcare sector, OTC and consumer healthcare sector, high growth market segments, regional hospital markets, and the pharma distribution sector,

- ☞ Updated coverage of the Chinese biosimilars/biologics market prospects and regulatory outlook.
- ☞ Updated coverage of emerging legal issues (including latest Chinese government crackdown on corruption in healthcare, FCPA/compliance and liability issues) and drug-related IP and trademark concerns.
- ☞ Comprehensive top line data, research findings and observations from our collaborative partners such as IMS Health, Kantar Health, Nicholas Hall, ZS Associates, Rubicon Strategy Group and RDPAC, as well as other reputable sources including the Chinese Pharmaceutical Association, SMEI and Sinohealth.
- ☞ All regulatory changes in 2015/H12016 are updated to present a clear and most up-to-date picture of the Chinese drug regulatory framework with summaries and analysis of all pharmaceutical related regulations in effect by mid-2015.
- ☞ Focused coverage of China's ongoing efforts to revamp its drug regulatory regime through amendments of the *Drug Administration Law*, its latest proposal and preparations to overhaul the drug pricing mechanism, deepening reform of its drug registration and evaluation regime, new policies to support drug innovation and high clinical value generics, and its initiative to re-evaluate all generic drugs with bioequivalence studies.
- ☞ An updated section covering proposed new drug-related laws and regulations under drafting process with selective previews of the draft versions.
- ☞ Extensive review and analysis of China's drug registration applications and approvals as well as Chinese drug innovation trends in recent years.
- ☞ Comprehensive review of Sino-foreign M&A, joint venture, strategic alliance, licensing, research partnerships, co-marketing, and new drug research events in 2015 and H1/2016.
- ☞ Expanded coverage on MNC strategies in China with healthcare reform in the backdrop, intellectual property/patent law amendments, data exclusivity, patent litigation, drug regulations, pharma marketing and distribution strategies, drug consumption patterns, the Chinese R&D and outsourcing sector, clinical studies/practices, healthcare reform, community healthcare sector, essential drug policy, regional drug consumption patterns, and the vaccine and API sectors.
- ☞ Numerous new case studies are added.

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

James J. Shen

June 30, 2016

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TABLE OF ABBREVIATIONS

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

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| SMEI – Southern Medicine Economic Institute under the CFDA | VAT – Value Added Tax |
| SOE – State Owed Enterprise | VC – Venture Capital |
| SPAC – State Pharmaceutical Administration of China | WM – Western medicine |
| STD – Sexually Transmitted Disease | WHO – World Health Organization |
| TC – Therapeutic Class | WTO – World Trade Organization |
| TCM – Traditional Chinese Medicine | |
| USTR – US Trade Representative | |

EXECUTIVE SUMMARY

Under the shadow of numerous challenges mostly stemmed from the troubled Chinese economy, regulatory shakeups, cost containment measures and healthcare reform turbulences, the Chinese pharmaceutical industry revenue growth slowed in 2015 to single digit (+9.1%) for the first time in the past decade, compared with 13.06% in 2014, 17.91% in 2013 and above 20% between 2007 and 2012, according to the *China Pharmaceutical Guide 2016 (11th Edition)* quoting official data.

While policy uncertainties continued to haunt Chinese pharma in 2015, industry analysts suggest that the sector's revenue is stabilizing and long term sustainable growth continue to be anticipated as policy and business environments improve. The Chinese drug market (at retail price level) is reported by Southern Medicine Economic Institute under the CFDA (SMEI) to have grown 12.9% in 2015, slightly down from 13.4% in 2014, to reach CNY 1,407.0 billion.

SMEI data suggests that CAGRs of Chinese pharmaceutical industry output value and revenues in the 12th Five-Year Plan period (2011-2015) is expected to be 16.6% and 15.2% respectively. The Chinese pharmaceutical industry profit growth slowed in the period due to macro-economic changes, drug price reform and cost containment measures, compared with 37.6% in the previous 12th Five-Year Plan period (2006-2010). The profit growth of Chinese pharmaceutical industry is projected to reach 11.9% in 2015.

According to a report on the progress of healthcare reform by NHFPC Minister LI Ban to the 18th Session of the 12th National People's Congress in late 2015, the Chinese government made CNY 4 trillion fiscal investment into healthcare, including CNY 1.2 trillion from the central government between 2009 and 2014. 53 major healthcare policies covering public hospital reform, universal BMI system building and drug supply security had been introduced under the direction of the State Council's Leadership Group for Deepening Pharmaceutical and Health System Reform, which is made up by 20 central government agencies. The average life expectancy of Chinese people increased one year between 2010 and 2015. The share of personal out-of-pocket expenditures in total healthcare expenditures dropped to 31.99% in 2015 from 35.29% in 2010, the lowest in two decades.

There is no doubt the healthcare reform will go on with unchanged ambitions. In the reality, with tax and other revenues drying up and under increasing threat of BMI system deficit amid a slowing Chinese economy, local governments are pressured by both the central government and the public to do more with less. Despite its superficial goals, the healthcare reform has so far mostly been hijacked by containment of drug costs and no longer about improving efficiency and fixing structural flaws.

Pushed to the corner, both domestic and multinational drug companies are now at the brink of business bottomlines. However, the trend of irrational cost containment is expected to intensify further in 2016, with the central government upholding the radical healthcare reform experiment in Sanming City of Fujian Province as a model for national

reference.

On the front of drug pricing, however, there have been few indications that relevant Chinese government agencies are getting ready to introduce the planned uniform BMI payment price scheme anytime soon, although the deadline was set at the end of September by the 2015 healthcare reform plan of the State Council. Nonetheless, the NHFPC managed to move the trial for drug price negotiation mechanism forward last year.

In the meantime, Chinese president XI Jinping categorically demanded the government to implement “the toughest drug regulation” by setting the highest standards, exercising the most stringent regulation, imposing the stiffest penalties for violations and instituting the most serious accountabilities.

Other than introducing multiple rules and standards for drug quality control covering the full drug development, manufacturing and application process from laboratory to hospital (e.g. GLP, GCP, GMP and GSP), the CFDA has stepped up its random inspections in terms of both frequency and strength as well as raised efforts to combat corruption within relevant government agencies this year with numerous CFDA and NHFPC officials under investigations.

The reform goal declared by the agency was to turn the former "firefighting" approach of food and drug regulation into a new model that emphasizes on early risk screening and prevention through stepping up risk surveillance, supervisory samplings, onsite inspections, undercover investigations and administrative enforcements.

The recent CFDA's move to elevate drug quality and reform drug approval system, though contradicted by other government agency's preoccupation to slash drug costs, provides a ray of future hope for MNCs. With a better policed pharmaceutical industry aligned to rational cost structures, MNCs can expect to compete with domestic companies on a more leveled ground in future and fill market vacuum from exiting irregular players. The real questions are that, with the world's largest population, what kind of healthcare solution and product mix China can and should get for merely 5%-6% of GDP? Is the country willing or able to pay more for better drugs and healthcare?

On the other hand, the Chinese pharma e-commerce sector has been brewing major revolutionary developments and is ready to fly pending official liberalization of online prescription drug sales. Under growing pressure from aggressive moves by e-commerce giants to enter drug distribution, leading pharmaceutical distributors rushed to reposition themselves to secure presence in the emerging pharma e-commerce sector in China.

The Chinese economy and its healthcare system are at crossroads and in transition again. This requires both domestic and MNC pharma companies to recalibrate their strategies and business models.

2015 inherited most old devils of the Chinese pharmaceutical business in prior years with no new fixes found. In the near future, the industry will continue to be challenged by rising uncertainties of the broad Chinese economy, more regulatory and healthcare reform turbulences and rising cost containment pressure. On the other hand, future prospects are

supported by upsides including a large and aging Chinese population plagued with surging health problems and chronic disease prevalence, increased government healthcare budgets and growing demands due to improved access to healthcare.

Local governments are set to put more price pressure on pharmaceutical companies in 2016, as they try to keep the public happy and at the same time balance the books of BMI programs, which are designed and funded to cover only essential healthcare needs, not to mention their fiscal crisis amid a slowing economy.

Despite short term difficulties, a few positive catalysts for long term prospects emerged last year, including 1) family planning policy liberalizations taking effect at the beginning of 2016 allow Chinese families to have second child, therefore creating substantially higher immediate and future demand for health and child care; and 2) recent crackdown on irregular clinical data and reform of the Chinese drug evaluation and approval system will lead to both short and long term benefits for MNCs.

For now, the short term outlook of Chinese pharmaceutical market remains mixed and blurred. But promising seeds are being sown today with hope of it turning into milk and honey one day. Nevertheless, most Chinese pharma industry observers agree that the market will keep on growing in the next few years, albeit at a slower rate.

Many drug company executives are still bullish about China's long-term growth prospects and drug spending is expected by IMS to reach as much as US\$185 billion by 2018. But the short-term picture is proving less rosy, with reforms in the hospital sector impacting prescribing and price pressures increasing for most drugs. The company expects the overall Chinese pharmaceutical market to continue the existing slowing growth trend in the next few years. The company projects the market to rise around 9% CAGR between 2015 and 2019, compared with 16% CAGR between 2010 and 2014.

Separately, SMEI expects the Chinese pharmaceutical industry in output value and revenue to grow 11.3% and 8.7% to reach CNY 3,210.0 billion and CNY 2,904.4 billion 2016. It forecasts the Chinese pharmaceutical industry output value and revenue to attain compound annual growth rates (CAGR) of 11-13% and 10.4% respectively in the 13th Five-Year Plan period (2016-2020), reaching CNY 4,840.0 billion and CNY 4,386.6 billion.

Industry experts recently pointed out that the fundamental aspects of the Chinese pharmaceutical industry has remained positive despite slowing growth, but they warned against a more complex Chinese marketplace in 2016. There will be lots of uncertainties, unbalances and frailty ahead. The future outlook is mixed, while most analysts agree that the market will keep on growing, but at a slower rate, continuing the trend which started two years ago.

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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: *The Online Database Edition is intended as an added value product for existing Pharma China gold & platinum package subscribers. It is not sold separately.*

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