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Unrivaled China Healthcare Intelligenece Since 1991

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ABOUT THE AUTHOR / PUBLISHER

WiCON | 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 31-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, IQVIA and *Financial Times* Business Information on China's healthcare news.

In 1991, he founded W*i*CON 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 *IQVIA China Update*, a monthly newsletter covering China's pharmaceutical market co-published by IQVIA and W*i*CON. He authored many China healthcare business publications in English throughout 1990s, including *Marketing Pharmaceuticals in China*, *Guide to Pharmaceutical Research Institutions in China*, and *Directory of Bulk Pharmaceutical Manufacturers & Products in China*.

In early 2006, following a restructure of WiCON's businesses, James Shen founded **W*i*CON | *Pharma China***, 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 Osaka and Beijing with frequent visits to the U.S. and Europe. 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 31 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. 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 types of players, wether they are foreign or local, large or small, newcomer or established, private or state-owned. However, to be a success story 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 31 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 WiON|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 W*i*CON | *China Pharmaceutical Guide 2019 (14th Edition)*

The W*i*CON | *China Pharmaceutical Guide 2019 (14th Edition)* is organized into the following 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 consumuption 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 2018/1H2019, and a large collection of feature articles from industry experts relating to competemporary 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/pharma 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, as well as coverage of the most recent government reorganization relating to healthcare and drug regulation.
- ☞ Comprehensive industry, market and international trade data as well as health statistics are updated with the 2018 (full year) and available data for H1/2019.
- ☞ Expanded coverage on IP, patent and anti-monopoly-related laws and regulations, e-commerce and digital marketing opportunities, the primary healthcare sector, the OTC and consumer healthcare sector, high-growth market segments, key regional hospital markets, and the pharmaceutical distribution sector,

- ☞ Updated coverage of the Chinese biosimilars/biologics 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 IQVIA, Kantar Health, Nicholas Hall, ZS Associates and RDPAC, as well as other reputable sources including the Chinese Pharmaceutical Association, SMEI, CPIIC and Sinohealth.
- ☞ All regulatory changes in 2018/1H2019 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-2018.
- ☞ Focused coverage of China's ongoing efforts to revamp its drug regulatory regime through amendments of the *Drug Administration Law*, the proposed *Vaccine Management Law*, the transformation of drug pricing mechanism, deepening reform of the drug registration and evaluation regime, new policies to support drug innovation, biosimilars and high clinical value generics, and the initiative to re-evaluate all generic drugs with bioequivalence studies.
- ☞ 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 and new drug R&D events in 2018 and H12019.
- ☞ Expanded coverage on MNC performance and strategic considerations 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.
- ☞ In addition to the existing five key case study areas, two more areas on pharma's alliance with health insurance companies and with e-commerce/digital health providers are added. Numerous new case studies are added, as existing cases are updated and filtered.

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

July 30, 2019

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ADR – Adverse Drug Reaction

AmCham – American Chamber of Commerce

API – Active Pharmaceutical Ingredients

APP – Administrative Protection of Pharmaceuticals

ANDA – Abbreviated New Drug Application

CAGR – Compound Annual Growth Rate

CCCIEMHP – China Chamber of Commerce for Import & Export of Medicines and Health Products

CAPC – China Association of Pharmaceutical Commerce

CFDA – China Food and Drug Administration (predecessor of NMPA)

ChP – Chinese Pharmacopoeia

CMH – China Monitor Health

CNCM – China National Corporation of Medicines

CNIPA – China National Intellectual Property Administration

CNY – Chinese Yuan

CPA – Chinese Pharmaceutical Association

CPIIC – China Pharmaceutical Industry Information Center

CRO – Contract Research Organization

DRG – Diagnosis Related Groups

ED – Erectile Dysfunction

FDA/USFDA – U.S. Food and Drug Administration

FDI – Foreign Direct Investment

FIEs – Foreign Invested Enterprises

FTCMs – Formulated TCMs

GCP – Good Clinical Practices

GDP – Gross Domestic Products

GLP – Good Laboratory Practices

GMP – Good Mnufacturing Practices

GSP – Good Supply Practices

IFPMA – International Federation of Pharmaceutical Manufacturer Associations

JV – Joint Venture

M&A – Merger and Acquisition

MIIT – Ministry of Industry and Information Technology

MOFCOM or MOC – Ministry of Commerce

MOF – Ministry of Finance

MOH – Ministry of Health

MoHRSS – Ministry of Human Resources and Social Security

MNCs – Multinational pharmaceutical companies (*in the context of this guide*)

MR – Medical Representative

NBS – National Bureau of Statistics

NCGHSR – National Coordination Group for Healthcare System Reform

NDRC – National Development and Reform Commission

NH – Nicholas Hall & Co.

NHC – National Health Commission, successor of NHFPC

NHFPC – National Health and Family Planning Commission, predecessor of NHC

NMPA – National Medical Products Administration (formerly CFDA)

NHSA – National Healthcare Security Administration

OECD – Organization for Economic Co-operation and Development

OTC – Over the Counter

QA – Quality Assurance

QC – Quality Control

PRC –People's Republic of China

R&D – Research and Development

RDPAC – R&D-based Pharmaceutical Association Committee in China

SATCM – State Administration of Traditional Chinese Medicine

SDA – State Drug Administration, predecessor of SFDA

SFDA – State Food and Drug Administration of China (predecessor of CFDA)

SAMR – State Administration for Market Regulation, governing body of NMPA

SIPO – State Intellectual Property Office

SMEI – Southern Medicine Economic Institute under the CFDA

SOE – State Owed Enterprise

SPAC – State Pharmaceutical Administration of China, predecessor of SDA

STD – Sexually Transmitted Disease

TC – Therapeutic Class

TCM – Traditional Chinese Medicine

USTR – US Trade Representative

VAT – Value Added Tax

VC – Venture Capital

WM – Western medicine

WHO – World Health Organization

WTO – World Trade Organization

EXECUTIVE SUMMARY

By James J. Shen, Publisher and Managing Editor, WiCON|Pharma China

China's economy slowed for most of 2018 and early 2019 amid the government's intermittent efforts to reduce reliance on debt-fueled growth, making it more difficult for businesses to obtain financing. Increasing tensions with the U.S., China's largest trade partner, have added to uncertainty. A weakening currency and slumping stocks haven't helped shore up confidence.

Things were not so pretty with the pharma industry either. While the Chinese pharmaceutical manufacturing industry saw its operating revenues grow by 12.6% to CNY 2,398.63 billion in 2018, the industry's profits rose only 9.5% to CNY 309.42 billion in the period, according to official data from the National Statistics Bureau.

Although the overall pharmaceutical market picture had been rather grim, with IQVIA reporting slower growth of Chinese hospital drug and retail pharmacy markets in 2018, last year was in fact worth remembering by at least some MNC pharma companies which regained high business growth for several quarters. Amid a market vacuum before local generic quality and clinical equivalent (GQCE) products arrive in droves, MNCs managed to beat their local counterparts in 2018. In addition, several big pharma companies upped their optimism for Chinese pharma prospects in 2019, after they posted better than expected first-quarter performance and growth in China, according to various sources.

The value of medical and health products China imported decreased for the first time in "many years" to about $50.43 billion in 2018, down by 9.75% year-on-year. Business insiders said the cause of the decrease is mainly the lower average price of imported medicine due to intensified competition among pharmaceutical companies, rather than changes in import volume.

At the beginning of 2018, I was brave enough to predict some light at the end of tunnel in this supposedly hopeful year of the "Earth Dog". Well, I was not entirely right or wrong – it turned out, despite inevitable challenges from government reorganization and policy swings, there were indeed flashes of light throughout last year which most likely will not last into 2019.

However, the light at the end of tunnel that renewed MNC optimism turned out to be no more than the brief daylight in between tunnels and fortune reversed for MNCs even before the turn of New Year. As I warned repeatedly during last year of the bump ahead, MNCs collectively became the biggest loser in the NHSA-sponsored national level volume-linked centralized drug purchase tender trial for four central municipalities and seven provincial level cities (the 4+7 trial) in December 2018. What's more worrisome, we are only at the beginning phase of this new initiative, which is championed by the government to substitute expensive MNC originator drugs with cheap local GQCE products.

By early 2019, the planned structural reform of China healthcare has now been expanded to all corners of the country. This round of "top level" design or reform blueprint is completed but it will take years before the medical system can digest its tasks and goals. The biggest move made by the Chinese government to deepen healthcare reform last year was a major cabinet reshuffle in March aimed at streamlining regulatory jurisdictions and processes. It has far reaching impacts on the country's healthcare and pharmaceutical regulation and is a game changer especially for healthcare cost containment area.

Amid a slowing Chinese economy, the government is dashing to close all loose-ends of healthcare spending, especially with drug expenditures, to prepare for the rainy days. The goal is to ensure widest healthcare coverage of the Chinese people with limited resources, which are unlikely to grow much in the foreseeable future. But this will be achieved at all costs, including compromises with healthcare quality, industry development and market environment, in order to protect social stability in time of slowing economy.

The latest NHSA-led national level volume-linked centralized drug purchase tender trial focused heavily on price competition which not only pushed out most MNCs and their off-patent originator drugs, but also crashed the hopes of many domestic manufacturers of GQCE products for better margins to recoup their related investments.

The pharmaceutical industry will be challenged during this unsettling period and it will be squeezed by both medical providers and the government. As drug regulatory standards go up following reform, the industry will be confronted by the growing pain to supply high quality products at low prices and secure the bottomline at the same time.

For sure, the outlook is completely gloomy either. There remain numerous brighter spots and areas of opportunity which offer substantial market potential. Before we explore these further, let's recap the broad Chinese economy and healthcare sector dynamics last year and peep into our projected outlook for 2019 and beyond.

Chinese pharma growth slowed further in 2018 amid a gloomy outlook

The Chinese pharma growth continued to slide in all terminal markets in 2018 as a result of slowing broad Chinese economy, intensified cost containment and healthcare reform fallouts. The chronic falling growth trend is anticipated by most industry observers to continue in 2019.

Based on pharmaceutical industry performance data in the first three quarters of 2018, SMEI President LIN Jianning observed that there was an increasing disparity among the growth rates of pharmaceutical manufacturing and distribution sectors. It is reported that the revenue growth of Chinese pharmaceutical manufacturing sector in the first ten months of 2018 was 13.6%, while its profit growth was much slower at 10.4%.

SMEI projected that the combined drug sales of three major Chinese terminal markets to rise 6.3% in 2018, reaching a total of CNY 1,713.1 billion (at retail prices). Specifically, the Chinese public hospital drug market (first terminal market) is expected to surge 5.4% to CNY 1,154.1 billion. Urban public hospital drug market is projected to grow only 4.5%

to CNY 848.5 billion, while county public hospital drug market is set to grow faster than its urban counterpart. The retail pharmacy drug market (second terminal market) is also forecasted to see lower growth at 7.5%, reaching a total of CNY 391.9 billion, including CNY 10 billion in online pharmacy drug sales, which represents 2.5% of retail pharmacy drug market. The primary healthcare drug market (third terminal market) is also not rising as fast as expected. It is predicted to grow 10.2% to reach CNY 167.1 billion in 2018.

IQVIA estimates in its Market Prognosis 2018-2022|Asia/Australia – China that the overall Chinese pharmaceutical market would grow slightly faster at 5.6% to reach CNY 826,271 million (at hospital purchase prices) in 2018, including audited hospital drug market (>100 beds) at CNY 556,522 million (+5.1%), unaudited hospital drug market (small hospitals, CHCs, clinics) at CNY 174,815 million (+8.1%), Retail Sector (Rx at prefecture level) at CNY 44,235 million (+4.4%) and Other Retail (OTC + county level) at CNY 96935 million (+4.4%).

NMPA continues drug regulatory system reform as it boosts support of drug innovation

Three years into the drug regulatory reform, the CFDA continued to make substantial progress in 2018 to overhaul the regime with numerous new regulations and draft documents released monthly.

By March 2018, after about five years as a standalone agency, the CFDA was merged into the gigantic SAMR and survive on as the National Medical Products Administration (NMPA) as a subordinate agency as a part of a major central government reshaffle. Other than spinning off its food related responsibilities, the NMPA is almost identical to its predecessor CFDA in terms of drug registration and regulation.

Under the government reorganization plan, the SAMR is created with functions of the SAIC, GAQSIQ and CFDA to be incorporated into the new administration. Responsibilities of the new agency include comprehensive market supervision and management, market entity registration and market order maintenance. Furthermore, the antitrust/antimonopoly regulation and enforcement responsibilities of the NDRC, MOFCOM and the State Council Antimonopoly Committee will also be consolidated into the new agency.

In April 2018, the State Council came out with a major new policy, *Opinions on Reform and Improvement of Generic Drug Supply Security and Application*, under which China will offer preferential tax rates to generic drugmakers, setting corporate income tax for qualified high-tech firms at 15%. The State Council also said it would draw up new incentives aimed at encouraging the development and production of generic drugs, which are expected to substitute expensive foreign originator medicines. To "balance the interests of patent holders with those of the general public", China will also aim to strengthen enforcement of intellectual property rights and establish early warning mechanisms to prevent generic drug producers from infringing patents. But at the same time, the document also provides for the first time a roadmap for compulsory licensing of patent drugs to improve access in time of catastrophic infectious disease outbreak, drug

shortage for prevention and treatment of major diseases and other sudden public health events.

Another major development in the same month was the State Council's decision to remove tariffs on certain imported drugs and later policies to reduce VAT of anticancer drugs.

On the front of drug quality and safety, The CFDA (later reorganized into NMPA) introduced at the beginning of 2018 the Guidance Opinions for Further Strengthening Food and Drug Standards which calls for formulation/revision of 3,050 national drug standards, including 1,100 traditional Chinese and minority medicine standards, 1,500 chemical drug standards, 150 biologic product standards, 200 pharma excipient standards and 100 pharma packaging standards.

Later in August 2018, the NMPA announced formation of the 11th National Pharmacopoeia Commission, which will prepare the 2020 Edition of the Chinese Pharmacopoeia (ChP) and other national drug standards. The Commission is composed of an executive committee and 26 specialized committees, which have a total of 405 members. The 2020 ChP is expected to include monographs of around 6,400 drug products, up 800 from 5,400 in the 2015 ChP. Monographs of 21.9% or 1,400 drug products in 2015 ChP will be revised. The 2020 ChP is expected to include monographs of around 6,400 drug products, up 800 from 5,400 in the 2015 ChP. Monographs of 21.9% or 1,400 drug products in 2015 ChP will be revised. The Chinese Pharmacopoeia Commission (ChPC) announced on August 13 that it has drafted a list of 40 biological products which are proposed for addition to the Part III of the 2020 ChP.

There were many developments on the front of deepening drug evaluation and approval system reform. Most notably, the NMPA and NHC released the Working Procedures for Evaluation of Foreign New Drugs in Urgent Clinical Need (2018#79) and its relevant dossier requirements on October 30. The document provides an accelerated registration path to foreign new drugs not marketed in China but marketed in the U.S., EU or Japan in the past ten years.

The agency was also reportedly organizing experts to classify 201 foreign new drugs under registration in China and 138 foreign new drugs which have yet been applied for marketing in China, in order to screen out orphan drugs for rare diseases, as well as drugs for diseases without effective cure and drugs with significant efficacy for life-threatening diseases. NMPA would concentrate its resources to accelerate review of such drugs so that orphan drugs can complete review within three months and other new drugs with substantial clinical needs can complete review within six months, thus shortening the approval process timeline of such drugs by one to two years.

By November 30, 2018, China had granted priority review status to 404 drugs from the mechanism's inception in 2016. Besides, the NMPA approved 38 innovative drugs from companies outside China in 2018, according to data published by the agency.

As to the front of drug pricing, the NDRC (later SAMR after government reorganization) continued to flex its muscles under the flag of anti-monopoly and policing of shortage

drug prices. The government appears to have back-paddled for at least some renewed control over drug prices through antitrust enforcements in the past few years.

Following a joint review by the MOHRSS and NHFPC, the final draft of *Guidance Opinions for Rules of BMI Drug Payment Standard Development* sought final comments from provincial level governments in February 2018. It was originally expected that the MOHRSS will issue the document alongside the 2017 NRDL, but in reality, it hasn't taken place by early 2019.

Also noteworthy, the NMPA issued a new policy document, *Guidance Opinions for Drug IT Tracing System Building* (Guo Yao Jian Yao Guan 2018#35), in November 2018.

The Chinese government has been pushing forward a number of legislative agenda on healthcare. Most recently, the National People's Congress (NPC) published drafts of four laws on its website for public comments before December 1, 2018. The Sixth Meeting of the 13th NPC Executive Committee has recently reviewed these draft laws. Proposed amendment for the PRC Drug Administration Law and the draft of PRC Essential Healthcare and Health Promotion Law are among the four.

Besides, China made concrete progress in December 2018 with a few more important draft laws relating to vaccine management, IP and foreign investment.

The Vaccine Administration Law that aims to impose "the most stringent" regulation of vaccines to ensure their safety and quality was submitted to the NPC for review on Dec 23, 2019. The draft law, which was released by the SAMR for public comments in November and later approved by the State Council.

The NMPA held the 2018 National Drug Regulation Conference between January 10 and 11, 2019. Top SAMR and NMPA leaders were all present at the conference, which reviewed the agency's work in 2018 and laid out its major tasks forward in 2019. SAMR Minister ZHANG Mao summarized the achievements of NMPA in 2018 with highlights of the following: 1) improving the existing drug regulatory system and facilitating the principle of "four most stringent" in drug regulation to ensure maximum safety risk prevention; and 2) accelerating the evaluation and approval of drug products.

Healthcare reform remains in deep water amid intensified cost containment

China's basic medical insurance system (BMI) now covers 1.35 billion people, according to the NHFPC in February 2018. The enrollment rate of the BMI has been steady and held at 95% of the population in 2017, said WANG Hesheng, Vice Minister of NHFPC, at a press conference on Feb 12, 2018. Meanwhile, the critical illness insurance scheme covers 1.05 billion people, said Wang. Future medical reform will focus on promoting balanced development of medical services in different regions, said Wang.

Despite the touted universal coverage of its pubic BMI system, China has an annual health protection gap of an estimated US$805 billion, a 2018 Swiss Re survey found. The study, done by Swiss Re Management Ltd and the Swiss Re Institute, said that the combined health protection gap in 2017 of the 12 Asian countries surveyed is estimated to stand at

US$1.8 trillion.

Commercial insurers may help fill the gap between rising medical spending and meager public coverage China's rising middle class is increasing its spending on healthcare, according to a recent feature article of Financial Times by Gabriel Wildau. Health insurance has now overtaken life insurance in China as the fastest-growing category in the industry as wealthy consumers look to supplement meagre public coverage. The rise of health insurance is creating opportunities for an industry battered by scandal, symbolized by the bribery conviction of the former chief insurance regulator and the subsequent folding of his agency into the banking regulator.

There are a wide variety of other activities in the area of healthcare reform and regulation in 2018 and early 2019. I will recap the most important developments in the period.

In April 2018, the State Council decided to roll out numerous measures to promote internet + healthcare so as to make premium medical resources more accessible to patients. A month later, the State Council issued its official document, Opinions for Enhancing Development of Internet Plus Healthcare, at the beginning of May. By September 2018, the NHC paced up its rein over internet medical services and telemedicine in September with three new documents, *Rules for Internet Medical Practices (Interim)*, *Rules for Internet Hospitals (Interim)* and *Guideline for Telemedicine Services (Interim).*

The Chinese healthcare reform in the first half of 2018 was centered on reorganizing government agencies to streamline their healthcare jurisdictions and resources. China unveiled a major cabinet reshuffle on March 13 to make the government better-structured, more efficient, and service-oriented. Subsequently, The National Health Commission (NHC) will be created to replace the current National Health and Family Planning Commission and the Leading Group for Deepening Healthcare reform under the State Council which will no longer exist after the reshuffle, while the commission will also take over governance of the National Committee for Senior Population from the Ministry of Civil Affairs. At the same time, the National Healthcare Security Administration (NHSA), which is directly under the State Council, was officially inaugurated on May 30, 2018. The agency will be responsible for formulating policies, plans and standards on healthcare systems in terms of medical insurance, maternity insurance and medical assistance, and ensuring their implementation. The administration will also supervise and administer related medicare funds, improve the platform for trans-regional medical services and expense settlement, and organize related parties to fix and adjust prices for drugs and medical services, among others.

Reform of pharmacy affairs management was a key aspect of Chinese public hospital reform last year. By June 2018, there were growing signs that the Chinese government is beginning to back away from the experiment of contracting out hospital pharmacies. Furthermore, the NHC and the SATCM issued a new policy, Opinions for Accelerating High Quality Development of Pharmacy Services, in November 2018. Most notably, the document bans contracting and renting out their pharmacies by public hospitals. They are

also banned from having profitable businesses contract-manage their pharmacies.

In August, the State Council released a new guideline, *Guidance Opinions on Reform and Improvement of Overall Regulatory System of the Medical Sector*. Days later, it released an official notice to divide the fiscal duties of central and local governments in healthcare. According to the document, the duty reallocation touches upon four aspects, which are: the public health sector, medical insurance, family planning, and overall capacity building.

The General Office of the State Council issued a new policy, *Opinions for Further Improving the National Essential Drug System*, in September 2018. The Commission later released the 2018 Edition of the *National Essential Drug List* (NEDL), which will go into effect on November 1, 2018. The new edition of NEDL contains a total of 685 drugs, including 417 western medicines and 268 formulated traditional Chinese medicines (including minority medicines).

Meanwhile, the NHSA approved in October 2019 the inclusion of 17 anti-cancer drugs in the category B of National Reimbursement Drug List (NRDL) under BMI, as part of the government's efforts to ease the financial burden on patients.

The NHSA-sponsored National Centralized Drug Purchase Trial, which began with centralized purchase of 31 drug products passing generic quality and clinical equivalence (GQCE) evaluation in 11 (or 4+7) trial site cities took place in December 2018 in Shanghai. Under this trial, the prevailing bidder on a particular drug will become the sole supplier for hospitals in all of those cities, but at a much-reduced price from before. The 11 cities covered by the trial make up between 30% and 50% of all drug consumption in China.

Throughout 2018, the Chinese government has intensified its efforts to contain healthcare costs with a series of BMI payment system reform and drug rationalization measures in 2018. The MOHRSS introduced in February 2018, before its BMI management jurisdiction was transferred to the newly established NHSA, a new healthcare reform document, Recommended Disease Group List for Disease Group-based Payment under the BMI. In an attempt to streamline review of drug prescriptions (Rx) in medical institutions and rationalize drug consumption, the NHC, the SATCM and the Central Military Commission issued a new document, the Drug Prescription Review Guidelines of Medical Institutions.

In January 2019, the National Medical Insurance Working Conference was held by the National Healthcare Security Administration (NHSA) in Beijing. NHSA Party Secretary and Commissioner HU Jinglin delivered a keynote speech at the conference. NHSA's major achievements in 2018 were recapped at the conference including:

- ☞ Launching a three-year action plan for medical insurance of poverty-stricken population;
- ☞ Advancing tax and price reduction of anticancer drugs, introducing negotiation for BMI inclusion of anticancer drugs, and implementing provincial level centralized tender purchase of anticancers;

- ☞ Initiating a special campaign to crackdown on BMI and healthcare frauds; and establishing related fraud reporting channels, strengthening BMI agreement management and beefing up protection of BMI funds;
- ☞ Starting the implementation of national level centralized drug purchase tender trial;
- ☞ Continuing to expand direct BMI settlement of out-of-province medical expenditures; and
- ☞ Promoting nationwide IT and standardization system building.

The NHC held a press conference in April 2019 during which a senior health official outlined the future direction of healthcare reform. As its next steps, China will deepen reform in the pharma sector through facilitating the country's essential drug system, improving the 4+7 trial, consolidating the GQCE evaluation and accelerating electronic drug tracing system building.

In June 2019, the National Healthcare Security Administration (NHSA) initiated the National Diagnosis-Related Group (DRG) Trial in a teleconference chaired by LI Tao, Deputy Commissioner of NHSA. The stated goal of trial is to realize five uniform outcomes: uniformed DRG standards; uniform DRG policies; uniform SOPs for DRGs, uniform DRG talent pool and uniform DRG models. The NHSA also released the list of 30 trial site cities, including four central municipalities and 26 prefectural level and above cities, including numerous provincial capitals.

The State Council issued a new document, *Notice on Major Tasks of Deepening Healthcare System Reform in 2019*, in the same month. The document laid out 15 new policy documents to be researched and formulated this year including the list of encouraged generic drugs, as well as other policies relating to streamlining use of medical consumables and centralized public hospital drug purchase tender.

At a press conference on overall hospital reform in June 2019, ZHU Hongbiao, an inspector with NHC System Reform Department, told reporters that the emphasis of overall public hospital reform in the next phase will be placed on refining hospital financing mechanism and deepening reform of medical service prices. The Chinese government allocated CNY 270.5 billion ($39.26 billion) of subsidies directly to public hospitals in 2018, up from CNY 84.9 billion in 2010, said Zhu.

China has also stepped up efforts to improve its basic public healthcare service program to better safeguard people's health, according to the NHC. Per capita subsidies for the program were raised from CNY 52.6 in 2017 to CNY 57.6 last year, read a statistical report on China's medical and healthcare sector issued by the NHC.

Meanwhile, to ease pressure on fiscal finance, ten central government agencies led by the NHC also issued a new document, *Notice on Promoting Streamlined Healthy Development of Social Capital in Medical Services*, on June 12, 2019.

Pharma industry in the process of revamping its business model to fit with new business environment

Last year's industry and market data does not paint a great picture of broad Chinese pharma performance, with the exception of a few MNCs. Structural issues with the Chinese healthcare system continued to haunt the pharmaceutical industry in 2018. Notwithstanding the touted pharma industry ambitions of the Chinese government, slogans are nothing but pies in the sky when it comes to paying for better medicines. The healthcare reform has long been hijacked by cost containment and gone astray from the pledged path of improving efficiency and fixing structural flaws. The crashing course of reform is deeply rooted in the growing contradictions between wishful goals and healthcare financial reality, as well as among different government policies and their pursuits.

With tax and other revenues drying up and under increasing threat of BMI system deficit amid a looming Chinese economic downturn, local governments are pressured by both the central government and the public to do more for healthcare with less financial resources. As local governments assaulted the pharma industry above the table with wave after wave of cost containment measures, public hospitals also squeezed drug companies under the table for funds through a variety of schemes. Shortage of low cost but clinically essential medicines has become widespread, forcing the central governmen t to step in and often intervene administratively.

Pushed to the corner, by large the Chinese pharmaceutical industry continued to operate at the brink of business bottomlines. Under pressures of escalating anti-corruption campaigns, increasingly sophisticated cost containment measures as well as policy shifts in drug pricing and reimbursements, both domestic and multinational drug companies had no choice but to make dynamic changes so as to meet the contemporary challenges of the Chinese healthcare business today.

The most noteworthy development in China healthcare last year was probably the introduction of a new national trial for volume-linked drug tender purchase scheme, which is led by the newly established NHSA. The trial began with centralized purchase of all existing drug products passing generic quality and clinical equivalence (GQCE) evaluation in 11 trial site cities.

While the trial seems to target MNC off-patent originator drugs for substitution by local GQCE products, many listed leading Chinese pharma players, besides MNCs, also felt the chills. Apparently, the prospects of domestic companies, which invested heavily in costly technical upgrading and GQCE evaluation projects, were over-expected, as they were once again forced to fight each other to lower prices, resulting in fast profit erosion and even losses.

Despite challenges, MNCs geared up its China business in 2018 amid a market vacuum before arrival of local GQCE products in a big way and with intensified maneuvers on a variety of fronts. Besides, MNCs actively recalibrated their China strategies, business

model & objectives and investment plans adapting various structural issues of the Chinese pharmaceutical market. Reorganization of MNC businesses in China, which began a few years back, continued last year and into 2019.

As the market get tougher and continuing an overall slowing trend that started in the previous year, more MNCs took steps in 2018 to selectively scale back their China business in areas such as discovery research (as their raise clinical development capacity in the country), generic drug JVs and drug wholesale distribution; engaging in more local partnerships and out-licensing deals, especially for their non-core and high risk off-patent originator drugs; investing in facility expansion to accommodate new business plans; and exploring emerging new business areas such as innovative new drugs, pharmaceutical retailing/e-commerce and digital health intiatives.

By pure luck, 2018 and early 2019 turned out to be a rather triumphant time for MNCs hoping to shift gear of their China businesses from off-patent originator drugs to innovative new medicines. A number of pharma MNCs from witnessing renewed high growth last year, although such easy victory is unlikely to last into 2019 with a rising tide of GQCE products come on stream. Besides, the NMPA approved 38 innovative drugs from companies outside China in 2018, according to data published by the agency.

On the front of domestic players, revenues and profits of the broad Chinese pharmaceutical manufacturing industry were up 13.3% and 13.0% respectively in the first three quarters of 2018, reaching totals of CNY 1,948,640 million and CNY 248,360 million respectively, according to official statistics. Core business revenues and profits of Chinese chemical drug formulation manufacturing subsector rose 19.8% and 9.2% respectively, reaching CNY 648,540 million and 91,570 million in the first three quarters. Export supply sales of the subsector rose 34.9% to CNY 18,140 million, while its account receivables rose 16.7%. The subsector also added four loss making companies and their losses increased 7% in the period.

By the end of January 2019, more than 140 A share-listed medpharm companies released their 2018 performance guidance. Among them, at least 90 such companies expected to be profitable and 50 such companies predicted fallen performance. By the end of April 2019, all of the 286 A share-listed Chinese pharmaceutical companies reported their 2018 performance. Among them, 27 had net profits over CNY 1 billion, while five companies had that above CNY 3 billion in the year. 12, 25 and 72 companies had gross profit margin above 90%, 80% and 70% respectively, compared with nine, 26 and 67 in 2017. 11 such companies invested more than CNY 1 billion into R&D

Separately, the growth of pharma e-commerce sector continues to be bottlenecked by regulatory back and forth in recent years. Not only the CFDA failed to fully liberalize the sector as anticipated, but also it hardened government control by banning online prescription drug sales, which has not been relaxed until early 2019.

Severe challenges on the domestic market has led to growing interests of Chinese pharmaceutical companies in the global market. This has translated into more overseas

expansion efforts including cross-border M&A and investment deals, in particular acquisition of foreign assets, by domestic players.

Meanwhile, licensing activities among Chinese and foreign companies remained a hotspot in 2018 with increased involvement of MNCs, some which chose to spin off their off-patent originator drug business to local players via co-marketing or licensing deals.

China sends conflicting signals in the field of pharma IP with progresses and setbacks coexisting last year

Conflicting signals continues to be seen in the Chinese pharma IP space last year. More innovative drugs from research-based MNCs were approved through accelerated paths, as the NMPA begins to take concrete steps to accept foreign clinical data so as to expedite review. On the other hand, central and local governments are also pushing to substitute off-patent originator drugs with bioequivalent generics, promoting indigenously-developed local new drugs, introducing more negotiation and tender measures to sharply lower prices of both generics and patent medicines, and side-kicking foreign innovators like Gilead, whose key patent claims of blockbuster HCV drug Sovaldi were partially invalidated in 2018.

To me, the Sovaldi case is likely a warning shot, which may be followed with more similar or even more drastic actions, should the trade confrontation between China and the U.S., whose complaints are shared by other Western nations, escalate further. Even without it, the Chinese has long been tempted to test compulsory licensing, as seen in numerous official policies.

On the front of antimonopoly enforcements, the sharp price hike of chlorpheniramine maleate API in June 2018, which led to short supply of select drug formulations, triggered an anti-monopoly investigation by the SAMR, which found that Henan Jiushi Pharma, the largest producer of Chlorpheniramine Maleate API, and its exclusive distributor Hunan Erkang Pharma had colluded to abuse their market monopoly position. The SAMR recently ordered the two companies to stop relevant violations and fined them a total of CNY 12.43 million. The agency said it would continue to step up anti-monopoly enforcement to ensure fair market order and protect consumer rights.

In January 2019, the National People's Congress released draft amendments to the Chinese Patent Law, proposing expanded and enhanced protections that may provide real benefits to companies that develop new drugs. Although clearly intended to motivate companies to prioritize seeking new drug approvals in China, the proposed patent term extension would appear to be limited to products that are first submitted for marketing approval to China and another country, and would not apply to products first filed only in China. As a practical matter, this may limit the usefulness of the provision. On the other hand, pharmaceutical companies would also benefit from proposed enhancements to the available damages for patent infringemen. But biotech and pharma innovators will be disappointed that the previously proposed patent law amendment do not include the creation of a mooted US-style patent linkage system, adding to fears that plans to do so

have now been jettisoned.

Daunting Challenges in the New Year, Despite Unchanged Long-Term Prospects

In 2018, Chinese pharma continued to be haunted by many old structural flaws with no fixes in sight as new challenges develop. The industry is expected to face daunting challenges in 2019 amid intensifying cost containment measures.

Local governments are set to put more financial pressure on pharmaceutical companies, as they try to keep the public and central government happy and the books of BMI programs balanced in a time of fiscal crisis amid an economic downturn. On the other hand, the pharmaceutical industry will continue to be confronted by a host of other challenges including continued uncertainties of the broad Chinese economy, non-stop drug regulatory and healthcare reform turbulences, more stringent compliance requirements, and risks associated with constantly changing pharmaceutical business environment. The biggest hope for MNCs lies with the reform of drug evaluation and approval system, which appears to be opening a new door for innovative medicines in China.

Although the sporadic reform of Chinese healthcare system and drug regulatory regime has created wide-ranging turbulences, the marketplace has nevertheless become cleaner for business with fallen sales & marketing expenditures.

After a number of central government healthcare conferences in early 2019 with their major tasks for the year outlined, including the National Medical Insurance Working Conference hosted by the NHSA, the *Medicine Economy* journal of SMEI published a feature article predicting four major trends being shaped for the Chinese healthcare sector in 2019 as follows:

Trend 1: Following introduction of the national level centralized hospital drug purchase tender trial and spread of volume-linked bulk buying tender purchase model, off-patent originator drugs are expected to lose out in the competition with domestic drugs passing generic quality and clinical equivalence (GQCE) evaluation, and will gradually be phased out of the Chinese pharmaceutical market.

Trend 2: Under pressure of intensifying cost containment and preference policies of GQCE products, pharmaceutical manufacturers will be forced to drop production and supply of many unprofitable drug products, causing growing shortages. It is expected the BMI agencies will respond by publishing lists of shortage drugs which are to be listed and purchased online directly.

Trend 3: In late 2018, the NHC has elevated the control of "supplemental drugs" which are subject to focused surveillance and control. Provincial level governments are required to establish their own lists of supplement drugs and a national level list will be developed on this basis. Thereafter, it is likely the Chinese government will centralize the purchase of supplemental drugs at the national level with uniform BMI payment standards introduced for such products. Drug products listed as supplemental drugs are expected to

see their sales falling off the cliff.

Trend 4: Anticancers refusing to reduce prices meaningfully may be abandoned all-together despite support policies for such products. Both central and local government are now preoccupied with reducing prices of anticancers through negotiation and a mix of other measures.

The short and intermediate term outlook of Chinese pharmaceutical market is set to be cloudy and tough, but long-term prospects are hopeful and warrant patience of those with sustaining power. Conversely, let's also remember that most Chinese pharma industry observers still agree that the Chinese healthcare market will keep on growing in the foreseeable future, albeit at a slower rate and with lower profitability. It is nevertheless important for MNCs to set realistic goals for China business.

SMEI's predicted that the revenues of Chinese pharmaceutical manufacturing industry will see slightly higher growth at 14.2%, reaching CNY 3,650 billion and its forecast for 2019 is on the basis of GDP growth above 6% and flat or positive export growth.

It is also forecasted that the overall Chinese drug market will grow 4.8% to reach CNY 1,795.5 billion in 2019, down from 6.3% in 2018. Specifically, the first, second and third terminal markets (hospital, retail pharmacy and primary healthcare segments) are all projected to rise at slower rates at 3.6%, 7.1% and 8.2% respectively.

The path forward will be packed with tricky gambles rather than sure treats for MNCs.

Several MNCs renewed their optimism in China recently after regaining strong growth in recent quarters, although MAT quarterly growth of the Chinese hospital drug market has been slowing consecutively since the beginning of this year.

But unfortunately, the inevitable onslaught of MNC off-patent originator drugs began shortly after report of these shiny statistics. As I repeatedly warned in my recent editorials, MNCs collectively became the biggest loser in the latest NHSA-sponsored national level volume-linked centralized drug purchase tender trial for four central municipalities and seven provincial level cities (the 4+7 trial). Although such a defeat seemed inevitable after the Chinese government touted originator drug substitution loud and clear, many MNC executives were still caught off guard by how bad it turned out to be. The victorious growth in the past few quarters must have blurred their eyes.

But the worst is yet to come. The NHSA-championed volume-linked tender model is expected to spread nationwide soon and, before that takes place, numerous provinces such as Anhui, Shandong, Sichuan, Hubei and Qinghai are already demanding pharma companies to offer the same lowest prevailing prices at the trial for their upcoming local tenders and some of them are also pushing for equivalent bracketing of local GQCE products and originator drugs. More local governments are set to follow their suit.

The outcome of 4+7 trial has shaken the pharmaceutical industry, both local and MNC players, and led to an immediate stock avalanche of Chinese listed pharma companies amid widespread investor panic. Even the central government was taken back by the

dramatic investor reaction and rushed to caution local governments against referencing prevailing tender prices of the trial unless they are able to match the volume commitments and payment terms.

The 4+7 trial is not the only headache facing pharmaceutical companies in China. Most recently, the government is making headways introducing numerous major cost containment moves through the BMI payment system reform and drug rationalization measures in hospitals. To me, the Chinese government is dashing to close all loose-ends of healthcare consumption, especially with drug expenditures, before the country's economy sinks further to prepare for the rainy days.

Nevertheless, I do not think the current picture is completely bleak either. There are still a few brighter spots and pockets of opportunity offering reasonable market potential. The first thing first for MNCs at this critical juncture is to manage their expectations over the Chinese market – set realistic goals, moderate investments, stay vigilant to defend their core values & technologies, and finally strive for steady and solid success, albeit at slower growth rates. The Chinese healthcare market does have infinite future potential, but to unleash it will depend on correction of many existing structural flaws and the bellwether of broad Chinese economy. China has a health protection gap of an estimated US$805 billion in 2017, according to a Swiss Re survey.

Next, it goes without saying that the biggest bright spot for MNCs will lie with innovative medicines, stemming from accelerated launch of new drugs in China. Such hope will be put to test in the next few years. NMPA approved 38 innovative drugs from companies outside China in 2018, according to data published by the NMPA. But don't pin too much hope on the state-backed BMI system which has limited resources and therefore capped growth potential or on unreliable commitments of the national level volume-linked price negotiation. MNCs should also be prepared for challenges in this arena from a rising number of me-too or me-worse but nevertheless much cheaper domestic new drugs, which have been vehemently supported and fostered by the Chinese government.

Despite the rising hope on innovative drugs, do not write off off-patent originator drugs just yet either. At least for now, the Chinese government does not want to alienate MNCs completely for the sake of elite access to innovative medicines and renewed need for foreign investment and technologies, especially at a time of its rising political and trade conflicts with the West, in particular the U.S. The national level centralized drug tender purchase trial is designed to purchase between 60% and 70% of all public hospital consumption volume of the 31 drugs with local GQCE products in the 4+7 trial site cities and this model may soon be adopted nationally. Remember hospitals are allowed under this approach to make their own decisions to purchase the remaining 30% to 40% of such drugs from suppliers prevailing in the provincial level tenders and other online-listed suppliers. So MNCs still have some room to maneuver in this market space, not to mention there will always be a market somewhere for the better quality and more effective originator drugs, considering that the ruthless cost containment will inevitably drive down quality of local GQCE products.

I would advise MNCs to stay away from excessive price concessions, like what some did in recent volume-linked tender trials and negotiations. Not only excessive discounts mean drastic and possibly unrecoverable price erosion for these MNC originator products, more importantly such actions will feed to the local conspiracy theory that MNCs are profiteering fat cats and further fortify the government will to punch more juice from foreign products with iron-fists.

Finally, innovation of China business models by MNCs will help identify and shape new opportunities. Such may include creative solutions such as tie-ups with private health insurers, innovative alliances with local companies, novel approaches to DTP retail drug sales and selective diversification into consumer healthcare, as well as smart opportunities with digital marketing and online sales.

The less sexy private drug market segment, financed by out-of-pocket payments of patients and payouts from commercial insurers, is likely to be where truly dependable and more profitable long-term prospects lie for research-based MNCs. Time is now ripe for creative partnerships and solutions with private insurance companies. As such, lobbying of the Chinese government for reduction of its intervention to the self-payment market should be moved up on the agenda of trade associations like RDPAC.

As IQVIA has forecasted, I am also cautiously optimistic about long-term prospects of the Chinese market for MNC pharma companies, given the huge potential demands still bottlenecked as well as growing desire of the Chinese for better healthcare and drug products. But the fast growth seen by several leading MNCs in the past few quarters are unlikely to sustain into even next year. Alas, the kind of high China business growth we saw in the past two to three decades may never return again.