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China Pharmaceutical Guide

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16th Edition (2021)

Written by:

James J. Shen, MBA

Unrivaled China Healthcare Intelligenece Since 1991

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W*i*CON International Group LLC
21 Bridge Street, Metuchen, NJ 08840, USA
Tel: +1 609 903 8881   Fax: +1 801 751 5728
Internet: www.pharmachinaonline.com   Email: jshen@pharmachinaonline.com

China Office
Suite 17D, Building B, Oriental Kenzo Plaza, 48 Dongzhimenwai Dajie, Dongcheng District, Beijing 100027, China
Tel: +86 10 8447 6010
Email: info@pharmachinaonline.com

Japan Office
3-10-10 Hakucho, Habikino City, Osaka Japan 583-0856
Email: info@pharmachinaonline.com

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 33-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 33 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 WiCON|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 2021 (16th Edition)*

The W*i*CON | *China Pharmaceutical Guide 2021 (16th 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 2020/1H2021, 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 2020 (full year) and available data for H1/2021.
- ☞ 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, PHIIC and Sinohealth.
- ☞ All regulatory changes in 2020/1H2021 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-2021.
- ☞ 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 2020 and H12021.
- ☞ 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, 2021

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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

BMI – Basic Medical Insurance

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 / PSR – Medical Representative/ Pharmaceutical Sales 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

NRCMS – New Rural Cooperative Medical System

NMPA – National Medical Products Administration (formerly CFDA)

NHSA – National Healthcare Security Administration

OECD – Organization for Economic Cooperation and Development

OTC – Over the Counter

PHIIC – China Pharmaceutical Industry Information Center

PRC –People's Republic of China

PSR/MR – Pharmaceutical Sales Representative/Medical Representative

QA – Quality Assurance

QC – Quality Control

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

UEBMI – Urban Employee BMI

URBMI – Urban Resident BMI

URRBMI – Urban and Rural Resident BMI (URBMI+NRCMS)

USTR – US Trade Representative

VAT – Value Added Tax

VBP – Volume-based Procurement

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

The global economy is expected to expand 4% in 2021, with China's economy expected to expand by 7.9% this year, World Bank said on January 5, assuming an initial COVID-19 vaccine rollout becomes widespread throughout the year.

Not surprisingly, the pandemic also took its tolls on Chinese pharma. SMEI reported that the combined drug sales of three major Chinese terminal markets declined 8.5% in 2020 as a result of covid-19 pandemic, reaching a total of CNY 1,643.7 billion, excluding private hospitals, clinics and village clinics, which are not covered. The year over year change of hospital, retail pharmacy and primary healthcare markets (terminal 1, 2 and 3 markets) were -12.0%, +3.2% and -11.8% respectively in 2020, down from 4.2%, 5.0% and 8.5% in 2019.

But the Chinese pharma manufacturing industry appears to have fared better. The Chinese chemical drug manufacturing industry, including both chemical drug formulations and active pharmaceutical ingredients, experienced revenue decline in the first half of 2020, but it rebounded in the second half. For the entire year of 2020, the industry revenue fell only slightly by 0.7%, reaching around CNY 12 trillion.

Affected by the covid-19 outbreak, the drug consumption by hospitals and pharmacies declined for the first time in the past decade. Reduction of patient visits compounded by cost containment and volume-based tender purchases (VBPs), SMEI President Jianning Lin estimated the Chinese hospital drug market would drop considerably in 2020, with all therapeutic categories (TCs) affected with the exception of oncology and immune-regulatory drugs.

Any optimism for Chinese pharma at this point is heavily dependent on how the broad global and Chinese economy will perform in 2021. The Chinese market appeared a brighter spot for companies worldwide after the country was able to control the outbreak domestically and returned to overall growth by the second quarter last year. But resurging Covid-19 cases in early 2021, as well as the virus' persistent spread overseas mean the pandemic is an uncertainty for Chinese authorities and businesses.

What has and has not changed for Chinese pharma in the past year, and where does the future lie?

Central government agencies continued to introduce a host of new healthcare reform measures throughout 2020 – in the center is China's relentless efforts to contain healthcare costs through measures including national level volume-based procurement (VBP) tender, new policies/experiments relating to BMI payment reform, management of BMI funds, and promotion of commercial health insurance.

The NHSA and MOHRSS issued right before the end of last year the 2020 Edition of the *National Reimbursement Drug List* (NRDL). While it is encouraging more innovative drugs, notably all homegrown PD-1 inhibitors are included in the latest NRDL, MNCs including MSD, BMS AstraZeneca and Roche all failed to win deals for their PD-1/L1 inhibitors in China's latest national drug reimbursement negotiations as local players slashed their products' prices by about 80% to secure national coverage.

At the same time, the Joint Procurement Office (JPO) of the National Level Centralized Drug Procurement and Application Trial released a notice on December 25, 2020 for initiation of the fourth round of national VBP tender. China started the national VBP trial in 2019. Since then, three rounds of the procurement have covered 112 varieties of medicine, with their average price down 54%. Based on the reimbursement rate of 60%, the program is estimated to save CNY 21.6 billion for public hospital patients and CNY 32.3 billion for the medical insurance fund annually, the NHSA said.

By early May 2021, the JPO released a notice for collecting relevant drug information related to the 5th batch of national level volume-based procurement (VBP) of drugs as of May 10, therefore setting off the new round of this national tender trial officially. The 5th batch of national VBP includes 60 drug products (by generic drug names) of 202 product specifications.

The JPO opened the bids for the 5th round of national level VBP on June 23, 2021 in Shanghai. 61 of the 62 tendered drugs succeeded at the 5th round of VBP, achieving an average of 56% price reduction and involving a total value of CNY 55 billion.

On what has and is changing, China’s drug developers are expected to ride on a surge in the size of the domestic market driven by policy reform, though intense price pressure will see off contenders failing to innovate, according to speakers at an industry conference in early 2021.

The contribution of innovative medicines to total sales in China’s pharmaceutical industry may rise to 36% by 2025 from 22% in 2017, said Song Ruilin, Executive President of the China Pharmaceutical Innovation and Research Development Association, citing projections from the IQVIA Institute and Citi. With the annual revenue of the domestic industry as a whole projected to double to CNY 2.7 trillion over that period, sales of innovative drugs could more than triple to CNY 960 billion, according to the forecast.

Now that China frequently updates its NRDL every year with coverage of more new medicines, according to GlobalData, there is a promising opportunity for innovative drug companies to foray into the world’s second-largest pharmaceutical market. Besides, the opportunities for innovative medicines to achieve reimbursement and market access in China has certainly improved. The Chinese pharmaceutical market will grow from nearly US$132 billion in 2018 to more than US$209 billion in 2022, the company predicts.

Nonetheless, drug innovators face a dilemma of either agreeing to sharp discounts to have their products included in the government’s reimbursement list in exchange for large procurement volumes, or charging far fewer customers who are willing to pay out of their own pockets.

What’s also positive for R&D-based MNC pharmaceutical companies, are many major developments on the Chinese pharma IP front last year. In October, China's NPC adopted the fourth amendment of the *Patent Law*, which will take effect on June 1, 2021. The highlights are the adoption of a patent linkage system, a patent term extension for pharmaceutical patents, higher damages for patent infringement, a provision easing the burden of proof for damages, the availability of design patents for partial designs and more options to reward employee inventors.

In a somewhat unsettling development, China adopted the *PRC Biosecurity Law*, which will become effective on April 15, 2021. The new law formalizes some restrictions that have been in place since 1998. Foreign individuals and organizations are not allowed to collect or store China's human genetic resources within the country. Instead, they must work with Chinese partners and obtain government approval to use such material for scientific research.

Besides, MNCs are testing new waters to offset lost revenues. For example, Pfizer is on the hunt for partnerships with Chinese biotech firms developing novel drugs, as the pharma giant regroups after Beijing's aggressive price-cutting campaign eroded profit margins of its mainstay blockbusters. AbbVie, on the other hand, emphasized on the exploration of diverse collaboration models and opportunities with various organizations in China, including government agencies, hospitals and universities, to create an open, multilayered, and multidimensional healthcare ecosystem will continue to be a focus for the company.

While positive thinking and creative efforts are always encouraged, I would advise MNCs and smaller international players to proceed with care and realistic goals. Pay attention to the broad Chinese economy and politics, think long term and deeper, and ask critical questions about impacts of Chinese projects on the competitive landscape globally. Better yet, study the history of rise and fall of MNCs in other Chinese sectors. Pharma is behind many sectors in terms of the China business curve and I guess a lot can be learnt from the lessons in other industries. Having the right mindset and strategy is above all for sustainable victories.

In the meantime, COVID-19 has been found to accelerate the trend of consumers in China purchasing insurance online, particularly for the health sector. There is also huge potential for digitally-provided healthcare in China partly because of its aging population and telemedicine may reshape China's healthcare/pharma market landscape.

Besides, various government measures have been unveiled to bolster the nation's telemedicine network to improve epidemic prevention measures at the grassroots and raise access to healthcare in less-developed areas.

Numerous MNCs have started to position early in this fast-growing opportunity area. Local players are also on the move. As the Chinese government is pushing telemedicine really hard to both promote access and reduce costs, I think MNCs are better prepared and positioned for now. But are pharma giants acting fast enough? Probably not yet, both in terms of the depth and scope of their involvements. It's time for them to show leadership.

Separately, new business pathways are emerging as China harmonizes drug regulation in the Guangdong-HK-Macao Great Bay Area and advance experiments in areas including

Hainan and Shanghai.

China is in effect creating special economic zones again, with an emphasis on healthcare. These developments spell new opportunities for research-based MNCs. Creative business pathways for bring advance drugs into China are emerging and definitely worth exploring. I am sure some early birds are already moving to position themselves.

Central government continues drug regulatory system reform as it boosts support of drug innovation

First and foremost, the various agencies of the Chinese central government issued in 2020 a total of 66 polices and regulations which have significant impacts on the pharmaceutical sector in the country, according to WiCON|Pharma China's Regulatory Monitor.

Among the total, 51 were issued by the NMPA, six from the NHSA, five from the NHC, two from the NPC and the rest is from the NIFDC and the China Office of Human Genetic Resources Management.

The Chinese government made numerous major moves along with many new regulations to advance drug regulatory system reform throughout 2020 and early 2021. Below is a timelined chronicle of them.

The SAMR issued the *Provisions for Control of Drug Manufacture* (SAMR Order #28) on March 30, 2020. The regulation, which became effective on July 1, 2020, is aimed at strengthening drug quality, quality & safety, as well as risk control. The NMPA shall develop complementary documents of the regulation as the next step, according to the SAMR.

After the 11th Chinese Pharmacopoeia Commission approved the *2020 Edition of the Chinese Pharmacopoeia* (ChP) (2020#78), the NMPA and NHC introduced the ChP 2020 on July 2. It went into effect on December 30, 2020.

The agency released the *Announcement on Infrastructural Building for IT Tracing of Major Drug Products (2020#111)* in October 2020. It requires MAHs to make all major drug products, including prevailing drug products at the centralized drug purchase tenders, narcotics, psychotics and blood products, essentially traceable before December 31, 2020.

The Chinese government continued to make progress with reform of the country’s drug review and approval system throughout the past year with many new measures and policies.

The SAMR issued on March 30, 2020 the *Provisions for Registration of Drug Products* (SAMR Order #27). The regulations became effective on July 1, 2020. The regulation is aimed at strengthening drug quality, quality & safety, as well as risk control. The NMPA shall develop complementary documents of the regulation as the next step, according to the SAMR.

The NMPA and NHC jointly introduced the 2020 Edition of the *Good Clinical Practices of Drug Clinical Trials* (2020 GCP) (2020#57), which became effective on July 1, 2020. The regulation has a total of 83 articles in nine chapters.

In a major effort to support drug innovation in China, the NMPA issued the *Working Procedure for Priority Review and Approval of Drug Marketing Authorizations (Interim)*, the *Working Procedures for Drug Marketing Evaluation and Approval with Attached Conditions (Interim)* and the *Working Procedures for Evaluation and Approval of Breakthrough Medicines (Interim)*, also in July, 2020.

The NMPA issued the *Dispute Resolution Procedures for Drug Evaluation Decisions* on September 1, 2020, effectively providing the patent linkage path. The document became effective from the date of issuance.

The agency also introduced the *Technical Guidelines for Conditional Approvals of Drugs in Urgent Clinical Needs (Interim)* in November 2020. The document took effect immediately on the date of release.

On the front of drug price reform and anti-monopoly enforcement, the SAMR issued a new document, the *Notice on Strengthening Anti-Unfair Competition Enforcement to Improve Fair Market Environment*, in June 2020.

The Supreme People's Court released on October 30, 2020 a draft of the *Provisions on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Drug Marketing Evaluation and Approval of Patent*.

Similarly, the Standing Committee of the National People's Congress voted to adopt the Amendment XI to the PRC Criminal Law right before the end of 2020. Particularly notable is inclusion of drug registration related frauds as criminal offences. Among other provisions, the amendment seeks to boost food and drug safety, and promote integration with laws including the PRC Drug Administration Law.

China delivers on multiple healthcare reform fronts with intensified cost containment thru national VBP trial, new NRDL and BMI payment schemes

The 2020 National Primary Healthcare Teleconference was held at the beginning of 2020 during which the Chinese government set the goals for a primary healthcare system of higher quality and efficiency with elevated capacity building in 2020.

Thereafter the Chinese government followed up with intensified cost containment. The NHSA said that China's third-round VBP, which concluded in August 2020, saved CNY 21.6 billion for public hospital patients and CNY 32.3 billion for the medical insurance fund annually. Later in February 2021, the JPO completed the fourth round of national level VBP, locking in another CNY 12.4 billion in savings.

Most recently, the JPO conclude the bids for the 5th round of national level VBP in June 2021 in Shanghai. 61 of the 62 tendered drugs succeeded at the 5th round of VBP, achieving an average of 56% price reduction and involving a total value of CNY 55 billion.

But the costs of medical care in China continue to increase for treatments, particularly those outside the scope of social security coverage, according to recent research by Willis Towers Watson (WTW), a leading global advisory, broking and solutions company.

NHC data also shows the average outpatient medical expenditures per visit at the grade 3 and grade 2 public hospitals surged 15.9% and 13.7% respectively at current prices in the first half of 2020, while the average inpatient medical expenditures per visit at the grade 3 and grade 2 public hospitals also rose 8.9% and 6.7% respectively at current prices.

Besides, the coronavirus pandemic is expected to result in long-lasting changes and new business models within China's health insurance system by increasing the commercialization of healthcare services and causing insurers to rethink their health strategy, according to a new report by Moody's Investors Service.

Throughout 2020 and early 2021, the Chinese government introduced sweeping reform policies and new regulations in the past year to expand healthcare reform targeting multiples areas including BMI system shakeup and fund management, cost containment, public hospital management, community healthcare, credit rating/blacklisting and corruption fighting.

Most notably, China adopted the *Law on Promoting Basic Medical and Health Care*, as the country's first fundamental and comprehensive law on basic medical and health care, which went into effect on June 1, 2020.

Six central government agencies, including the NHC, Ministry of Education, MOF, MOHRSS, NHSA and NMPA, introduced a new policy, *Opinions for Strengthening Pharmacy Affairs Management of Medical Institutions to Promote Drug Rationalization*, in February 2020 for immediate implementation. The latest policy aims to beef up drug cost containment efforts through pharmacy affairs management.

The State Council issued a major policy, *Opinions on Deepening Medical Insurance System Reform*, in March 2020. Guiding principles of the document is to build a uniform and multi-tiered medical insurance system with universal population enrollment, balanced fund raising from urban and rural areas, clear obligations and responsibilities, and appropriate coverage. The role of the BMI fund in strategic buying is upheld to promote coordinated development of medical insurance and high-quality healthcare services, and to support implementation of the Healthy China initiative.

Three central government agencies, the NHSA, the MOF and the STA issued the *Notice on Urban and Rural Resident BMI Tasks in 2020* in June 2020. The goal is to facilitate the central government decision to establish a uniform urban and rural resident BMI as well as critical illness systems.

The NHSA issued two new documents, the *Operating Standards for Drug Price and Tender Purchase Credit Rating (2020 Edition)* and the *Determination Basis for Drug Price and Tender Purchase Credit Rating (2020 Edition)*, in November 2020.

The NHSA and MOHRSS completed the revision of and issued the 2020 Edition of the *National Reimbursement Drug List* (NRDL) before the end of 2020. Compared with the previous 2017 NRDL, 119 drugs (spanning 31 therapeutic classes) were added to the 2020 NRDL, while 29 were removed. The 2020 NRDL shall go into effect on March 1, 2021. Negotiation was conducted for a total of 162 exclusive drugs. The overall negotiation success rate is reported by the NHSA to be 73.46%. The average price reduction of those succeeding negotiation was 50.64%.

More recently, the State Council issued a new volume-based procurement (VBP) policy document, *Opinions on Promoting the Normalization and Institutionalization of Centralized Volume-based Procurement of Drugs*, on January 28, 2021. The document includes 20 measures in seven major areas, laying out the roadmap for centralized VBP of drugs in future.

The NHSA also issued two new BMI regulations, the *Interim Measures for BMI Designated Medical Institution Management* and the *Interim Measures for BMI Designated Retail Pharmacy Management*, in January 2021. The new interim measures define and clarify the rights and responsibilities between BMI regulatory agencies, BMI agencies, BMI designated medical institutions and BMI designated retail pharmacies.

On telemedicine promotion, the Ministry of Industry and Information Technology (MIIT) and the NHC jointly issued a policy document, the *Joint Notice for Stepping Up the Infrastructure Building of Telemedicine*, in November 2020. The blueprint is the central government's latest move to promote telemedicine and bridge the urban-rural healthcare gap. The NHSA, meanwhile, issued the *Guidance Opinion for BMI Payment of Internet + Healthcare Services* in the same month.

Last but not the least, six central government agencies including NHC, MIIT, MPS, MOF, MOFCOM, State Taxation Administration, SAMR, NHSA and SATCM issued a new document, the *Notice for Highlights of Correction of Irregularities in Pharma Procurement & Sales and Medical Services*, in June 2020.

In a related development, the Supreme People’s Court and the NHSA signed a MOU in September 2020 to establish an information exchange mechanism for commercial briberies in pharmaceutical commerce, under which a periodical reporting system for commercial bribery cases in pharmaceutical commerce shall be established.

MNCs remain committed to Chinese market as the country opens wider for innovative medicines

The Third China International Import Expo (CIIE 2020) was held in November 2020. The convention was reportedly participated by top ten and many leading medpharm companies, which reportedly launched over 120 new products and technologies at the convention.

A slew of MNCs, including Pfizer, Novartis, AstraZeneca, Sanofi, Roche, J&J, Bayer, Fresenius, Novo Nordisk, AbbVie and Takeda, showed their support to the Chinese government by pledging commitments to the country’s market and signing multiple deals at the event, even as many of them, if not all, were experiencing huge setbacks with recent sales of their flagship off-patent originator brands in China. Nonetheless, foreign companies continued to be blessed in the past year with more new drug approvals, which understandably renewed their hope for the promised land.

FY2020 – The combined total revenues of seven leading multinational pharmaceutical companies in China reached $21.4 billion in 2020. Affected a range of factors including the Covid-19 pandemic, volume-based procurement of drug products (VBP), BMI drug price negotiation and new product launches, the Chinese performance of MNC pharma companies diverged last year. The pack was again led by AstraZeneca with China revenue of $5.4 billion, followed by MSD and Roche. Lilly announced its Chinese revenue for the first time at $1,117 million in 2020.

3Qs/2020 – Eight MNC pharma companies reported, along with their global business results, their China performance data in the first three quarters of 2020. In addition, Bayer said its Q3 performance in China was outstanding though it did not disclose specific sales data. Pfizer Upjohn and Sanofi saw its China sales fall 18% and 11% respectively in the period, while Roche’s business in the country was almost flat with 1% growth. But other MNCs including MSD, AstraZeneca, Eli Lilly and Novo Nordisk managed to grow at above 10% rates.

H1/2020 – Seven MNCs, including AstraZeneca, Roche, MSD, Sanofi, Novartis, Novo Nordisk and Pfizer Upjohn, reported their business results in the first half of 2020, including selective China performance data. The pact was led by AstraZeneca by China sales, followed by Roche and MSD. The Impacted by volume-based procurement (VBP) initiatives, Chinese revenue of Sanofi and Pfizer Upjohn declined more than 10% in the first half. Other than Pfizer Upjohn, which did not report its sales figure in China but admitted 21% revenue drop in the country, the total China revenues of six other above-mentioned MNCs reached around US$10 billion or CNY 70 billion in the period. The total 2019 China revenues of the above-mentioned seven MNC companies is estimated by Pharmacube.com to be around CNY 140 billion.

As business dampen for their off-patent originator drugs amid the expanding national trial for volume-based procurement of drugs, MNCs increasingly resort to partnership deals with local companies in defense of their market positions in China.

Meanwhile, cross-border M&A, licensing and R&D partnerships remain heated in the past year.

China's biotechnology M&A transactions have almost doubled in 2020, with interest perking up among investors amid a global rush to develop a cure for the Covid-19 disease, reports the South China Morning Post.

The pace of in-licensing by Chinese pharmaceutical companies accelerated in 2020, according to PhIRDA quoting a recent feature article of Sina Pharmaceutical News.

Oncology drugs remained the hotspot for Chinese in-licensing deals last yar, while the trend had been flat for endocrinology and nervous system drugs. Affected by the covid-19 pandemic, the in-licensing deals for anti-infectives, which received little attention in the past, shot up significantly. Besides, such deals in ophthalmology also increased persistently.

Domestic players have increasingly turned to R&D for future growth as they boost fundraising to facilitate M&A, pipeline and expansion.

By January 30, 2021, a total of 216 A share-listed Chinese medpharm companies disclosed their financial performance in 2020. Among them, 129 companies or nearly 60% forecasted better performance last year. Among them 87 guided sharp performance growth. 83 of the 216 A share-listed Chinese pharmaceutical companies forecasted losses for the year of 2020. Among them, 12 companies expect to add over 100% in losses.

Local champions had seen a harvest of new drugs in 2020, continuing a trend from 2018. In the past three years, the Chinese pharmaceutical industry had consistently secured at least ten new drug approvals for domestic innovative drugs and over 200 INDs acceptances annually.

In 2020, China approved a total of 11 domestic innovative new drugs, including six oncology drugs, two anesthesia drugs and three hepatitis C drugs. More than 20 new drug applications (NDAs) and 386 INDs for domestic innovative new drugs were filed in the same year.

A total of 18 Chinese biotech companies launched IPOs or secondary IPOs in 2020. So far there are more than 30 such companies trading A shares at domestic stock exchanges or H shares at the Hong Kong Stock Exchange. This number is predicted growing to around 100 in the next five years. Besides, there will be more listings by traditional Chinese pharmaceutical companies which transform into innovative players.

Chinese biotech players are also gaining a foothold in globalizing their business with multiple regulatory filings for domestic innovative new drugs in the developed markets, especially in the U.S., as well as a fast rising number of international out-licensing deals of such drugs in 2020. The trend is expected to continue and surge.

Has the Game Changer for MNCs and Innovative Drugs Finally Arrived?

MNCs continued to see setbacks with their off-patent originator drugs in China in the past year, as China escalates its campaign to contain healthcare costs.

Some international big pharma companies such as AstraZeneca PLC and Bayer AG in the past have managed to secure contracts for their drugs at latest VBPs, but only by slashing prices by as much as 80%. However, such temporary truces will not last long and companies betting on the game of lower price for volume will lose all eventually.

In fact, I have long warned MNCs about the danger of relying excessively on off-patent originator drugs and the state-sponsored BMI system, as well as engaging in price competition with domestic players at VBPs. In a sign that MNC pharma giants are waking up to the harsh reality of healthcare with Chinese characteristics, some have sent representatives to the third and fourth rounds of national VBP with bid prices far above the cap set by authorities, in effect disqualifying themselves and at the same time staging a silent protest collectively to the government, according to some industry observers, who also suggest that MNCs are in fact doing reasonably well without the VBPs by concentrating on a blend of other opportunity pockets including the flexible budgets of public hospitals, the self-payment needs, primary healthcare facilities and retail pharmacies, as well as private hospitals. Besides, we are also seeing more partnership deals between MNC and local players for co-marketing and sales of their off-patent originator drugs.

This also matches my long-time assertion that MNCs should narrow down on and position precisely for their target patient population and at the same time set realistic goals for the Chinese market. Again, don’t play the same Chinese characteristics game as your domestic competitors and try to win on the strength and higher standards of R&D-based MNCs in corporate dedication, business ethics and integrity, innovativeness, quality commitment and support excellence. The demand for imported premium drug products from Chinese elites and upper-middle class has been and will remain solid and unwavering – it is unlikely to be changed by the VBPs, domestic me-too products or pricing tactics of local players. If anything, MNC pharma giants are only to be defeated by themselves, if they choose to become "foreign companies with Chinese characteristics", abandoning their own strength.

By the end of Q3, 2020, Roche blamed pandemic-related hospital constraint and drug price cuts to its business slowdown in China. In early 2020, Roche Holding CEO Severin Schwan forecasted continuing double-digit growth in China betting on strong demand for the company's cancer medicines.

Then came the giant good news and it may prove to be a real game changer for R&D-based MNC pharma companies.

In October 2020, the National People's Congress (NPC) formally adopted an amendment of the *PRC Patent Law*, which will take effect on June 1, 2021. It is the fourth version of the law since it was introduced in 1985. The newly amended law includes significant changes in the intellectual property legal framework with regard to pharmaceuticals in China.

Highlights of the amended Patent Law of PRC include increasing damages for infringement, a new patent open license system, and patent term extensions to compensate for time spent awaiting regulatory approval for pharmaceutical products. The amended law also establishes an early resolution mechanism for pharmaceutical patent disputes. It has long been a grievance of companies that China's punishment of patent infringement was too lenient to act as a deterrent.

The newly amended Chinese Patent Law and proposed regulations will fundamentally change the legal framework governing how drugs are approved in China, according to Xin Tao and Philip Katz of Hogan Lovells. The most significant change for life science companies is adoption of Hatch-Waxman-like incentives to encourage companies to develop and seek approval in China of new, innovative drug products, and to encourage generic companies to challenge reference product patents, they commented.

The latest development will indeed be a game changer for research-based pharmaceutical companies, foreign or domestic. Although the Chinese government is fighting tooth and nail to contain healthcare costs, it is now more convincing than ever before that it is quite serious about supporting drug innovation with savings from other areas such as generic drugs, adjuvant products and, to some extent, TCMs.

To foster growth of the innovative drug sector, the Chinese government is set to cut out and reserve a piece of the drug market for high-end novel new drug products. By no means, however, it will let R&D-based companies take a free ride and the price squeeze will not go away.

Although the market for innovative drugs will be more regulated where MNCs have a head-start, they should be prepared for tough battles on all fronts with domestic research-based companies, which will focus on me-too products and can compete flexibly.

Remember at all times that domestic competitors will have all possible backings from the government and don't believe for a minute it may be otherwise. Mind you that what its ultimate goal is to boost China's drug innovation and build a champion pharmaceutical industry in the world.

Meanwhile, another development may turn out to be more troubling for both MNCs and their Chinese R&D partners. Newly Nasdaq-listed Legend Biotech, a subsidiary of Chinese CDMO Genscript Biotech and Johnson & Johnson's CAR-T partner, announced that the Chinese authorities the arrest of ZHANG Fangliang, Chairman of Genscript and Chairman & CEO of Legend. The arrest is believed to be related to the special inspections of the management of human genetic sources by China's ministry of science and technology along with related authorities.

China very tightly regulates exports of human genetic resources. It also bans the import of most plasma products. In June 2019, China passed a new regulation further tightening the grip on collection and use of human genetic resources, including blood samples that can read out DNA. Foreign organizations and individuals, as well as organizations directly controlled by them, are not allowed to collect or preserve China's human genetic resources, and cannot provide such resources abroad.

Notably, the *PRC Biosecurity Law* was passed by the NPC's Standing Committee in less than a year from its first review – this signifies the strengthening of regulations for the biotechnology and life sciences industry in the midst of the COVID-19 pandemic, according to legal experts of DLA Piper.

The release of the *PRC Biosecurity law* reflects China's strategic positioning of biosecurity as part of its national security system. Notably, the regulations for genetically modified organisms, are not explicitly included in the Biosecurity law. Although the fundamental principles for prevention from invasion by foreign species and the protection of biological resources (such as wild animals and plant genetic resources) are established by the *PRC Biosecurity Law*, the detailed regulations for these subject matters are yet to be promulgated.

We are keeping a close eye on further developments as the relevant governmental authorities provide more clarity.