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15th Edition (2020)

Written by:

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Unrivaled China Healthcare Intelligenece Since 1991

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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 32-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 2020 (15th Edition)*

The W*i*CON | *China Pharmaceutical Guide 2020 (15th 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 2019/1H2020, 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 2019 (full year) and available data for H1/2020.
- ☞ 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 2019/1H2020 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-2020.
- ☞ 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 2019 and H12020.
- ☞ 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, 2020

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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 – 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

NRCMS – New Rural Cooperative Medical System

NMPA – National Medical Products Administration (formerly CFDA)

NHSA – National Healthcare Security Administration

OECD – Organization for Economic Co-operation and Development

OTC – Over the Counter

PHIIC – China Pharmaceutical Industry Information Center

PRC –People's Republic of China

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

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 appears to be reaching the bottom of a cyclical slowdown as 2019 draws to a close, aided by an agreement that will prevent further tariff increases on goods shipped to the U.S. and de-escalate a trade war that's battered the global economy. Domestic stimulus efforts, ranging from tariff cuts to support for infrastructure spending, are also buoying sentiment. But then, coronavirus hit Wuhan and infection exploded in the city and quickly spread nationwide and even internationally, clouding the country's economy once again.

Things were not so pretty with the pharma industry either at the beginning of 2020. The Round 2 Purchase Tender of the National Level Centralized Drug Purchase Program concluded on January 17. The average price reduction by prevailing suppliers in the Round 2 is reported to be 68% while the highest single price reduction was 97%. Leading domestic players including Kelun Pharma, Qilu Pharma, Hengrui Medicines, Fosun Pharma and Yangzijiang Pharma emerged as big winners, as only four out of 26 participating foreign companies won bids for five originator products after big price cuts. Bayer was also the boldest and it reduced price of its Acarbose by 91% to win.

In the supposedly lucky *Year of the Pig* (2019), MNCs continued to see robust China business growth in amid a market vacuum before flooding of local GQCE products. Such admirable performance was achieved following negotiated NRDL listing and successful 4+7 tender bids, though no information is available about their bottom-lines. 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 in 2019.

Despite their surprise short-term gains ahead of the storm, it is by no means a smooth-sailing voyage forward for MNC pharma companies in China last year. While they have been busy introducing newer, innovative drugs to China at unprecedented speed, foreign pharmas' older medicines have come under pressure in a bulk procurement scheme that's cutting some off-patent drugs' prices through a bidding process.

Even IQVIA has lowered its Chinese pharma market growth project to 3%-6% annually before 2023 in its latest report, *The Global Use of Medicine in 2019 and Outlook to 2023*.

Foreign companies are taking enormous risks to do business in China. They are navigating an unprecedented array of risks, from slowing growth to the trade war and civil protests in Hong Kong. The latest saga of NBA ban in China unveils the minefield even further. But that hasn't stopped many of them from pushing deeper into the vast Chinese market.

According to the Chinese calendar, 2020 will be the *Year of the Rat*, which *Fengshui* masters say will be another year of extensive change as the universe continues in its

accelerated transitional period but, given the rat's traits, the world will be equipped to cope.

The U.S.-China trade war, political instability and a weak global economy all conspired to produce a tough 2020 for the Asia-Pacific, according to an article from The | Diplomat by Anthony Fensom.

Chinese pharma growth slowed further in 2019 amid a gloomy outlook

The Chinese pharma growth continued to cool in 2019 as a result of healthcare cost containments, 4+7 trial and its expansion, and introduction of rationalization schemes such as DRG, among other factors.

The three major Chinese drug terminal markets rose 4.8% in 2019, reaching a total of CNY 1,795.5 billion at retail sales prices, recently released SMEI data shows. This figure does not include drug sales through private hospitals and clinics, as well as village clinics. When they are accounted, the over Chinese drug market size in 2019 is projected to exceed CNY 2 trillion.

Separately, the overall Chinese drug market is estimated by PHIIC to rise 4.2% to CNY 17,141 billion in 2019. The center projects sales of 25 drug products covered by the 4+7 trial to shrink 1.18% by value and rise 12.16% by volume in 2019 in representative hospitals covered by PHIIC. It also estimates the Chinese sales value of innovative drugs to be CNY 11.12 billion in 2018, a 40% jump from CNY 8.06 billion in 2017. Such sales were equally shared by novel chemical drugs and biologics in 2018.

The Chinese pharmaceutical market is expected to grow slower at 4% in 2019, according to Han Wu, President of Sinohealth. Nonetheless, he continued to maintain a positive outlook of the Chinese pharmaceutical market due to a mix of different drivers including the country's huge population base, aging Chinese population and rising prevalence of chronic diseases.

SMEI predicts the Chinese pharmaceutical manufacturing industry (eight medpharm sub-industries) to grow 10.1% in 2019 to reach CNY 267.2 billion. It further projects the Chinese drug market to grow 4.8% in 2019 (vs. 6.3% in 2018) to reach CNY 1,795.5 billion. The hospital, retail pharmacy and primary healthcare markets (terminal 1, 2 and 3 markets) are projected to grow 4.2%, 5.0% and 8.5% respectively in 2019, down from 5.4%, 7.5% and 10.2% in 2018.

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

The Chinese government made numerous major regulatory moves and introduced more regulations to advance reform in 2019.

China passed a number of key legislations relating to healthcare in 2019. The National People's Congress (NPC) passed the *Vaccine Administration Law of PRC*, which stipulates the "strictest" management by requiring a whole-process supervision system and toughening penalties on producing and selling fake or substandard vaccines. As the country's first legislation dedicated to vaccine management, the new law went into effect on Dec. 1, 2019.

The NPC also adopted in August 2019 the amendment to the *Drug Administration Law of PRC*, which will give greater leniency to people who import small amounts of medicines which are unapproved in China but sold legally overseas. Under the previous law, such drugs were classified as "fake drugs". The amended law has 155 articles in 12 chapters and it went into effect on December 1, 2019.

The NMPA later issued a document promoting implementation of the newly amended *Drug Administration Law of PRC* in September 2019. In the document, the agency confirmed withdrawal of GMP and GSP certifications, while strengthening random inspections of GMP and GSP compliance.

Before the end of 2019, the NPC 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, the law will take effect from June 1, 2020.

On the front of drug registration, the CDE accepted a total of 8,056 drug registration applications (by application numbers and excluding 2nd review applications) in 2019, up from 7,428 applications in 2018, according to Yaozh.com recompiling NMPA data. Among the total, 6,459 applications are for chemical drugs, 416 for TCMs and 1,158 biologics.

To continue its overhaul of the drug evaluation and approval system and support innovative R&D, China also introduced many more new rules and regulations in the area of drug registration in 2019. Such includes the NMPA's *Announcement over Matters Related to Further Improving Linked Evaluation and Approval of APIs, Excipients and Packaging Materials Used in Drug Products* in July 2019 and the *Guidelines for Use of Real-World Data to Support Drug R&D and Evaluation (Interim, 2020#1)*, in January 2020.

Into the new year, the State Administration of Market Regulation, the governing agency of NMPA, announced its legislation plan in 2020 on March 27 this year. The agency plans to draft and submit seven laws and regulations for approvals, as well as 48 departmental rules and regulations including the *Provisions for Registration of Drug Products* and the *Provisions for Control of Drug Manufacture*, which were issued in March 2020 and went into effect on July 1, 2020.

Meanwhile, China moved to ensure full-process regulation of vaccines, from manufacturing to inoculation. But there were few developments for internet drug sales and the policy for online drug transactions is still under discussion via public comments,.

Over 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. On the other hand, the NHSA issued a new policy, *Opinions for Perfecting Contemporary Drug Price Regulation (Yi Bao Fa 2019#67)*, in December 2019 for immediate effect.

Most recently in June 2020, the NHSA released its second draft of the Guidance Opinions for Drug Price and Tender Procurement Credit Rating System. Major provisions of the document include: 1) setting up the drug price and tender procurement discredit list; 2) introducing credit rating of pharmaceutical enterprises; 3) tiered handling of discredit and

violation practices and 4) publication of discredit handling information.

Healthcare reform remains in deep water and preoccupied with cost containment growing shortages

To lighten the fiscal financial pressure, ten central government agencies led by the NHC issued a new document, *Notice on Promoting Streamlined Healthy Development of Social Capital in Medical Services*, at the beginning of 2019.

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.

By the end of May 2019, the State Council has moved to incentivize the growth of private medical institutions with streamlined approvals and greater policy support as experts underscored the importance of enabling more talent flow to the private medical sector. The cabinet decided to expand the room of development for private medical institutions. Employees of public hospitals may now apply for the opening of private medical facilities while they are still in service or on suspension from duty without pay.

The State Council later issued a new document, *Notice on Major Tasks of Deepening Healthcare System Reform in 2019*, in June. 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.

Subsequently, XIONG Xianjun, Director General of the Pharmaceutical Service Administrative Department of NHSA, announced that the national level centralized drug tender purchase scheme shall be expanded further in 2019. Besides, China will set up new medical alliances in 100 cities and 500 counties across the country in 2019, according to Xinhua News quoting a NHC official at an earlier press conference in the same month.

The country also has big plans for primary healthcare. The nation's policymakers want one general practitioner for every 2000 residents by the year 2030 – which means training 500,000 GPs in 12 years to more than triple the current GP workforce. The NHC also issued a basic standard for community healthcare facilities, requiring at least 30 beds to be open for patients in each hospital, and the utilization rate for sickbeds should above 75%.

Four central government agencies led by the NDRC issued the *Work Plan for Building Regional Medical Centers* and a notice to establish national and regional mental medicine+CNS centers in November 2019 to facilitate supply side reform in the healthcare sector and implement Healthy China initiative.

Fast forward to the new year, the 2020 National Primary Healthcare Teleconference was held in January 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.

On Centralized hospital drug purchase tenders, the State Council Issued a policy document, *Trial Plan for Nationally-Organized Centralized Drug Purchase and Application*, in January 2019 to lay out the roadmap of this important experiment (4+7 trial). Subsequently, The NHSA sought to advance the 4+7 trial expansion with a new document, *Notice on Relevant Arrangements for Expanding the National Centralized Purchase and Application Trial*, in August 2019. By November 2019, the Healthcare Reform Leaders Group of State Council released the *Certain Policy Measures for Further Deepening Pharmaceutical and Healthcare System Reform through Centralized Drug Purchase and Use* to deepen and expand the experiment of national level centralized drug purchase and use trial nationwide.

There were none but one development in the area of essential drugs last year. In January 2019, the NHC and SATCM issued a joint document, *Notice on Further Strengthening the Management of Essential Drug Inventory and Application by Medical Institutions*, which provides a detailed roadmap and reinforces requirements for prioritized inventory and consumption of essential drugs in all public medical institutions.

As for major moves of cost containment by China last year, the NHSA initiated the National DRG Trial in a May 2019 teleconference. Later in October 2019, the NHSA issued two documents on diagnosis-related groups, the T*echnical Guidelines for China Healthcare Security-Diagnosis Related Group (CHS-DRG) Grouping and the Payment & CHS-DRG Grouping Plan*, in a move to implement the DRG payment system reform trial.

The NHC introduced the first batch of the *List of Drugs Subject to State Rationalization Surveillance and Control (Chemical Drugs and Biologics)*, or the so-called the national adjuvant drug list, in July 2019.

The NHSA and MOHRSS released the *2019 National Reimbursement Drug List* (NRDL) under the BMI, WRI and Maternity Insurance in August 2019. The latest 2019 NRDL contains 1,322 Western medicines, 1,321 formulated TCMs (including 93 ethnic medicines), and 892 TCM crude drugs. There are an additional 128 drugs (including 109 WMs and 19 formulated TCMs) proposed for negotiation, all of which have high clinical value and more expensive.

In the meantime, the NHSA initiated and concluded a new round of access negotiation for the 2019 NRDL in November. Out of the 150 premium drug products from over 70 manufacturers which were selected for 2019 NRDL listing through negotiation, experts chosen by the NHSA and MOHRSS succeeded in reaching agreements for 97 such drug products.

By the end of 2019, the National Drug Usage Monitoring Platform was launched, according to the NHC Information Center. It is reported that 8,840 medical institutions have registered on the platform, which already has 600,000 average daily visits.

Fast forward to the new year, the General Office of the National Health Commission (NHC) issued in January 2020 the *Clinical Pathways for Relevant Disease Groups (2019)* for reference by all levels of healthcare agencies and all levels/categories of medical institutions.

In the same month, the 2020 National Primary Healthcare Teleconference was held in

during which the Chinese government set the goals for a primary healthcare system of higher quality and efficiency with elevated capacity building in 2020.

The Central Committee of the Chinese Communist Party and 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.

Similarly, 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 State Council issued a new document, *Opinions on Major Departmental Task Assignments to Facilitate the Government Work Report of the State Council*, in June 2020. It is provided that China will reform its disease prevention and control system, beefing up capacity building for infectious disease prevention and treatment, refine infectious direct reporting and early alert system, and persist on epidemic information transparency. Relevant policies shall be introduced before the end of 2020.

Paradigm begins to shift for Chinese pharma as MNCs struggle to fit in with the new normal

Structural issues with the Chinese healthcare system continued to haunt the pharmaceutical industry in 2019. 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.

China is doubling down on its efforts to radically overhaul its healthcare system by driving down prices of off-patent drugs to free up state funds for novel, cutting-edge therapies. The campaign is putting pressure on profit margins for both foreign and domestic drug makers. The 4+7 trial that started in late 2018 had seen prices plunge by more than half, while cheaper generic drugmakers undercut their global peers. Its “success” emboldened Beijing to expand the program nationwide in 2019 and then initiate a second round of supply contracts for its public hospitals.

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 government to step in and often intervene administratively.

Pushed to the corner, the Chinese pharmaceutical industry is now at the brink of business bottom-lines. 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 pharmaceutical industry is reeling: Chinese drugmakers issued a flood of profit warnings last year, while their global counterparts such as AstraZeneca Plc and Sanofi cited the procurement plan as a damper for earnings. Foreign pharmaceutical giants are pivoting toward innovative treatments to make up for the tumbling sales of their off-patent drugs after local rivals undercut them on pricing.

The most noteworthy development in China healthcare throughout last year was implementation of the National Level Centralized Drug Purchase and Use Program in four central municipalities and seven provincial level major cities (4+7 trial), which was first trialed in late 2018. The trial began with centralized purchase of 31 drug products passing generic quality and clinical equivalence (GQCE) evaluation in 11 trial site cities and expanded in 2019 to 25 provinces and regions and 35 drug products in September 2019.

By early 2020, five central government agencies led by the NHSA initiated the Round 2 of the National Level Centralized Drug Purchase and Use Program, which is set up to purchase 33 drug products from therapeutic categories of diabetes, hypertension, oncology and rare diseases. The average price reduction by prevailing suppliers in the Round 2 to be between 60% and 80% with the highest single price reduction at 93%. Bayer AG's diabetes drug acarbose had its price slashed by 80%.

In the aftermath of the coronavirus outbreak, industry watchers said in March 2020 that many ongoing drug trials are facing disruptions with people in clinical drug testing, unable or unwilling to report to hospitals for fears of catching the virus. Along with clinical trials, the Pharma industry may even face some shortages of APIs supplied by the Chinese pharma companies.

It all comes down to mounting challenges and roadblocks ahead for pharma MNCs in China, thus hampering near term and future prospects though opportunities continue to remain in select areas.

As the 4+7 trial and its expansion program advanced, the market for MNC off-patent originator drugs at tier 1 and 2 Chinese cities shrank quickly. Many MNCs responded by pushing further into lower tier urban and even rural areas. Both Sanofi and Pfizer are believed to be raising their bets on the county level hospitals and community healthcare facilities. At the same time, an array of MNCs including Pfizer, Lilly, GSK, Merck and Allergan hurried to jump on the China's speeding e-commerce train for untapped

opportunities.

In addition, big pharma companies are testing different approaches. On the one hand, they are speeding up the disposal of manufacturing and drug development facilities, as well as licensing of even core off-patent originator product assets to Chinese companies in order to reduce exposure to systemic China risks. Recent examples include spinoffs of Suzhou Novartis and GSK (Suzhou) facilities to Jiuzhou Pharma and Shanghai Fosun respectively, as well as a deal between Eli Lilly and Eddingpharm for promotion and distribution of Ceclor and Vancocin, two well-established Lilly antibiotics, in China

MNCs will be pressured to offload more of their off-patent originator products to domestic players in future, as prices are to be pushed so low in future that foreign companies simply cannot afford to promote these products in China at their global standards.

On the other hand, MNCs are also changing their R&D strategy in China, shifting from owning and operating their own research centers in the country to focusing more on building partnerships with Chinese research companies. Numerous foreign companies closed or downsized their Chinese R&D operations with slashed investments. At the same time, some companies continued to invest in drug development and translational research along with more local partnerships.

Indeed, MNCs must test the Chinese market with their different strategic options and find their own successful and sustainable path forward. Whatever the right formula, however, the bottom line, which I would caution all MNCs equally, is to stay away from integrating with Chinese characteristics along the way. Always remember, being different from your local competitors is probably the most important reason why reputable MNC pharma companies are still enjoying certain prestige among the Chinese people and therefore deserve certain climate-proof market share in the country.

In the meantime, 312 A Share-listed Chinese medpharm companies reported their 2019 performance by April 30, 2020. 40 of the 312 such companies had revenues exceeding CNY 10 billion (up from 34 in 2018) and 26 of them had net profits above CNY 1 billion in 2019. On the other hand, nine of them had losses above CNY 1 billion, including Hengkang, Yatai Pharma and Jilin Pharma, in the same year.

According to a separate report, 80% of listed Chinese pharmaceutical companies increased their R&D spending and seven such companies saw over 50% R&D spending growth in the first three quarters of 2019. Besides, 14 such companies invested more than 10% of their revenues in R&D.

There was a total of 63 fund-raising deals for startup companies in the Chinese biotech and medpharm sectors in the first half of 2019, totaling US$1,645 million, according to vcbeat.top. But trade tensions are undermining the flow of Chinese venture capital to US Biotechs, which have seen a drastic drop in Chinese funding for the industry.

Investment return of Chinese biotech startups is becoming an increasing concern. By late 2019, a total of 12 pre-profit Chinese biotech startup companies have won listing at the Hong Kong Stock Exchange (HKSE) from April 2018, when HKSE altered its rules to allow listing of startup companies which have yet to turn profitable. Seven of them saw

their share prices falling below their IPO level with Ascletis dropping as much as 75%.

The number of recorded mergers and acquisition deals in China's pharmaceutical sector remained high in 2019, with 437 cases and total deal value climbing 12 percent to US$22.1 billion, a 4-year high thanks to overseas investors' upbeat sentiment and mega deals in the private equity sector, according to a recent PwC report. These results also reflect favorable policies such as nationwide volume-based procurement, dynamic adjustment to the National Drug Reimbursement List, and encouragement of innovation, as well as the promotion of new capital market listing regulations.

China sends conflicting signals in the field of pharma IP but the U.S.-China Phase 1 Trade Deal May Be A Game Changer

Conflicting signals continues to be seen in the Chinese pharma IP space in 2019. 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 continued to push substitution of 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.

Fast forward to January 2020, despite various skepticisms on the concluded “phase 1” US-China trade deal, multinational drugmakers found much to be cheerful about.

Specifically, the document includes three provisions related to pharmaceutical patent dispute resolution, patent term extension and counterfeit medicines, promising to strengthen protection for drugs at a time China’s regulatory agency has sped up reviews and shortened the time gap between overseas and Chinese OKs.

The first provision, Article 1.11, stipulates that China would set up a mechanism commonly known as patent linkage in the US, as established in the Hatch-Waxman Act of 1984. It functions “much like a traffic control system” involving the FDA, the USPTO and the court.

Furthermore, according to Article 1.12 of the trade deal, China has committed to extending patent terms for unreasonable, lengthy delays that aren’t the applicant’s fault. The compensation will not exceed 5 years and the resulting effective patent term – counting from the date of marketing approval in China – will be no more than 14 years.

Lastly, Article 1.18 prods China to take quick action against counterfeit pharmaceutical products including API, bulk chemicals or biological substances. Among them is a requirement to share inspection information with the US and publish data on enforcement measures online every year, “including seizures, revocations of business licenses, fines, and other actions.”

Furthermore, the deal allows supplemental experimental data, which was forbidden in the past – meaning drugmakers can now add new evidence to support consideration of their patents after they first filed for it.

On March 6, 2020, the U.S. Trade Representative's Office (USTR) released its *2019 Report to Congress on China's WTO Compliance*, the 18th such report but perhaps the most insightful. Since 2018's report, USTR's assessment of China's record in terms of complying with WTO rules and observing the fundamental principles on which the WTO agreements are based has not changed. China's record remains poor. As detailed in 2019's report, China's trade regime has generated many WTO compliance concerns.

Despite Challenges, Long-Term Prospects and Opportunities Remain

The rapid transformation in China's pharma industry, especially in innovative drugs, will benefit the leading MNCs and domestic companies, according to a 2019 CitiResearch report. The market share of the top 10 multi-national companies (MNCs) will rise to 25% in 2025 (from 16% in 2018), on Citi estimates, and of the top 10 Chinese companies to 28% (from 15%). MNCs will largely grow through innovative drugs, the biggest growth driver of the sector, and the domestic companies largely through generics and biosimilars. CitiResearch estimates MNCs' patented drugs and China's domestic innovation sales to grow at CAGRs of +60%/+50% in 2018-25E. Potential winners would be AZ and Merck among MNCs, and SBP, Hengrui and Hansoh among the Chinese companies.

China to open sector even further – After joining the ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) in 2017, the Chinese government has initiated major reforms to facilitate commercialization of innovative drugs. Clinical trial requirements and quality are moving towards global standards. All this could mean much faster growth for MNCs with innovative therapeutics, as well as for Chinese R&D leaders.

A series of legislative and regulatory reforms have prompted global players to reappraise their China strategies. Key drivers include (i) accelerated development and NMPA review processes, (ii) accelerated timeline for inclusion into the NDRL, albeit with price concessions, (iii) strong enforcement of intellectual property as Beijing seeks to broaden healthcare access to an increasingly larger urban middleclass population, with similar living standards to western markets. At the same time, it is clear to global players that returns for post LOE drugs will continue to decline given reimbursement reforms (hospital mark-ups, centralized procurement etc).

China's entry into international organizations for drugs registration and development is catalyzing major reforms in the country's pharma sector, the second largest in the world, and offers big opportunities to both global players and Chinese firms. CitiResearch expects the country's pharma sector to grow at an 8% CAGR in 2018-25E, to CNY 2,708 bln (US$393bn), led by 1) innovative drugs (15% from Chinese companies; 19% from foreign players – by value), 2) generics and 3) biosimilars. With the biggest growth driver being innovative drugs, the leading global players cannot afford to ignore China. In this Must C, we analyze each of these growth drivers and identify the biggest potential beneficiaries.

Innovation to drive top global players' market share – The underdeveloped innovative drugs market in China is rapidly changing due to faster govt reimbursement and higher commercial insurance for imported innovative drugs. China is adopting global standards

in clinical trials, and policy reform is shortening waiting time for drug development & commercialization. Winners would be foreign players with innovative therapeutics and an established presence in China – AZ (18% pharma sales from China) and Merck (6%). R&D leaders in China should also benefit – SBP, Hengrui and Hansoh.

Consolidation to strengthen generics leaders – China, as a developing country, will rely mostly on generics for its universal healthcare. Mandatory biological equivalency tests will eliminate inferior generics and bring about consolidation in the sector through potential beneficiaries SBP, Hengrui and Hansoh.

Biosimilars market is in its infancy – Biosimilars are new to China, and hence Citi seea big potential in the segment before eventual crowding increases pricing competition. More reimbursements would make biologic therapeutics affordable. Early movers would benefit. In the long term, winners would need sustainable manufacturing and sales.

The Godsend window of opportunity for MNCs to recalibrate China strategy and reallocate resources

First and foremost, I think the current trade deal is more of a temporary truce than a reliable sustainable agreement. For the time being, China will need to deliver some of its promises right away to keep the U.S. happy and at bay, but the first potential flop point down the road may come around the third quarter of next year, when the U.S. presidential race reaches its critical phase. If China concludes then that its best interest is with Trump, we may see a prolonged opportunity window, which may even lead to some painstaking but meaningful reform eventually. Otherwise, expect turbulences.

Some experts argue that the Phase 1 Deal has set the Chinese purchase goal too high at US$200 billion for the next two years and there is no way China can achieve this. To this, I would say opportunity knocks for the MNC pharma companies, although such luck may not be sustainable. But who knows, it's China.

Additionally, the pharmaceutical market is one area China can demonstrate some concrete changes to appease the U.S. for now. In fact, many reforms, both regulatory and IP, are to the country's own benefit, which include enhanced access to better medicines by at least some of its population and more incentives for domestic drug innovation.

While such are positive developments for MNC pharma companies, it is important not to fall for the trap one more time. As I said, the Chinese market opportunities due to the MNCs are driven more by their product portfolios than the size of their presence or investment in China. Yes, MNCs may need to have at least some manufacturing and product development capacity in China, given it is a larger market even at the barebone, but such should be business decisions made on top of long-range strategic vision, rather than market access quid pro quos.

The biggest catch for long term success of MNCs in China is whether their core products are innovative, competitive and differentiated enough against their peers and domestic rivals? I guess what's tied with this is whether these companies are prepared to make the absolutely best effort protecting/policing their own IPs and are vigilant/smart enough not to create and foster their own competitors. I would strongly urge companies to start by

reviewing and recognizing their past mistakes with China business.

The historical window of opportunity is now at the door for MNCs that are ready to recalibrate their China strategies and reallocate resources. The window could be just a few months or a bit longer, during the timeframe forex control may become more relaxed and reactions to major business decisions are expected to be more benign. In any event, I would advise companies to plan and act sooner than later.

Be Ready for the Dire Aftermath of the Post-Pandemic China Market

Although the coronavirus outbreak appeared to have eased in China by April 2020, many experts continued to be alarmed by the possibility of renewed outbreaks in the country.

Even assuming the best scenario and China is back in normal business soon, the aftermath of this outbreak is still nothing short of daunting. The coronavirus outbreak overseas is still peaking overseas and global economy / demand tanked, which means the export-dependent China cannot recover on its own.

The standstill caused by the outbreak has triggered eruption of many Chinese economic and financial structural issues which are long overdue for correction. The danger of Chinese economic hard-landing or even total collapse seems inevitable.

Central and local governments will be strapped financially and they are set to bring healthcare cost containment to an unprecedented level. Long delays in payment and bad debts are likely to come back haunting businesses for a very long time. Six central government agencies, including the NHC, Ministry of Education, MOF, MOHRSS, NHSA and NMPA, already issued a new policy, Opinions for Strengthening Pharmacy Affairs Management of Medical Institutions to Promote Drug Rationalization, in late February for immediate implementation.

The ongoing coronavirus outbreak seems to be the final nail in the coffin of globalization. We are going to live in a very different world after the outbreak with restructured supply chain emphasizing domestic production of strategic products from masks, toilet paper to medicines. Already, U.S. politicians are talking about reactivating Puerto Rico as the country's future API production center, while Sanofi announced plans to build substantial API manufacturing capacity for EU.

Geopolitical conflicts among countries, especially between China and the U.S., are rising with growing ideological clashes. Quarrels over the origin of coronavirus outbreak has added heat to the fire. Cold war is almost inevitable, if it is not ongoing already. Sooner or later, nations and large businesses, including MNC pharma companies, may have to choose their camps.

It remains to be seen how things will evolve during and after the outbreak. Hopefully things will be calmer but we will see. For now, it is advisable to hold off on any investment plans or business ambitions in China.