



China Pharmaceutical Guide

中国医药市场指南

16th Edition (2021)

Written by:

James J. Shen, MBA

Unrivaled China Healthcare Intelligence Since 1991

Published by WiCON International Group LLP

WiCON 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

Disclaimer

While every effort has been made to ensure that information in this publication is correct, no liability can be accepted for any loss incurred in any way whatsoever by any company or individual relying on the information herein. To the best of our knowledge the information given is accurate at the date of publication.

Copyright © 2021 by WiCON International Group LLC

All Rights Reserved. No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic magnetic tape, mechanical, photocopying, recording or otherwise – without prior permission of the copyright owner.

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 WiCON International Group in the USA to provide strategic consulting and competitive intelligence to international healthcare companies in order to assist and facilitate their market entry into China. He has worked with many large and mid-size international pharmaceutical companies on a diverse range of projects including entry strategy development, strategic alliances and joint ventures, marketing and distribution agreements, product registration and clinical trials, licensing and technology transfer, API sourcing, and M&A due diligence.

As an entrepreneur, James Shen co-founded *Beijing Jicai Pharmaceutical Technologies Ltd.* in 1992, one of the first private pharmaceutical research institutions in China, and took over its management in 2001. He is also a co-founder of *Nanjing Zinox Pharmaceutical Co. Ltd.*, an emerging generic pharmaceutical company in China.

James Shen was the Managing Editor of the well-known *IQVIA China Update*, a monthly newsletter covering China's pharmaceutical market co-published by IQVIA and WiCON. He authored many China healthcare business publications in English throughout 1990s, including *Marketing Pharmaceuticals in China*, *Guide to Pharmaceutical Research Institutions in China*, and *Directory of Bulk Pharmaceutical Manufacturers & Products in China*.

In early 2006, following a restructure of WiCON's businesses, James Shen founded **WiCON | 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 lead to a more stable and healthier market environment.

There are success stories from all types of players, whether they are foreign or local, large or small, newcomer or established, private or state-owned. However, to be a success story requires 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 WiCON | *China Pharmaceutical Guide 2021 (16th Edition)*

The WiCON | *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 consumption patterns);

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

Volume III – *Annual Review, Trends, Opportunities and Strategic Considerations* (including a complete review of latest data, business trends, regulatory & IP/legal developments and healthcare reform progress of the Chinese pharmaceutical industry and market in 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

TABLE OF CONTENTS

VOLUME 1 OVERVIEW OF THE CHINESE PHARMACEUTICAL & HEALTHCARE SECTORS.....	1
ABOUT THE AUTHOR / PUBLISHER	3
PREFACE	5
TABLE OF CONTENTS	9
LIST OF TABLES.....	17
LIST OF CHARTS.....	36
TABLE OF ABBREVIATIONS.....	37
EXECUTIVE SUMMARY.....	39
PART I OVERVIEW OF THE CHINESE PHARMACEUTICAL SECTOR.....	51
Chapter I-1 China’s Broad Business Environment.....	53
1.1 Fast Economic Growth and Change as China Integrates into the World	53
1.2 Economic Reform	54
1.3 WTO Entry Brought Further Reform and Regulatory Changes, Despite Many Problems and Issues	58
1.4 China’s Basket of Challenges: The Country Faces A Disadvantageous Demographic Shift	64
1.5 Demographic Trends and Challenges.....	66
1.6 Rising R&D Investments and Patent Applications	78
1.7 Foreign Investment: Structure, Trends & Outlook.....	82
1.8 China’s 2021 Policy Priorities: Achieving Continuous, Stable, and Sustainable Growth	92
1.9 US-China Trade War: Phase One Trade Deal Largely A ‘Failure’, As Purchases Fall Well Short of Targets	94
1.10 What is the True Size and Growth of Chinese Economy?	96
1.11 Trends in U.S. Multinational Enterprise Activity in China	97
1.12 Data-Driven Perspectives on US-China Business.....	99
1.13 Business Climate and Outlook – Position Papers and Surveys of Foreign Companies in China	101
1.14 AmCham Survey: Supply Chain Challenges for US Companies in China	109
1.15 Multinationals to Shift Supply Chains out of China in 2020 – MUFG.....	111
1.16 AmCham Releases In-Depth Analysis of U.S.-China Economic Relationship.....	112
1.17 China’s 14th Five-Year Plan (2021-2025): <i>Signposts for Doing Business in China</i>	114
Chapter I-2 Background: The Chinese Pharmaceutical Sector.....	117
2.1 Introduction.....	117
2.2 Government Guidelines for Pharmaceutical Industry Development.....	124
2.3 Pharmaceutical Sector Reform As A Part of Healthcare Reform	133

Chapter I-3 Overview: The Chinese Pharmaceutical Industry	142
3.1 Overview	142
3.2 The Pharmaceutical Formulation Sector.....	145
3.3 The Bulk Drug/Active Pharmaceutical Ingredient and Excipient Sector.....	149
3.4 The Biopharmaceutical Sector.....	162
3.5 The Human Vaccine Sector.....	167
3.6 Pharmaceutical R&D in China – <i>Domestic Chinese Companies</i>	175
3.7 Pharmaceutical R&D in China – Foreign Companies	181
3.8 Pharmaceutical Outsourcing Sector (CRO and CDMO).....	190
3.9 China's Innovative Turn and the Changing Pharmaceutical Landscape.....	195
3.10 Fostering China Pharmaceutical Innovation System Report 1: 2015-2020 Review and Future Outlook.....	199
3.11 Leading Pharmaceutical Companies in China	203
3.12 Leading Pharmaceutical Distributors in China	212
3.13 Leading Retail Pharmacy Chains in China	214
3.14 Leading Chinese CRO and CDMO/CMO Companies.....	216
Chapter I-4 Foreign Investment in The Pharma Industry.....	219
4.1 China's Foreign Investment Regulatory Framework	219
4.2 Major Tax Categories for FIEs and Foreigners.....	232
4.3 Forms of Foreign Investment in the Pharma Sector.....	234
4.4 Encouraged, Restricted and Banned Areas for Foreign Investment in the Pharmaceutical Industry	235
4.5 Growth of Foreign Investment in the Pharma Sector.....	240
4.6 Major issues and challenges facing MNC pharma companies in China	249
4.7 Three Holistic Advices to Pharma MNCs in China	252
4.8 China Accelerated Approvals of New Drugs from Foreign Countries.....	254
Chapter I-5 The Ethical Pharmaceutical Market	256
5.1 Special Characteristics of the Chinese Ethical Pharmaceutical Market.....	256
5.2 An Orientation to the Chinese Hospital Drug Market	256
5.3 An Orientation to the Retail Pharmacy Sector.....	260
5.4 An Orientation to the Primary Healthcare Drug Sector	267
Chapter I-6 The OTC Pharmaceutical Market.....	269
6.1 Snapshot of the Chinese OTC Market	269
6.2 Regulatory Progress on OTC Drugs	271
6.3 Chinese OTC Drug Market under Rapid Transformation	273
6.4 Enthusiastic Pharmaceutical Industry Seeks to Expand OTC Drug Sales	274
6.5 Drug Companies Foray into Consumer Healthcare to Counter Pharma Pitfalls	276
6.6 Healthcare Reform Casts Shadow on Future of the Retail Pharmacy Sector.....	277
6.7 CFDA Considers Ban of OTC Drug Ads on Mass Media.....	278

Chapter I-7 Pharmaceutical Import and Export	280
7.1 Background.....	280
7.2 Present State of China’s International Trade of Medicines and Health Products.....	281
7.3 Custom Duties on Drug Import.....	283
7.4 ANDA Approvals Boost Chinese Pharma's Global Ambitions	285
7.5 Cheap Chinese ICIs May Shake Global Oncology Market.....	286
7.6 Trends and Outlook.....	288
PART II HEALTHCARE PROVISION AND FINANCING	289
Chapter II-1 Overview	291
1.1 Improving Healthcare Provision	291
1.2 Rising Lifespan and Health Literacy of the Chinese Population	295
1.3 Composition of the Chinese Population.....	297
1.4 Ageing in China: The Implications for Healthcare	300
1.5 Economic Burden from Chronic Diseases May Slowdown China’s Growth.....	302
1.6 2020 Annual Health Sector Development Report.....	303
1.7 Health China 2020 Strategic Research Report.....	316
1.8 Healthy China 2030 Plan	317
1.9 State Council Issues the Action Plan for Healthy China Initiative.....	319
1.10 China's Health Protection Gap Largest in Asia	320
1.11 Chinese Health Expenditure Projected to Reach 9.1% of GDP by 2035	321
1.12 China’s Healthcare Crisis: Both Rich and Poor Travel Abroad	321
1.13 Central Government Issues New Policy for Healthcare Sector Development Before 2022	323
1.14 Chinese Health Authorities Pledge to Prioritize Rural Development	324
Chapter II-2 Structure and Composition of Medical Provision.....	326
2.1 Composition of the Chinese Medical Sector.....	326
2.2 Grade Structure of Chinese Medical Institutions	329
2.3 Regional Distribution of Healthcare Resources	330
2.4 Distribution of Healthcare Resources by Medical Specialty.....	335
2.5 Human Resources in China’s Healthcare Industry.....	337
2.6 Growing Sector of Private Healthcare Providers in China.....	339
2.7 China Builds a General Practitioner System by 2020	340
2.8 Government Encourages the Formation of Medical Service Consortiums	342
2.9 Regulations for Management of BMI Designated Medical Institutions and Retail Pharmacies	345
2.10 China's Telemedicine Industry To Take Off on Official Policy for Internet + Healthcare Development	345
2.11 Internet Economy to Save China Upto CNY 610B Healthcare Expenditures Annually by 2025	348
2.12 MIIT and NHC Issues Joint Notice for Stepping Up the Infrastructure Building of Telemedicine	349

2.13	NHC Advances Infrastructural Building of Community Hospitals.....	350
Chapter II-3 Healthcare Reform		351
3.1	A Review of China’s Healthcare System Reform in the Past Three Decades	351
3.2	Chinese Leadership Mapped A New Blueprint of Healthcare Reform	359
3.3	The Healthcare Reform Plan in the 13th FYP (2016-2020) and 14th FYP (2021-2025).....	361
3.4	Major Healthcare Reform Direction for 2021.....	369
Chapter II-4 Healthcare Financing and Insurance Programs.....		373
4.1	BMI Enrollment and Healthcare Financing in China.....	373
4.2	The Annual Healthcare Security Sector Development Statistical Report	379
4.3	The Annual National Basic Medical Insurance Sector Development Report	381
4.4	Urban Employee Basic Medical Insurance (UEBMI) and Maternity Insurance.....	385
4.5	Urban Resident Basic Medical Insurance Program and New Rural Cooperative Medical Scheme	390
4.6	Critical Illness Insurance Coverage for Urban and Rural Residents	392
4.7	Work-related Injury Insurance Program.....	393
4.8	Medical Assistance Program for Civil Servants.....	394
4.9	Medical Assistance Program for the Poor.....	395
4.10	Commercial Health Insurance.....	397
4.11	Controversial Answer to China’s Health Insurance Needs	403
4.12	Hainan Lecheng Expands Its Global Special Drug Insurance Online to All Chinese Residents	405
4.13	Swiss Re Sees Short-term Health insurance as Growth Driver in China.....	406
4.14	Chinese Online Health Insurance Market to Grow 43% Annually Until 2025	407
4.15	BMI Supplemental Health Insurance Trends Up in China.....	408
4.16	MOHRSS Issues Internet+ Action Plan, Citing BMI Settlement by Social Security Card via Payment Services	411
4.17	Notice to Divide Fiscal Responsibilities of Central and Local Governments for Healthcare.....	411
4.18	Amendment of the Provisions for Health Insurance Administration	412
4.19	The Opinions on Deepening Medical Insurance System Reform	413
4.20	<i>The Guidance Opinions on Advancing BMI Fund Regulatory System Reform</i>	<i>416</i>
4.21	Data Analysis of Chinese Healthcare Spending and BMI System Finance 2000-2020	417
4.22	COVID-19 to Accelerate Health Insurance Changes in China	422
4.23	China to Improve BMI Outpatient Coverage As It Reforms Individual Accounts	423
Chapter II-5 Drug Reimbursement.....		425
5.1	Drug Reimbursement under BMI, WRI and MI Programs	425
5.2	NHSA and MOHRSS Issue the 2020 National Reimbursement Drug List (NRDL)	431
5.3	NHSA Sets Timeline for Phasing Out Provincial Level Additions of NRDL	433
5.4	The 2020 NRDL Revision Work Plan and Application Guidelines	433
5.5	Rationalized Medicine Drug List of the Chinese Military (RMDL).....	436
5.6	The Guidance Opinion for BMI Payment of Internet+ Healthcare Services	436

Chapter II-6 Measures of Healthcare Cost-containment	438
6.1 Price Control.....	438
6.2 Centralized Hospital Drug Purchase Tenders.....	443
6.3 The National Essential Drug System	460
6.4 National Formulary and Clinical Guidelines	471
6.5 Clinical Pathway/DRGs	473
6.6 Drug Prescription Review Guidelines of Medical Institutions.....	481
6.7 National Drug Price Negotiation.....	482
6.8 National Adjuvant Drug List.....	484
6.9 Drug Consumption Surveillance and Overall Clinical Appraisal of Drug Products	486
6.10 Health Technology Assessment (HTA) for BMI Reimbursement Listing.....	488
6.11 Pharmacy Affairs Management of Medical Institutions.....	489
6.12 Plan for Generic Drug Supply Security and Use Policies	491
6.13 Tiered Medical Service System.....	494
6.14 The “Two Invoice System” in Public Hospital Drug Procurement.....	495
6.15 Drug Price and Tender Purchase Credit Rating System.....	497
6.16 BMI Fraud Crackdown and Fund Regulation	498
6.17 Other Cost-containment Measures	499
PART III DISEASE AND DRUG CONSUMPTION PATTERNS.....	503
Chapter III-1 Growth of Drug Consumption and Demand	505
1.1 Sharp Growth in Drug Consumption and Healthcare Expenditures	505
1.2 The State of Health of the Chinese Population	509
1.3 Health Awareness and Literacy	510
1.4 China’s Struggle With Demographic Change	511
1.5 IQVIA: Potential of Chinese Pharma Lies in the Country’s Huge Patient Base and Unique Disease Patterns.....	512
Chapter III-2 Popular Diseases and Morbidity	515
2.1 Leading Diseases	515
2.2 Leading Causes of Death	521
2.3 An Extensive Overview of Chronic and Epidemic Diseases in China.....	523
2.4 Recent Trends with Cancer Challenges in China.....	552
2.5 Finally, China Comes to Grips with Its Cancer Epidemic.....	558
2.6 Prevalent Health Problems of Senior Citizens in China.....	559
2.7 Medium and Long Term Plan for Prevention and Treatment of Chronic Diseases	561
2.8 China Sets Up National Framework for Prevention and Treatment of Rare Diseases	561
2.9 The 2020 Lancet China Report on Health and Climate Change	563
Chapter III-3 Medical Institution Attendance and Expenses.....	565
3.1 Composition of Medical Care System in China.....	565
3.2 Hospital Attendance	567

3.3	Healthcare Expenditures and Medical Expenses	572
3.4	Study: Chinese Medical Costs to Continue Rise in the Next Two Years	574
Chapter III-4 Drug Consumption Patterns in Medical Institutions.....		575
4.1	Patterns of the Chinese Hospital Drug Market	575
4.2	Drug Consumption in Chinese County Level Hospitals	592
4.3	Drug Consumption of Public Primary Healthcare Facilities.....	597
4.4	Drug Consumption of Urban Community Healthcare Centers	598
4.5	Drug Consumption in Rural Township Health Centers.....	600
4.6	Chemical Drug Consumption of Chinese Public Medical Institutions	602
4.7	Hospital Sales of 25 Drug Products under 4+7 Trial	607
4.8	Market Performance Review of Drug Products Included in the NRDL through BMI Negotiation 2016-2020	607
4.9	Elevated Consumption of NRDL Drugs	612
Chapter III-5 Retail Drug Consumption Patterns.....		615
5.1	Overview of the Chinese Pharmaceutical Retail Sales	615
5.2	Consumption Patterns of Retail Pharmacy Sales of Medicine and Health Products	624
5.3	Structure of Chinese B2C Online Pharmacy Market	639
Chapter III-6 Consumption Patterns of OTC Drugs.....		642
6.1	Structure of Chinese OTC Drug Market	642
6.2	Leading Chinese OTC Companies and Brands.....	652
Chapter III-7 Regional Drug Consumption Patterns.....		655
7.1	Gap Between Cities and Rural Areas	655
7.2	Regional Hospital Markets for Drug Products.....	656
7.3	Regional Markets by Pharmaceutical Distributor Sales.....	668
7.4	Regional Retail Pharmacy Markets for Drug Products.....	672
7.5	Regional Primary Healthcare Drug Markets.....	677
7.6	Regional Spending of the Chinese Basic Medical Insurance System	678
Chapter III-8 Market Shares of Local, JV and Imported Drugs		680
8.1	Hospital Market – Domestic vs. MNC Drugs.....	680
8.2	Retail Pharmacy Market – Domestic Companies vs. JV/Foreign Players	692
8.3	China Performance of Foreign Pharma Companies in 2019 and H1/2020	693
8.4	Future Trends and Outlook	697
Chapter III-9 High Growth Market Segments.....		699
9.1	Chinese Innovative Drug Sales 2013-2019E	700
9.2	IQVIA: Review and Outlook of Chinese Drug Market for NCDs.....	700
9.3	The Chinese Drug Market for Three Key Chronic Diseases (Anti-hypertensives, Oral Hypoglycemics and Lipid-reduction Drugs).....	702
9.4	The Chinese Diabetes Drug Market.....	715

9.5	The Chinese Cardiovascular Drug Market.....	725
9.6	Overview of Chinese Oncology Drug Market	728
9.7	Chinese mAb Market to Grow 13.7% CAGR between 2017 and 2022	731
9.8	The Chinese mAb Market – Rosy Prospects Along with Fierce Competition	733
9.9	China Represents 41.5% of NSCLC Drug Markets in APAC	734
9.10	China and India Drives Growth of APAC Ovarian Cancer Drug Market	734
9.11	Asia Pacific Breast Cancer Market to Grow at CAGR of 8.5% Before 2021	735
9.12	Bispecific Antibodies in China	735
9.13	Targeting the Affluent: Differential Access to Targeted Therapies in China.....	738
9.14	The Chinese Hepatitis Drug Market	742
9.15	Review and Forecast of Chinese Antiviral Drug Market 2013-2030E.....	743
9.16	Chinese Asthma and COPD Drugs Markets Poised for Steady Growth	744
9.17	The Chinese Drug Market for Mental Disorders Has Huge Potential.....	747
9.18	Alzheimer's Is China's Biggest Future Health Problem and Biggest Healthcare Industry Opportunity	749
9.19	Chinese Hospital Drug Market for Parkinson's Disease Growing at Double Digit Rates	753
9.20	Chinese Geriatric Drug Market Offers Great Potential.....	754
9.21	Prospects of Chinese Pediatric Drug Market	755
9.22	Emerging Orphan Drug Market Is Hope for Millions of Chinese with Rare Diseases	756
9.23	The Chinese Blood Products Market	762
9.24	Chinese Transmucosal Delivery Drug Market to More Than Double by 2027.....	763
9.25	China, The World's Second Largest Clinical Nutrition Market	764
9.26	Chinese Enteral Nutrition Market Predicted to Rise 2021-2025 and Beyond.....	765
9.27	Chinese Precision Medicine Market Set to Witness a Robust CAGR of 12.82%	766
9.28	Asia Pacific and Chinese CRO Market Value Projected to Expand By 2025	767
Chapter III-10 Snapshot of Generic & biosimilar Drug Consumption.....		768
10.1	Overview of the Chinese Generic Drug Market.....	768
10.2	Generics Continue to Dominate Chinese Pharma Market.....	770
10.3	Chinese Biosimilars Surge between 2018 and 2020 Due to New NMPA Regulations	770
10.4	Market Share of Originator Drugs on the Rise, As That of Generics Fall	771
Chapter III-11 The Chinese Vaccine Market.....		773
11.1	Overview of the Chinese Human Vaccine Market	773
11.2	Chinese Human Vaccine Market Prospects Rosy.....	780
11.3	Chinese Human Vaccine Market Driven by HBV, Meningococcal, HAV, Influenza, Hib, Rabies and Varicella Vaccines.....	782
11.4	Vaccine Consumption of Major Urban Chinese Hospitals	783
11.5	Asia-Pacific Influenza Vaccines Market to Surpass \$1.7B by 2022.....	786
11.6	The Chinese Animal Vaccine Market.....	787

VOLUME 2 CHINESE PHARMACEUTICAL IP AND REGULATORY GUIDE	791
.....	
TABLE OF CONTENTS	793
LIST OF TABLES	797
LIST OF CHARTS	802
TABLE OF ABBREVIATIONS	803
PART IV CHINESE PHARMACEUTICAL REGULATORY AND IP GUIDE	.805
Chapter IV-1 Overview	807
1.1 Drug Regulatory Statistics	807
1.2 Overview and Statistics of Clinical Trials, Drug Evaluation and Registration in Recent Years	809
1.3 Review of Drug Applications under Special Approval, National S&T Major Project and Priority Review Paths with CDE 2004-2020.....	834
1.4 Annual Report for Adverse Drug Reaction Monitoring.....	838
1.5 National Drug Abuse Monitoring Annual Report	839
1.6 NIFDC Issues the 2020 National Drug Sample Inspection Annual Report	840
1.7 Review of New Chinese Pharmaceutical/Healthcare Regulations in 2020 and H1/2021	841
1.8 Major Drug-related Policies, Regulations and Laws under Drafting Process	847
1.9 Drug Regulatory Reform Direction in 2021	848
1.10 Reform of China's Drug Evaluation and Approval System	851
1.11 Chinese Generic Drug Applications Rebound in 2018 After Two-Year Decline	865
1.12 China Joins ICH in Pursuit of Global Harmonization of Drug Development Standards	867
1.13 NMPA Issues <i>Action Plan for Accelerated Advancement of Intelligent Drug Regulation</i>	868
1.14 Highlights of the 2020 Amendments of the <i>Provisions for Registration of Drug Products and the Provisions for Control of Drug Manufacture</i> on MNC Pharma	869
1.15 Hainan Medical Tourism Zone: New Pilot Policies Rolled Out	871
1.16 China Introduces New Program for Early Access to New Drugs in the Greater Bay Area...	876
Chapter IV-2 Important Laws and Regulations	877
2.1 The Drug Administration Law of the People's Republic of China.....	877
2.2 Regulations for Implementation of the <i>Drug Administration Law of the PRC</i>	880
2.3 The Vaccine Management Law of PRC	886
2.4 Major Regulations under the <i>Drug Administration Law of PRC</i>	887
2.5 Other Drug Related Laws and Regulations.....	890
2.6 China Ups Drug Regulation, Biosecurity and IPR Protection in Amendment XI to the Criminal Law (Unofficial Translation Included).....	892
2.7 China's New Export Control Law Triggers More Trade and Investment Complications.....	896

Chapter IV-3 Major Government Agencies and Industry Associations in The Pharma Field898

3.1 State Administration of Market Regulation (SAMR)	899
3.2 The National Medical Products Administration (NMPA) under the SAMR	901
3.3 The Center for Drug Evaluation under the NMPA.....	908
3.4 The National Health Commission (NHC).....	910
3.5 National Healthcare Security Administration (NHSA).....	914
3.6 Ministry of Human Resources and Social Security (MOHRSS).....	918
3.7 Ministry of Industry and Information Technology (MIIT).....	918
3.8 Ministry of Commerce (MOFCOM or MOC)	919
3.9 National Development and Reform Commission (NDRC).....	920
3.10 Inter-ministerial Conference for Vaccine Regulation.....	923
3.11 State-owned Assets Supervision and Administration Commission of the State Council (SASAC)	923
3.12 State Administration of Traditional Chinese Medicine (SATCM)	924
3.13 State Administration of Disease Prevention and Control (SADPC)	925
3.14 China National Intellectual Property Administration (CNIPA).....	926
3.15 Pharmaceutical Industry Associations in China	928

Chapter IV-4 Drug Regulatory Framework in China (1) – Drug Registration Regime933

4.1 Overview of Drug Registration Reform.....	933
4.2 Overview of the Provisions for Registration of Drug Products (2020).....	939
4.3 Clinical Research for Drug Registration	945
4.4 Rules, Standards & Technical Guidelines / Drug Evaluation Management	954
4.5 Breakthrough Drug / Priority Review / Special Approval of Drug Registration.....	963
4.6 Conditional Approvals of Drugs in Urgent Clinical Needs	979
4.7 Registration of Copy/Generic Drugs and Generic Quality and Clinical Equivalence (GQCE) Evaluation.....	988
4.8 Registration and Registration of Import Drugs	1002
4.9 Registration of Biosimilars	1006
4.10 Registration of OTC Drugs	1007
4.11 Registration of Certain Drug Related Products, Foods for Medical Purpose and Health Foods	1008
4.12 Application and Approval of Supplemental Registrations	1012
4.13 Drug Registration Reconsideration	1013
4.14 Post Approval Changes to Pharmaceuticals.....	1015
4.15 Onsite Verification for Drug Registration	1019
4.16 Linked Review and Approval of APIs, Pharma Excipients and Packaging Materials	1019
4.17 Chinese Pharmacopoeia (ChP) and Drug Standards	1025
4.18 GLP for Preclinical Research and GCP for Clinical Research	1027
4.19 The Drug Marketing Authorization Holder (MAH) System	1033

4.20	Use of Real-World Data to Support Drug R&D and Evaluation and Compassionate Use of Investigational Drugs	1035
4.21	Nature Determination of Drug and Device Combination Products	1037
4.22	What’s New for Drug R&D and Evaluation Communication in China?	1037
4.23	Rare Diseases and Orphan Drugs	1039
4.24	Interpretations for Application of Criminal Laws for Faking Drug and Medical Device Registration Data.....	1040
Chapter IV-5 Drug Regulatory Framework in China (2) – Others		1042
5.1	Pharmaceutical Manufacturer Licensing, Manufacturing and GMP.....	1042
5.2	Regulation of Pharmaceutical Excipients	1048
5.3	Drug Labeling and Packaging.....	1049
5.4	Pharmaceutical Distribution and Distributor Licensing.....	1053
5.5	Vaccine Distribution	1064
5.6	Drug and Excipient Import Process	1069
5.7	Pharmaceutical Regulatory Inspections and Enforcements	1074
5.8	Classified Control of Prescription and Non-prescription Drug Products.....	1078
5.9	Drug Advertising	1082
5.10	Drug Pricing and Price Control.....	1088
5.11	Post-marketing Surveillance/ADR Reporting/Tracing.....	1097
5.12	Counterfeit, Fake and Sub-standard Drugs	1107
5.13	Control of Narcotic, Psychotropic and Radioactive Drugs	1110
5.14	Internet Information Service and Online Sales of Drug Products.....	1115
5.15	Drug Prescription/Rational Drug Use/Clinical Practices/Chinese Orange Book.....	1120
5.16	Pharmaceutical Technology Transfer / Administrative Protection / IP	1131
5.17	Anti-corruption/Compliance/Black Listing/Confidentiality	1138
5.18	Drug Donations.....	1156
5.19	International Regulatory Cooperation / Harmonization.....	1165
5.20	Drug Import & Export Control and Certifications.....	1178
5.21	Physician Sales Representative (PSR) Registration.....	1180
5.22	Others.....	1183
Chapter IV-6 Intellectual Property Rights and Legal Issues		1186
6.1	Pharmaceutical Patent Protection	1203
6.2	Patent Linkage / Patent Term Restoration / Compulsory Licensing	1212
6.3	Data Exclusivity and Trade Secret Protection.....	1237
6.4	Patent and Trademark Registration.....	1248
6.5	Enforcing Patents – China's Bad Faith Entities List	1257
6.6	Patent and IP Strategies for China	1260
6.7	Protecting and Policing IPRs in China.....	1261
6.8	Patent Invalidation Strategies in China.....	1266
6.9	Pharmaceutical Patent Litigation in China.....	1271
6.10	Recent Changes To Biotech And Chemical Patent Examination	1278

6.11	Counterfeit Drugs.....	1281
6.12	Judicial Interpretations of Law Applications over Drug Safety	1288
6.13	China’s Supreme People’s Court Issues Law Interpretation for Intellectual Property Infringement.....	1294
6.14	The Tort Liability Law: Impacts on Pharma	1296
6.15	Considerations for Compliance and Corruption Risks.....	1301
6.16	Antitrust/Antimonopoly	1318
6.17	A Comprehensive Overview of Pharmaceutical Antitrust in China.....	1334
6.18	Big Data Policy and Legal Issues in the Healthcare Industry	1355
6.19	New Challenges Ahead: How to Comply with Cross-Border Data Transfer Regulation in China	1362
6.20	Health Care Data Compliance in China: FAQ	1366
6.21	The Impact of Scientific Data Administrative Measures on Foreign Companies in China.....	1369
6.22	How Data Protection Matters for Pharmaceutical Companies in Mainland China? – <i>Ensuring Compliance and Mitigating Risk</i>	1374
6.23	Regulation on the Management of Human Genetic Resources.....	1380
6.24	Intellectual Property Theft	1385
6.25	A Guide to the Two Invoices System in Chinese Pharmaceuticals Distribution	1389
6.26	In Depth: Decoding China’s First Civil Code	1391
6.27	China Signs Off on PRC Biosecurity Law: What This Means for Industry Players in China?	1394
6.28	Mind The Gap – The IP Protection Law vs. Reality in China.....	1396
6.29	China Tightens Technology Export Control Rules.....	1398
6.30	AmCham: China’s Anti-Foreign Sanctions Law: How Businesses Should Prepare	1401
VOLUME 3 ANNUAL REVIEW, TRENDS, OPPORTUNITIES & STRATEGIC CONSIDERATIONS		1407
TABLE OF CONTENTS.....		1409
LIST OF TABLES.....		1415
LIST OF CHARTS.....		1423
TABLE OF ABBREVIATIONS.....		1425
PART V ANNUAL REVIEW AND OUTLOOK OF THE CHINESE PHARMACEUTICAL INDUSTRY AND MARKET		1427
Chapter V-1 The Broad Chinese Economy: Review and Outlook.....		1429
Chapter V-2 Annual Review of the Chinese Pharmaceutical Industry and Market..		1433
2.1	Data Overview: Chinese Pharmaceutical Market Landscape	1433
2.2	Data Overview: Pharmaceutical Industry Performance	1449
2.3	China Performance of Foreign Pharma Companies in 2019, 2020 and H1/2021	1453
2.4	Performance of Domestic Pharmaceutical Companies in 2020 and H1/2021.....	1477

2.5	What Has and Has Not Changed for Chinese Pharma in the Past Year, and Where Does the Future Lie?.....	1484
2.6	Review of Regulatory Developments in 2020 and H1/2021.....	1488
2.7	China Delivers on Multiple Healthcare Reform Fronts with Intensified Cost Containment thru National VBP Trial, New NRDL and BMI Payment Schemes.....	1502
2.8	China Makes Huge Advances on the Front of Pharma IP with Patent Law Amendment in 2020 as It Steps Up Antitrust Policing	1512
2.9	Big Questions Remain over China's Patent Linkage System.....	1519
2.10	What to Expect in China's 14th Five Year Plan? Decoding the Fifth Plenum Communique	1521
2.11	China Plans “Unprecedented” Investment into TCM with Doubling Budget in the 14th Five Year Plan Period.....	1527
2.12	China Unveils Action Plan on Building High-Standard Market System with Pharma Highlighted	1528
2.13	Revisiting the Basis of Your China Strategy in the Post-Covid New Normal	1530
2.14	As MNCs Refocus on Innovative Drugs, Feel the Pulse of China's IP Landscape.....	1534
2.15	Foreign Drug Giants Undercut by Up to 95% in 3rd Round of National VBP	1538
2.16	MNCs Renew Commitments at CIIE as China Pushes Telemedicine and Special Healthcare Zones.....	1540
2.17	Pharma Companies to Cut Prices of News Drugs by 51% for BMI Reimbursement under the 2020 NRDL.....	1543
2.18	Local Drugmakers Dominated China's 4th Round of National VBP Again, As MNCs Hold Their Ground	1544
2.19	Sales Expenditure Far Exceeds R&D Spending at A Share-listed MedPharm Cos in 3Qs/2020	1546
2.20	Snapshot of R&D Spending of Listed Chinese Biopharma Firms 2018-2020.....	1547
2.21	China Appears to Open Wider to Innovative Medicines as It Intensify Healthcare Cost Containment.....	1547
2.22	China Boosts Support of Anticancer and Orphan Drugs thru Tax and Price Cuts	1551
2.23	An Improving Chinese Regulatory Landscape with New Challenges Ahead – <i>Genomics and National Security</i>	1555
2.24	Performance Review of Drug Products Included in the NRDL through BMI Negotiation 2016-2020.....	1563
2.25	Opportunities and Threats Co-Exist for MNCs as China Deepens Healthcare Reform with Intensified Cost Containment Initiatives.....	1565
2.26	Review of China Healthcare Sector Performance in H1/2021	1567
2.27	China Signals Businesses Face Greater Regulation in Coming Years	1569
2.28	What Are China's Pharma Prospects as the Country Enters Another Round of New Normal?	1570
Chapter V-3 Review of Chinese Pharma M&A, Licensing and Collaborative R&D Deals / IPO events.....		1576

3.1	M&A, Licensing and Collaborative R&D Deals in 2020 and 1H/2021	1576
3.2	Review of China’s Innovative Drug Licensing Transactions in 2020	1604
3.3	Review of Out-licensing Deals of China-Originated New Drugs	1608
3.4	Review of In-licensing Deals of Chinese Pharma Companies in 2020	1612
3.5	Chinese Biotech Remains Heated with Surging M&A and IPO Deals in 2020	1615
3.6	China’s Pre-Revenue Biopharma Players Continue to be Embraced by Markets, Investors	1616
3.7	Chinese Biopharma Companies Staging A Gold Rush at HKSE and SSE STAR Board	1618
3.8	Chinese Biotech/Healthcare Listings Help Elevate HK IPO Market To Third Place Globally in H1/2021	1620
Chapter V-4 What Does the Future Hold for China's Healthcare Economy?		1622
4.1	Amcham: China’s Favorable Business Environment in 2021	1622
4.2	Chinese Pharma Prospects Remain Cloudy Despite Optimism	1625
4.3	Despite Challenges and Mixed Outlook, China’s Long-Term Prospects and Opportunities Remain	1627
4.4	IQVIA: China’s Medicine Spending Growth to Accelerate Post-COVID Driven by New Original Medicines	1636
4.5	Chinese Pharma in the Year of the Ox	1639
4.6	Has the Game Changer for MNCs and Innovative Drugs Finally Arrived?	1640
4.7	SMEI Forecasts Rise of Startups, Premium Generics, Self-paid Meds and e-Commerce in 2021	1644
4.8	Outlook of Chinese Biopharma Industry in 2021: Growth and Differentiation	1645
4.9	MNC Growth in China Slowed But Not Beaten – Threats and Opportunities Ahead.....	1651
4.10	Pilot Zones Offer Present Opportunities and Growing Potential to MNC Pharma Companies	1654
4.11	China Tightens Grip on Pharma Industry as It Initiates the 5th Round of VBP	1656
4.12	Confronted by Demographic Challenges, Will China's Drug Market Prospects Hold Up?	1659
4.13	SMEI: Chinese Drug Market under Transformation with Growing ex-Hospital Drug and Innovative Medicine Sales by 2029	1661
4.14	U.S.-China Trade Deal Shows Potential for Improved U.S. Intellectual Property Rights in China	1661
4.15	China's New Amended Patent Law and Draft Implementation Rules – All That Was Expected and More to Come.....	1664
4.16	China’s Census 2021: 5 Takeaways for Foreign Investors.....	1670
PART VI CONTEMPORARY TRENDS, OPPORTUNITIES AND STRATEGIC CONSIDERATIONS		1675
Chapter VI-1 Introduction		1677
Chapter VI-2 Market Dynamics and Strategic Considerations		1679
2.1	China: A Change in Attitude	1679
2.2	Finally, China Comes to Grips with Its Cancer Epidemic.....	1683

2.3	Cross-Sector Collaboration to Enhance Market Access for Pharmaceutical Companies in Asia: <i>Six Steps to Make It Work</i>	1684
2.4	The View of China from Headquarters	1688
2.5	China’s Blueprint for Its Pharmaceutical Sector	1690
2.6	Lesson from China’s National Drug Price Negotiation in 2020	1696
2.7	Merck, Bristol Myers, AstraZeneca and Roche Lose Bid to Expand PD-1/L1 Reach in China after Failing to Secure 2020 NRDL Listing through Negotiation.....	1706
2.8	Reimagining the Pharmaceutical Sales Rep Model in Asia	1708
2.9	Issues in Chinese Foreign Direct Investment in U.S. Early Stage Biotechnology Companies	1710
2.10	Chinese Pharma and Biotech Companies Tap U.S. Talent.....	1712
2.11	Kangmei’s \$4bn Accounting Error Highlights China Risk	1713
2.12	China: Survival of the Fittest or Cheapest?	1715
2.13	Celebrity Doctor Pay Exposes China’s Healthcare Gap	1719
2.14	Can China’s R&D Sector Shake Its Reputational Issues?.....	1721
2.15	Production of Trustworthy Real World Data and Evidence in China.....	1723
2.16	China’s Crackdown On Genetics Breaches Could Deter Data Sharing	1725
2.17	Impact of the China-U.S. Trade Deal on Intellectual Property Protection Related Professionals	1727
2.18	Patent Term Extension and Patent Linkage for Pharmaceutical Patents in China	1730
2.19	Next Up in China Trade War: Biotech Purge?	1738
2.20	Coronavirus A Growing Threat to Global Supply Chains – Pharma Hit First	1741
2.21	International Generic Drugmakers Have A China Dependency Problem	1742
2.22	ContractPharma: Bye-Bye China?	1744
2.23	China's Biopharma Strategy: Challenge or Complement to U.S. Industry Competitiveness?	1750
2.24	U.S. Is Investing Millions to Bring Drug Making Back from China and India	1751
2.25	Crowdfunding Can’t Cure China’s Health Care	1753
2.26	Hainan Announces First QFLP Fund, Insurance to Cover Foreign Anti-Cancer Drugs.....	1755
2.27	Some Chinese Health Insurance Practices Undermine Consumers' Perception of the Market	1758
2.28	Challenges Posed to Chinese Biotechs in Post-Pandemic Era.....	1759
2.29	China vs. India: the Fight for Pharma Supremacy	1761
2.30	Simultaneous Development of Zanubrutinib in the U.S. and China Demonstrates Regulatory Differences	1763
2.31	Review of Chinese Pharma Licensing Trends 2015-2019	1764
2.32	GlobalData: New Chinese Priority Review Designation Fails To Attract Foreign Companies	1770
2.33	GlobalData: New Chinese Priority Review Designation Fails to Attract Foreign Companies	1771
2.34	Review of Drug Approvals under the Priority Review and Breakthrough Paths 2016-2021	1773
2.35	Nature: Characteristics of Expedited Programs for Cancer Drug Approval in China	1774

2.36	Review of Chinese Innovative Drug Research Failures.....	1776
2.37	Bloomberg: China Drugmakers Take Aim at Pharma’s Lucrative Cancer Fighters.....	1782
2.38	PharmCube Reviews Development Trends of First-in-Class and Me-Too Drugs in China	1782
2.39	Review of China Healthcare Financing 2014-2021	1785
Chapter VI-3 Promising Opportunities of the Present and Future		1788
3.1	China’s Biopharma Rise: Opportunities and Threats	1788
3.2	MNCs Boost Drug Research and Clinical Trials for Diseases Prevalent in China and Other Asian Markets.....	1790
3.3	Why Big Pharma Is Targeting China's Deadliest Diseases	1792
3.4	Review of Domestic Class 1 New Drug Applications and Approvals 2003-2020	1794
3.5	Review of New Drugs Under Development in China in 2019 and H1/2020	1801
3.6	Review of Chinese Import Chemical Drug IND Applications in 2020.....	1808
3.7	Snapshot of MNC Products Listed in the 2020 NRDL	1811
3.8	Snapshot of Nine China-originated New Drugs under BLA/NDA and Approved in the U.S.	1812
3.9	Why Chinese Biotech Inventions Have Yet To Make An Impact Globally, Despite Patenting Surge.....	1813
3.10	The Race to the Top: Does China Have What It Takes for Biosimilars?	1815
3.11	China Pulls Out Stops for Biosimilar Development.....	1816
3.12	Biosimilars and Healthcare Policy: What China Can Learn from EU and US	1819
3.13	McKinsey: Running on the China Bridge to Innovation.....	1819
3.14	McKinsey: Managing China's Growing Oncology Burden	1821
3.15	New Opportunities in Emerging Markets	1827
3.16	Fear of Substandard Medicines Has Led to Expanding Opportunities for US Pharma in China	1830
3.17	Progressive Reforms Shifting The Cancer Medicine Landscape in China.....	1831
3.18	Emerging Crowdfunding Schemes for Healthcare – Cancer Coverage for Pennies a Month in China	1833
3.19	Chinese Tourists to Japan Switch from Shopping Sprees to Medical Services.....	1836
3.20	Chinese Patients Head to India for Latest Drugs after Domestic Crackdown.....	1838
3.21	Chinese Hospitals Set to Sell Experimental Cell Therapies.....	1841
3.22	Is the Stage Set for Precision Medicine to Take Off in Asia?	1843
3.23	Trade Deal Could Help China’s Biotech Upgrade, If Honored.....	1846
3.24	Why Chinese Biotech Companies Are Not for Faint-Hearted Investors.....	1848
3.25	China Has Become A CEO-Level Priority for MNC Pharma Companies: The Trend and The Implications.....	1851
3.26	CitiResearch – China at Inflection Point: Big Opportunity for MNCs, Domestic Leaders	1854
3.27	Recent Patent Reforms to Bolster Pharma Innovation in China: GlobalData	1856
3.28	Preparing for China's Patent Linkage System	1857
3.29	How the Coronavirus Is Helping to Fix China’s Broken Healthcare System	1861
3.30	Chinese Consumers Increasingly Prioritize Immune Health.....	1862

Chapter VI-4 Trends and Prospects in Pharma Outsourcing.....	1865
4.1 CMO/Manufacturing Outsourcing in China and Asia	1870
4.2 Will China Lose Its Cost-Competitiveness in Pharma Manufacturing?.....	1876
4.3 China Needs 30 Times Its Outsourcing Capacity to Meet Biologics Demand Created by Drug Pricing Reform: Wuxi Bio CEO.....	1879
4.4 China CDMO Market 2018-2021: The R&D Cost of New Drugs Continues to Rise While the Success Rate Decreases YoY.....	1880
4.5 Chinese CRO Market Set to Grow Substantially	1882
4.6 Trends and Prospects of Clinical Research in China	1884
4.7 Potential Compliance Risks in Clinical Research Outsourcing to China.....	1888
4.8 Regulatory Changes Position China as a Global Clinical Trial Destination	1892
4.9 How to Fulfill China’s Potential for Carrying Out Clinical Trials	1893
4.10 Asia: Preferred Destination For Clinical Trials.....	1894
4.11 China Isn’t Yet Ready to Conduct Clinical Trials for the Pharma Industry	1899
4.12 Why Asian CROs are Turning to the European Biotech Market	1901
4.13 Chinese Government Launch Support Program for Biopharma CRO and CMO Service Platforms	1904
4.14 New Roads to China for CROs and CMDOs.....	1905
4.15 Chinese Pharma CRO Industry to More Than Triple by 2025.....	1909
4.16 Outsourcing in China: How Far Can It Go?.....	1911
4.17 Biologics Manufacturing in China: <i>Competition Heats Up Among CMOs & Their Clients</i>	1915
4.18 Chinese CDMO Sector Growing But Unlikely To Make Global Impact.....	1919
VOLUME 4 SALES & MARKETING, ENTRY STRATEGIES AND CASE STUDIES.....	1923
TABLE OF CONTENTS	1925
LIST OF TABLES	1935
LIST OF CHARTS.....	1936
TABLE OF ABBREVIATIONS	1937
PART VII PHARMACEUTICAL SALES, MARKETING AND DISTRIBUTION	1939
Chapter VII-1 History and Overview	1941
1.1 Pharmaceutical Sales and Distribution in China Before Early 1980s	1941
1.2 Breaking Up of the Old System	1942
1.3 The Present State of the Pharmaceutical Marketing, Sales and Distribution System in China – An Overview	1943
Chapter VII-2 Major Promotional Practices and Government Affairs	1949
2.1 National and Local Drug Reimbursement Lists.....	1949
2.2 Pricing of Drug Products	1954

2.3	Centralized Hospital Drug Purchase Tenders.....	1957
2.4	Product Launches.....	1960
2.5	Clinical Research	1961
2.6	Public Relations	1962
2.7	Lobbying for Industrial Policies and Regulations.....	1963
2.8	Building a Better Government Affairs Function in China.....	1963
2.9	Advertising for Pharmaceutical and Healthcare Products/Services: Prior Approval Is Required	1970
Chapter VII-3 Marketing and Sales of Ethical Drugs in Urban Hospitals		1972
3.1	Mainstream Hospital Marketing and Sales Models	1972
3.2	The Hospital Drug Purchase Approval Process	1974
3.3	Hospital Drug Purchase Channels.....	1975
3.4	Hospital Marketing/Sales Organization and Execution	1976
3.5	Key Factors in Hospital Marketing and Sales.....	1978
3.6	Developing Effective Market Coverage and Sales Force Strategies in China	1979
3.7	Shifting from Network Marketing to Evidence Based Medicine in China	1982
3.8	More Chinese Pharma Cos Cuts Sales Force and Switch to Agency Sales.....	1984
3.9	China Adopts the Medical Representative Registration System	1985
Chapter VII-4 Marketing and Sales of Ethical Drugs through Urban Retail Pharmacies		1987
4.1	Channels of Retail Pharmacy Sales and Distribution.....	1987
4.2	Process and Key Components of Retail Pharmacy Sales.....	1988
4.3	Key Factors in Sales of Ethical Drugs through Retail Pharmacies	1988
4.4	Case in Point: Pfizer’s Retail Pharmacy Sales Efforts in China.....	1989
4.5	Four Transformations – Unlocking Success in China's Pharmaceutical Retail Market	1990
Chapter VII-5 Sales & Marketing of OTC Drug Products in Cities		1992
5.1	Channels of OTC Drug Sales.....	1992
5.2	Process and Key Components of OTC Drug Sales	1993
5.3	Key Factors in OTC Drug Sales	1994
Chapter VII-6 Sales, Marketing and Distribution of Drugs in the "Third Terminal Market"		1995
6.1	Pharmaceutical Sales & Distribution Channels to the "Third Terminal Market"	1995
6.2	Sales and Marketing Strategies for the "Third Terminal Market"	1996
6.3	Special Characteristics of the "Third Terminal Market"	1997
Chapter VII-7 Pharmaceutical Distribution.....		1999
7.1	Overview – MOFCOM’s <i>2020 Pharmaceutical Distribution Industry Operation and Statistical Analysis Report</i>	2000
7.2	Important Regulatory Requirements on Pharmaceutical Distribution	2007

7.3	Pharmaceutical Distribution Channels in China	2008
7.4	GSP Requirements for Pharmaceutical Distributors	2011
7.5	Logistics in Pharmaceutical Distribution	2011
7.6	Opening of the Chinese Pharmaceutical Distribution Sector	2013
7.7	Recent Trends in Pharmaceutical Distribution	2014
7.8	Chinese Pharmaceutical Distribution Landscape and Models	2015
7.9	Building Distributor Channel Management Capabilities in China	2019
7.10	How the Distribution Challenge for Pharma is Going to Change in China	2024
7.11	The Challenges of Managing China’s Highly Fragmented Distributor and Dealer Networks	2027
7.12	Fitch: Further Consolidation of China’s Drug Distribution Sector Inevitable	2029
7.13	Margin Pressure and Consolidation for China’s Pharma Distributors	2030
7.14	New Two-Invoice System in Pharma Distribution Launched in 2017	2030
Chapter VII-8 e-Commerce and Digital Marketing Opportunities for Pharma Companies.....		2033
8.1	China Preparing for a Digitized Healthcare Landscape	2033
8.2	China to Experiment Internet Healthcare Expansion at Six Provincial Level Trial Sites	2035
8.3	Regulatory Developments for Telemedicine in China	2035
8.4	Kantar Health: Analysis of Digital Health in China.....	2038
8.5	China to Grow Big on e-Healthcare Data	2039
8.6	How Telemedicine Might Reshape Pharmacies in China	2042
8.7	How Tencent’s Medical Ecosystem Is Shaping the Future of China’s Healthcare.....	2043
8.8	IQVIA Conducts Survey of Physician Behaviors at the Internet Clinic Platforms in China	2046
8.9	IQVIA’s Digital Channel Survey Finds All Levels of Doctors Spend Similar Hours for e-Learning	2048
8.10	Can China’s Tech Titans Succeed in Healthcare?	2049
8.11	The Hidden Challenges of China’s Booming Medical AI Market	2052
8.12	Healthcare-Related AI Patent Surge in China Reflects Momentum in MedTech Innovation	2055
8.13	China’s Big Data Draws Pharmaceutical Companies Around the World.....	2056
8.14	COVID-19 Makes Digital Care the Norm in China.....	2056
8.15	Ping An Good Doctor: Cross-Sectional Survey	2059
8.16	Kantar: Chinese Physicians' Digital Behaviour During COVID-19 Outbreak	2060
8.17	MNCs Tap Potential in Internet Healthcare Thru Alliances with Local e-Commerce Giants	2061
8.18	The Rise of Digital Healthcare Services amid COVID-19: Talk with AZ China President	2063
8.19	MIIT and NHC Issues the <i>Joint Notice for Stepping Up the Infrastructure Building of Telemedicine</i>	2065
PART VIII MARKET ENTRY STRATEGIES AND EXECUTION		2067
Chapter VIII-1 Preparations for a Market Entry Strategy		2069

1.1	The Need for a Carefully-Researched Market Entry Strategy	2069
1.2	Long Term Perspective	2069
1.3	Information Sources	2070
1.4	Getting Expert Help	2073
1.5	Market Research	2073
1.6	Selecting the Right Products	2074
1.7	China’s Evolving Pharma Partnering Landscape: The Right Partner Profile	2075
1.8	What Healthcare Companies Looking To Get Into China Must Know	2079
1.9	Five Elements to Consider When Choosing the Next Emerging Market to Enter	2081
Chapter VIII-2 Strategic Approaches for Market Entry		2084
2.1	Direct Export of Finished Products	2084
2.2	Sino-foreign Joint Ventures	2086
2.3	Solely Foreign-owned Companies in China	2087
2.4	Licensing and Technology Transfer	2088
2.5	Merger & Acquisition (M&A)	2090
Chapter VIII-3 Execution of The Market Entry Strategy		2092
3.1	Product Registration	2092
3.2	New Drug Clinical Trials and Patient Recruitment in China	2092
3.3	Latest Regulatory Developments on Ethical Review in Chinese Clinical Trials	2095
3.4	Selection of a Local Distributor for Imported Drugs	2097
3.5	Selection of a Chinese Partner for Joint Venture	2098
3.6	Product Launch	2099
3.7	Promotional Activities and Advertising	2099
Chapter VIII-4 Challenges and Realities for Operating in China		2101
4.1	The Importance of Patience	2101
4.2	The Value of Relationship	2101
4.3	Dealing with Chinese Style Laws	2102
4.4	The Ethical Challenges of Doing Business in China’s Healthcare Economy	2102
4.5	Commercial Briberies Seen as a Leading Risk as Chinese and Foreign Governments Step Up Enforcements	2104
4.6	Behind China’s Corruption Crackdown: Whistleblowers	2107
4.7	Compliance in China: Ongoing Regulatory and Operational Challenges	2109
4.8	Staff Turnover and Talent Retention A Growing Problem	2112
4.9	Choosing Your General Manager for China	2114
4.10	Managing Sino-Foreign Joint Ventures in China	2117
4.11	Recruiting R&D Leaders in China and India	2122
4.12	Recruiting Medical Executives in China	2126
4.13	Managing Clinical Trials in Asia and China	2128
4.14	Resourcing Clinical Research Programs in China	2131
4.15	Protecting the Accuracy of Clinical Trial Data in China	2134

4.16	Why Your NDA Does Not Work For China	2136
4.17	How To Protect Trade Secrets In China When Employees Leave	2136
4.18	How to Protect Your Brand in China	2139
4.19	IFPMA and RDPAC Introduce New Code for Pharma Marketing Practices	2144
4.20	In Generic Drug Plants in China and India, Data Falsification Is Still A Problem	2145
4.21	Recordation of Patent License Agreement In China	2147
4.22	Patent Protection of Multinational Joint Invention in China.....	2148
PART IX MINI CASE STUDIES		2151
Chapter IX-1 China Experiences of Foreign Drug Companies		2153
1.1	Ranbaxy’s Successful Entry and Surprising Exit of the Chinese Market	2153
1.2	Zuellig Pharma/Cardinal Health in China – A One-Time Successful Case and Business Model for China’s Pharmaceutical Distribution Sector with A Disappointing End.....	2155
1.3	West Pharmaceutical Services – Tapping into China’s Growing Healthcare Industry.....	2159
1.4	Novo Nordisk China – Focusing on Diabetes and Ample Room for Growth.....	2161
1.5	Abbott Succeeds in China by Focusing on Nutrition Business.....	2166
1.6	Bayer’s Big Bet on China	2167
1.7	Bayer Troubled by Integration of Acquired OTC Business in China.....	2170
1.8	Roche’s Unique, Global Strategy for China.....	2171
1.9	Helping Establish Private Health Insurance for Cancer in China – <i>A Roche Story</i>	2177
1.10	A Decade Old Drug Launch in China with Important Insights Today – <i>BMS’s Experience with Baraclude in China</i>	2178
1.11	Ipsen Outlines Strategies for Continued Growth in China – <i>The Success Story of a Mid-size Company</i>	2183
1.12	SciClone Pharmaceuticals: Building a Product Portfolio Optimized for China’s Evolving Pharmaceutical Market.....	2185
1.13	DelMar Pharma – Leveraging U.S. Resources and Chinese Partnership for Drug Development and Commercialization	2191
1.14	Why Did One of the World’s Largest Generic Drug Makers Exit China?	2193
1.15	CleveXel’s Collaboration with Guilin Pharma for Development of Artesunate Injection ..	2196
1.16	Lessons from Glaxosmithkline’s Record \$492 Million Bribery Fine in China.....	2199
1.17	GSK: One Multinational’s Lessons Learned in China	2201
1.18	MSD and Nanjing Simcere Went Their Own Ways	2203
1.19	Merck Finds Shortcut for Anticancer Keytruda into China via Medical Tourism	2205
1.20	Merck’s Gardasil Preps for Head-to-head with GlaxoSmithKline’s Cervarix in China, with Big Sales Targets Ahead.....	2206
1.21	Pfizer Builds Viagra Success in China Despite Fierce Competition and Generics	2208
1.22	Pfizer Makes Bold Moves to Maximize China Business under New Leadership	2210
1.23	Eli Lilly Spins Off Non-core Assets to Chinese Companies.....	2211
1.24	Eli Lilly Launches LEAP to Expand Lower Tier Market Access in China	2213
1.25	Sanofi to Center Its China Business Strategy on Primary Healthcare	2214

1.26	Sanofi CEO Pledges More Investment, R&D Facility, 16 New Drugs and Digital Healthcare for China	2215
1.27	Ten Years and \$100M+ Later, GSK Shuttters A China R&D Site amid Reorganization	2218
1.28	GSK’s Digital Strategies for Reaching New Buyers in China	2219
1.29	GSK CEO Pledges to Learn from Mistakes in the Chinese Vaccine Market	2221
1.30	China: AstraZeneca’s New Engine for Growth and Innovation	2222
1.31	AstraZeneca Markets an Herbal-Based Remedy to Expand in China	2228
1.32	Boehringer Ingelheim Increases Focus on Chinese Rural Areas and Bets on CDMO Market	2230
1.33	Gilead Sciences Takes Off in China with Commitment to Cure Hepatitis	2232
1.34	Despite Strong Albumin Sales, CSL Complains of Barriers in China Business	2234
1.35	Eisai Gives Chinese Doctors and Patients Upper Hand against Cancer, Serious Illnesses	2235
1.36	Kobayashi Pharma: China Business Growth without China Presence	2236
1.37	Exploring Ways to Establish Presence in China as Part of APAC Region Push: Lupin Pharma	2238
1.38	GNC: China Strategy Hits Tariff Shoals	2239
1.39	China Gives Merck, BMS Cold Shoulder On Reimbursement List as PD-1 Battle Enters New Phase	2242
1.40	Astrazeneca Rounds Out Stellar China Year – And Beats Roche To The Punch – with Imfinzi Lung Cancer Nod	2244
1.41	Xian Janssen: Embrace Better Future with New Solutions	2246
1.42	Takeda Aspires to Become A Top Ten MNC Pharma Co. in China	2248
1.43	Novartis Aims to Double China Business by 2024	2249
1.44	Novartis, Once Wary of Chinese M&A, Dives into BeiGene's Cancer Immunotherapy	2251
1.45	Amgen's China Strategy Forward: Collaborating with Local Partners on Win-win Terms?	2252
Chapter IX-2 R&D and Outsourcing Case Studies		2256
2.1	Birth of A New Novel Anticancer, Made in China	2256
2.2	Huya Bioscience – Tapping into China for Novel Drug Candidates	2257
2.3	BeiGene Strives to Become China’s Genentech	2259
2.4	Two Emerging Companies Leverage the Strength of Both China and the U.S. for Growth	2261
2.5	Chinese Innovation: BGI’s Code for Success	2264
2.6	China Learns the Lesson of Vaccine R&D Bubble – The Story of Chongqing Brewery’s in Development of Its Novel HepB Vaccine	2268
2.7	Research Partnership between BMS and Simcere: The Right Chemistry amid A Global Paradim Shift of Drug R&D?	2270
2.8	China’s Academic “Black Market” Fooled Canadian Medical Journal	2275
2.9	A Setback for Chinese Drug R&D	2277
2.10	USFDA Found China Data Irregularities for Key Study of Pfizer and BMS’s Eliquis	2281
2.11	How Chinese Suppliers to Global Drug Firms Hide Bad Test Results	2282
2.12	Chinese Companies Make Progress on New Drugs from TCM Herbs	2284
2.13	A Better Pill from China – <i>Chinese Pharma Firms Target the Global Market</i>	2285

2.14	Novartis: Why the Firm Opened and Closed A Major R&D Facility in China	2287
2.15	Pfizer to Use GE's Mobile Biotech Factory to Make Next-Generation Drugs in China.....	2290
2.16	Cross-sector Synergy: China Innovation at Merck	2291
2.17	Pfizer Seeks Deals With Chinese Biotechs to Offset Lost Revenue	2297
2.18	AZ Licenses Junshi's PD-1 in China in a Bizarre Commercialization Deal	2298
Chapter IX-3 Human Resource Management Case Studies		2300
3.1	AstraZeneca China: Continued Mission on People	2300
3.2	Novartis China: The Learning Strategy	2301
3.3	Trends in Managing Pharmaceutical R&D and Medical Affairs Professionals	2303
3.4	Sanofi Turns to AI to Cut Chinese Recruitment Churn.....	2307
Chapter IX-4 Legal Case Studies: IPR/Counterfeits/AML/Others.....		2310
4.1	Sankyo vs. Beijing Wansheng: First Lawsuit over Process Patent for Preparing Pharmaceutical Composites.....	2310
4.2	Pfizer vs. 12 Local Drug Companies: <i>Landmark Lawsuit over Viagra Patent</i>	2311
4.3	Eli Lilly vs. Beijing Ganli – <i>Battle over Insulin</i>	2313
4.4	Boehringer Ingelheim vs. Chaitai Tianqing over Tiotropium Bromide	2314
4.5	Legal Battle between Sanofi and Jiangsu Hengrui over Docetaxel	2315
4.6	Merck vs. Henan Topfond over Chinese Patent for Finasteride.....	2316
4.7	Aurisco Challenges Gilead's Chinese Patent for Viread.....	2316
4.8	Fake Drug Sting Operation – <i>GSK Experience</i>	2318
4.9	Legal and Ethical Implications of ELAD Clinical Trial Death	2319
4.10	Ruling over Liabilities of Distributors and Hospital in Fake Armillarisi-A Injection Case.....	2321
4.11	Novartis Sued and Challenged for Deaths Linked to Its Hepatitis B Drug Sebivo	2322
4.12	Illegal and Off-Label Use of Roche's Avastin Led to Serious ADRs in Shanghai	2323
4.13	Off-label Use of Bayer Healthcare's XARELTO under Challenge in China	2325
4.14	Review of the 11-Year Trademark Fight between Roche and Southwest Pharma	2326
4.15	Merck & Co. Loses Trademark Fight against Tianjin Zhongxin Pharma	2329
4.16	Pfizer Loses Final Battle for Chinese Trademark of Viagra	2330
4.17	Johnson & Johnson Loses Trademark Lawsuit against SAIC's Trademark Review Board	2330
4.18	Bayer Settles Six-Year Trademark Infringement Lawsuit with Henan Baier Pharma	2331
4.19	Siemens Sued in the U.S. by Former Employee over Briberies in China	2331
4.20	China's Anti-Japanese Boycott Extended to Pharmaceuticals	2332
4.21	The Impact of Restricted Data-flows on China's Digital Healthcare Solutions.....	2334
4.22	SIPO Invalidates Gilead Sciences' Viread Patent in China.....	2336
4.23	China Rejects Patent for Gilead's Expensive Hepatitis C Drug.....	2337
4.24	Gilead's Key Sovaldi Patent Claims Partially Invalidated in China	2338
4.25	MSF Challenges Gilead's HCV Patent Application in China	2339
4.26	Bayer Loses Avelox (Moxifloxacin) Patent Battle in China	2340
4.27	Eli Lilly vs. Changzhou Watson: China's Supreme Court Sides with Local Firm After Court Designated Technical Investigations	2341
4.28	Three Supreme Court Cases on Pharmaceutical Patents.....	2341

4.29	Novartis Lost Gleevec Infringement Lawsuit in China against Jiangsu Hansoh Pharma ...	2344
4.30	Review of China’s High Profile Investigation of GSK for Corruption	2345
4.31	GSK Sued by Couple It Hired to Investigate Whistleblower	2361
4.32	The “Dignified” Drug-Dealer – A Case for Thought over Patient Access to Medicines, Parallel Import, Compulsory Licensing and Drug Pricing	2362
4.33	Pfizer Fined by Shanghai Government for Irregular Pharmacy Display Fees	2365
4.34	Shanghai Fines Novo Nordisk CNY 2.6 Mln for Distributor License Violation.....	2366
4.35	Shanghai AIC Hits Foreign Firms with Fines for Compliance Violations	2367
4.36	Chinese MOF Fines 19 Pharma Companies for Inflating Drug Prices	2368
4.37	Other Anti-Monopoly Enforcement Cases.....	2369
4.38	Chinese Antitrust Authority Imposes Maximum Fine in Rare Abuse of Collective Dominance Case	2379
4.39	China Imposes \$117M Fine for Resale Price Maintenance for the First Time in the Pharma Industry	2381
4.40	FCPA Compliance Cases and Other Related Foreign Lawsuits	2385
4.41	China’s Conditional Approval of Bayer’s Acquisition of Monsanto: Lessons for Future Merger Cases in China	2391
4.42	Bayer Pharma Hit with China-attributed Malware.....	2393
4.43	Who Owns the Coronavirus Cure? China’s Move to Patent Gilead’s Experimental Drug for The Novel Virus Could Lead to Legal Wrangle	2393
4.44	The Case of Remdesivir from the Chinese Perspective – Patent Applications on Inventions for Pharmaceutical Use	2395
4.45	Beijing High Rejects Novartis’ Trademark Registration of "Alcon".....	2397
4.46	First Pre-Trial Injunction Granted for a Drug Patent in China: Astellas Pharma v Zhejiang Hisun Pharmaceutical.	2399
4.47	CNIPA Invalidates BMS's Chinese Patent for Low Dose Entecavir	2403
4.48	CNIPA Invalidates Pfizer's Chinese Patent of Sutent (Sunitinib).....	2404
4.49	Illumina Sues BGI Over Coronavirus Patent Infringement in China	2405
4.50	DSM Wins Patent Case against China’s Anhui Tiger Vitamin	2405
4.51	CNIPA Upholds Bayer's Rivaroxaban Patent – <i>A Top 10 Chinese Patent Re-Examination and Invalidation Cases of 2020</i>	2406
Chapter IX-5 Success and Failure Stories of Domestic Companies.....		2409
5.1	3SBio – The Success Story of a Chinese Biogeneric Company	2409
5.2	Zhejiang Hisun Pharmaceutical Ltd. – <i>A Showcase for International Business Transformation of Chinese Pharmaceutical Companies</i>	2412
5.3	Anheart Builds Its Oncology Pipeline Following Five Rs	2416
5.4	GenePharma – <i>The Story of a Small Niche Chinese Biotech Company</i>	2419
5.5	Fosun Pharma Expands Global Business Via M&As and Innovative R&D	2421
5.6	Backed by China, Ambrx No Longer Dependent on Partnerships with MNCs	2425
5.7	BeyondSpring Pharma: Communicating Across US-China Lines	2427
5.8	EOC Pharma Strives to Bring Potential Oncology Blockbusters to China	2428

5.9	Luye’s Schizophrenia Drug Approval in China Challenges J&J’s Risperdal Consta.....	2429
5.10	BeiGene: The Poster Child Of China’s Booming Biopharma Market	2431
5.11	Three Key Takeaways From BeiGene’s CEO	2434
5.12	Can Alibaba Health Information Technology Transform China’s Pharma Industry?.....	2437
5.13	How Alibaba and JD.com Compare in Their Healthcare Endeavors	2441
5.14	Yaobili Set to Change China’s Pharmaceutical Industry with New Model.....	2442
5.15	I-Mab BioPharma And Its Dual Drug Portfolio	2443
5.16	Shanghai Henlius Biotech Maps Out Its Biosimilars Future	2446
CHAPTER IX-6 Creative Alliances among Pharma cos and Insurers		2449
6.1	Roche to Expand Cancer Sales through Joint Supplemental Insurance Policy with Swiss RE	2449
6.2	Pfizer China, PICC and MediTrust Co-launched China’s First Pay-for-Performance Oncology Insurance	2450
6.3	Insurer Manulife-Sinochem Inks Deal with Healthcare Platform 111 Inc.	2451
6.4	Tsumura to Penetrate China’s Herbal Drug Market with the Help of Ping An Insurance	2452
6.5	Amgen Striding Ahead in Innovative Medical Solutions.....	2453
CHAPTER IX-7 Alliances between Pharma and e-commerce/IT Cos		2455
7.1	GSK, AliHealth Join Hands to Build Vaccine Promotion Channel with Initial Focus on Cervarix	2455
7.2	GSK Ties Up with JD to Offer Integrated Online Medical Services	2456
7.3	Reckitt Benckiser, Alibaba Join Hands to Market Quality Health Products to China	2456
7.4	Merck and Alibaba Health Announce Collaboration to Develop Patient-Centric Digital Services in China	2457
7.5	Allergan and AliHealth to Launch Digital Platform for Medical Aesthetics Market	2459
7.6	Lilly China and Microsoft Enter Digital Health Partnership Using AI to Empower Medical Innovation in China.....	2460
7.7	Pfizer Eyes Huge Potential in Online Sales of Its Health Products in China.....	2461
7.8	Novartis and Tencent Enter Strategic Partnership for Digital Medicine	2463
7.9	AstraZeneca CEO Gambles on China’s Internet of Things	2464
7.10	Ping An Good Doctor Ties Up with Jointown Pharma to Enpower Primary Healthcare	2465
APPENDICES		2469
Appendix I Drug Administration Law of the PRC		2471
Appendix II Regulations for Implementation of the Drug Administration Law of the PRC.....		2497
Appendix III Regulations on Administrative Protection for Pharmaceuticals		2516
Appendix IV The Provisions for Registration of Drug Products.....		2520
Appendix V Special Review and Approval Procedure for Drug Registration of the CFDA/NMPA.....		2547

Appendix VI Administrative Reconsideration Measures	2553
Appendix VII Provisions for Drug Insert Sheets and Labels	2558
Appendix VIII The Provisions for Control of Drug Manufacture.....	2563
Appendix IX Provisions for Control of Drug Distribution.....	2584
Appendix X Provisions for Drug Advertisement Examination	2590
Appendix XI 2020 Amendments To The Chinese Patent Law	2597
Appendix XII Biosecurity Law of the Peoples Republic of china	2607

LIST OF TABLES

Table 1.1 China’s state and private shares of fixed asset investment (FAI) 2017-2019...	57
Table 1.2 Number of Pharmaceutical Businesses in China 1997-2019	142
Table 1.3 Segmentation of Global API Companies 2017.....	150
Table 1.4 Country Share of Established API Providers Globally 2017	150
Table 1.5 Growth of the Chinese API/Bulk Drug Sector 2002-2019.....	152
Table 1.6 Growth of the Chinese API/Bulk Drug Sector 2002-2019.....	152
Table 1.7 Revenue in Chinese API Industry 2012-2017	153
Table 1.8 China Biologic Companies Listed in Hongkong Stock Exchange 2019.....	164
Table 1.9 Financing of Chinese Biologic Companies 2019	164
Table 1.10 Status of Chinese Biopharma Companies in SSE Star Market 2020	165
Table 1.11 New Chinese biopharma IPOs 2019-2020	165
Table 1.12 Pharma Producers Listed on STAR Market 2021	166
Table 1.13 Innovative Drug Producer to List on STAR Market 2021	167
Table 1.14 Top 20 A Share-Listed MedPharm Cos by R&D Spending H1/2020	179
Table 1.15 Top 20 H-Share Pharma Companies by R&D Spending H1/2020.....	180
Table 1.16 R&D Centers of RDPAC Members in China	187
Table 1.17 Share of Chinese Clinical Trials by Region 2019	195
Table 1.18 Innovative Drugs Approved in China (by TC 2016-2020 #)*.....	200
Table 1.19 Innovative Drugs Approved in China (by TC 2016-2020 %)*	200
Table 1.20 Share of innovative drugs* in Rx market (2018)	201
Table 1.21 Performance of Top 20 Listed Chinese Pharma Cos by Revenue 2020.....	203
Table 1.22 Top 10 A-shared Listed Chinese MedPharm Cos by Net Profit H1/2020....	204
Table 1.23 Top 10 A-shared Listed Chinese MedPharm Cos by Gross Margin H1/2020	204
Table 1.24 Top 10 A-shared Listed Chinese MedPharm Cos by Revenue H1/2020.....	205
Table 1.25 Top 20 A-shared Listed Chinese MedPharm Cos by Revenue H1/2020.....	205
Table 1.26 Chinese Companies in Top 500 China Fortune 2020	206

Table 1.27 Chinese Pharma Cos in Top 100 of Torreya’s The Pharma 1000 in 2020 ...	208
Table 1.28 Top 20 Chinese Non-State-Controlled Healthcare Cos 2020 by Hurun	209
Table 1.29 Top 20 Listed Chinese Pharma Cos by R&D Spending 2020	210
Table 1.30 Top 20 A Share-listed Pharma Cos by Sales Expenditures 2020	211
Table 1.31 Top 20 Chinese OTC Drug Producers 2019	212
Table 1.32 Top 20 Chinese Distributors by Sales Revenues in 2020	213
Table 1.33 Top 20 Pharma Distribution Companies 2019	213
Table 1.34 Top 20 Chinese Retail Pharmacy Companies by Sales Revenues in 2020 ..	214
Table 1.35 Top Ten Chinese Retail Pharmacy Chains by Overall Core Strength in 2018	215
Table 1.36 Top Ten Chinese Retail Pharmacy Chains by Direct Operation Strength in 2018	215
Table 1.37 Top 29 Listed Chinese CROs by Revenue in 2020	216
Table 1.38 Table 1.56 Pharma Foreign I Companies 2018-2019	217
Table 1.39 Top 25 Listed Chinese CRO/CDMO Companies in 2019	218
Table 1.40 First Ten Sino-Foreign Pharmaceutical Joint Ventures in China	241
Table 1.41 Foreign Investment in the Chinese Pharmaceutical Industry in the 1990s ..	242
Table 1.42 Pharma Foreign Investments in China between 2000 and 2006	243
Table 1.43 Top 10 Pharma MNCs in China by Investment	244
Table 1.44 Number of Retail Pharmacy Chain Companies 2011-2020	260
Table 1.45 Number of Retail Pharmacy Stores 2011-2020	261
Table 1.46 Chinese Foreign Trade of Medicines and Health Products in 2018 (1)	282
Table 1.47 Chinese Foreign Trade of Medicines and Health Products in 2018 (2)	282
Table 1.48 Chinese Import of Medicines 2014-3Qs/2019	283
Table 1.49 Chinese Monthly Import of Medicines in 2019	283
Table 1.50 # of ANDA Approvals Issued by USFDA to Chinese Cos 1974-2020	285
Table 2.1 Improvement of Medical Provision in China	291
Table 2.2 Comparisons of Healthcare Provision by China vs. Other Countries (1)	292
Table 2.3 Comparisons of Healthcare Provision by China vs. Other Countries (2)	293

Table 2.4 Comparisons of Healthcare Provision by China vs. Other Countries (3)	293
Table 2.5 Comparisons of Healthcare Provision by China vs. Other Countries (4)	294
Table 2.6 Birth, Death and Population Natural Growth Rate.....	295
Table 2.7 Rising Life Expectancy of the Chinese Population.....	296
Table 2.8 Composition of the Chinese Population by Urban/Rural Division and Sex ..	297
Table 2.9 Composition of the Chinese Population by Age	298
Table 2.10 Composition of the Chinese Population by Education.....	299
Table 2.11 Medical Institutions and Its Inpatient Beds by Type and Ownership.....	305
Table 2.12 Healthcare Personnel by Professional Categories in China 2010-2020	306
Table 2.13 Healthcare Personnel by Medical Institute Type and Ownership	307
Table 2.14 Outpatient Visits and Inpatients by Medical Institution Type in 2018-2020	309
Table 2.15 Workload of Chinese Physicians by Hospital Type 2017-2020	310
Table 2.16 Occupancy Rate and Average Days of Hospitalization by Hospital Type 2017-2020.....	310
Table 2.17 Medical Service Statistical Summary of Township Health Centers.....	311
Table 2.18 Number of Village Clinics and Healthcare Professionals	311
Table 2.19 Statistical Summary of Community Healthcare Service Centers.....	312
Table 2.20 Statistical Summary of Community Healthcare Service Stations	312
Table 2.21 TCM Medical Institutions and its Inpatient Beds by Type and Ownership .	313
Table 2.22 Outpatient Visits and Inpatients in TCM Medical Institutions by Type in 2018-2020.....	313
Table 2.23 Share of Primary Healthcare Facilities with TCM Services (%)	314
Table 2.24 TCM Healthcare Professionals in China	314
Table 2.25 Structure of Outpatient and Inpatient Medical Expenditures 2019-2020.....	315
Table 2.26 Medical Institutions by Specialties and Affiliations.....	327
Table 2.27 Inpatient Beds of Medical Institutions by Specialties and Affiliations	328
Table 2.28 Medical Institutions by Ownership Type	329
Table 2.29 Inpatient Beds of Medical Institutions by Ownership Type.....	329
Table 2.30 Inpatient Beds of Medical Institutions by Hospital Grade	329

Table 2.31 Number of Medical Institutions by Grade 2013-2020	330
Table 2.32 Number Growth (%) of Medical Institutions by Grade 2013-2020.....	330
Table 2.33 Regional Population Distribution in China 1990-2019.....	330
Table 2.34 Regional Distribution of Medical Care Providers in China Q1/2021	331
Table 2.35 Regional Distribution of Medical Institutions in H1/2020	332
Table 2.36 Regional Distribution of Medical Institutions and Inpatient Beds in 2019 .	333
Table 2.37 Regional Distribution of Healthcare Professionals in 2019.....	334
Table 2.38 Distribution of Inpatient Beds by Medical Specialty 2005-2012	336
Table 2.39 Distribution of Physicians by Medical Specialty 2000-2012.....	336
Table 2.40 Healthcare Personnel in China 1990-2020.....	337
Table 2.41 Healthcare Personnel in China 2010-2020.....	337
Table 2.42 Distribution of Healthcare Professionals in Cities and Counties 1990-2019	338
Table 2.43 Key Healthcare Reform Goals for 2017	363
Table 2.44 Key Healthcare Reform Goals by 2020	363
Table 2.45 Overview of Chinese BMI System In 2020 (Unit: CNY Million).....	373
Table 2.46 Makeup of Healthcare Expenditures in China between 1980 and 2020	376
Table 2.47 Overview of Chinese BMI System In 2020 (Unit: Million CNY).....	380
Table 2.48 Financial Overview of the Chinese BMI System in 2020	381
Table 2.49 Enrollment Structure of UEBMI by Employer Type 2018-2020.....	382
Table 2.50 Enrollment Structure of UEBMI by Employment Status 2012-2020	382
Table 2.51 Claims and Outpatient Visits under UEBMI 2012-2020	382
Table 2.52 Average Expense and BMI Payout Per Inpatient of UEBMI 2012-2020.....	383
Table 2.53 Share of Inpatient Expenses Reimbursable under UEBMI by Hospital Levels 2020.....	383
Table 2.54 Enrollment of Urban Residents in URBMI Programs 2020	383
Table 2.55 Financial Performance of URBMI Program 2012-2020.....	384
Table 2.56 BMI Claims and Inpatient Expenses at Different Hospital Levels 2012-2020	384

Table 2.57 Share of Inpatient Expenses Reimbursable under URBMI by Hospital Levels 2020.....	384
Table 2.58 Overview of Chinese URBMI System 2018	390
Table 2.59 Growth of Healthcare Expenditures in China 2000-2020	417
Table 2.60 Makeup of China’s Healthcare Expenditures 2012-2020.....	418
Table 2.61 Government Healthcare Spending in National Fiscal Finance 2009-2019 ..	418
Table 2.62 Makeup of Chinese Fiscal Healthcare Spending 2017-2019 (CNY mln)	419
Table 2.63 Health Insurance Income and Payment 2000-2019.....	419
Table 2.64 BMI System Financial Performance 2000-2019	420
Table 2.65 UEBMI System Financial Performance 2000-2019.....	420
Table 2.66 URBMI System Financial Performance 2000-2019	421
Table 2.67 BMI System Financial Performance by Province 2018-2019	422
Table 3.1 Growth of Drug Consumption in China 2001-2021E	505
Table 3.2 Growth of Healthcare Expenditures in China 1980-2020	506
Table 3.3 Share of Per Capita Drug Expenditures in Healthcare	508
Table 3.4 Top Ten Cancer in China by # of New Patients in 2020	513
Table 3.5 Top Ten Cancer in the U.S. by # of New Patients in 2020.....	513
Table 3.6 Chinese PD-1/PD-L1 Market Landscape 2018-2020.....	513
Table 3.7 Innovative Drugs Approved thru Priority Review in China 2019-2020	514
Table 3.8 Examples of China Launch Time Gap of Comparable Products: MNCs vs. Domestic.....	514
Table 3.9 Leading Diseases by Two-Week Morbidity in 2013	515
Table 3.10 Leading Disease Categories by Two-Week Morbidity in 2013 vs. 2008 (%o)	516
Table 3.11 Leading Diseases by Two-week Morbidity in 2003	517
Table 3.12 Leading Diseases by Two-week Morbidity in 2008.....	518
Table 3.13 Morbidity Rate of Chronic Diseases in 2003 and 2008	518
Table 3.14 Trend of Leading 10 Diseases among Inpatients of Urban Hospitals	519
Table 3.15 Leading 10 Diseases among Inpatients of County Level Hospitals.....	520

Table 3.16 Leading Casues of Death and Composition in Urban Areas 2015.....	521
Table 3.17 Leading Causes of Death in Certain Regions of China in 2012	522
Table 3.18 Leading Causes of Death among Chinese Males in 2012.....	522
Table 3.19 Leading Causes of Death among Chinese Females in 2012	523
Table 3.20 Chinese Cancer Prevalence and Patterns	552
Table 3.21 Regional Distribution of Chinese Cancer Patients and Deaths.....	552
Table 3.22 Top 5 Cancers by Morbidity Rate 2017 (Male vs. Female).....	552
Table 3.23 Top 5 Cancers by Morbidity Rate in Urban Areas (Male vs. Female).....	553
Table 3.24 Top 5 Cancers by Morbidity Rate in Countryside (Male vs. Female)	553
Table 3.25 Five-Year Cancer Prevalence in China (2011).....	553
Table 3.26 Breakdown of Cancer Survival Patients: Age Groups (2011).....	554
Table 3.27 Breakdown of Cancer Survival Patients: Male vs. Female (2011)	554
Table 3.28 Breakdown of Cancer Survival Patients: Urban vs. Rural (2011)	555
Table 3.29 Composition of Medical Care Providers in China 1950-2019.....	565
Table 3.30 Composition of Medical Care Providers in China 2019-2020.....	566
Table 3.31 Composition of Medical Care Providers in China Q1/2020-Q1/2021.....	566
Table 3.32 Number of Outpatient Visits and Inpatients in Medical Institutions 1980-2019	567
Table 3.33 Outpatient Visits and Inpatients by Medical Institution Type in 2016-2020	568
Table 3.34 Outpatient Visits and Inpatients by Medical Institution Type in Q1/2021...	569
Table 3.35 Regional Distribution of Outpatient Visits and Inpatients in Q1/2021	570
Table 3.36 Average Days of Hospitalization 1985-2019	571
Table 3.37 Occupancy Rate and Average Days of Hospitalization by Hospital Type 2017-2020.....	571
Table 3.38 Regional Distribution of Medical Institutions and Inpatient Beds in 2016 .	571
Table 3.39 Overall Healthcare Expenditures in China 2013-2020	572
Table 3.40 Composition of Healthcare Expenditures in China 2013-2020	572
Table 3.41 Structure of Outpatient and Inpatient Medical Expenditures 2015-2016	572
Table 3.42 Structure of Outpatient and Inpatient Medical Expenditures 2017-2018	573

Table 3.43 Structure of Outpatient and Inpatient Medical Expenditures 2019-2020.....	573
Table 3.44 Outpatient and Inpatient Medical Expenditures by Hospital Levels H1/2020	574
Table 3.45 Chinese Hospital Drug Sales Value 2015-H1/2021.....	575
Table 3.46 Top 10 Drug Suppliers to Chinese Hospitals MAT Q2/2021	576
Table 3.47 Top 10 TCs by Chinese Hospital Drug Sales Q1 & Q2/2021	576
Table 3.48 Top 10 Drug Products by Chinese Hospital Drug Sales Q1-Q2/2021	577
Table 3.49 Top 10 Drug Suppliers to Chinese Hospitals MAT 2018-2020.....	577
Table 3.50 Top 10 Drug Products by Sales Value in Chinese Hospitals 2018-2020.....	578
Table 3.51 Top 10 TCs in Chinese Hospitals 2020	578
Table 3.52 Top 10 Drug Suppliers to Chinese Hospitals by Sales in MAT Q2/2020.....	579
Table 3.53 Top 10 Drug Products in Chinese Hospitals by Sales in Q2/2020	579
Table 3.54 Top 10 TCs in Chinese Hospitals by Sales in Q2/2020.....	580
Table 3.55 Public Medical Institution Drug Sales by Channel Type 2019-2020.....	580
Table 3.56 Public Hospital Drug Consumption 2010-2020	581
Table 3.57 Public Medical Institution Drug Sales by Product Type 2015-2020 (1)	581
Table 3.58 Public Medical Institution Drug Sales by Product Type 2015-2020 (2)	581
Table 3.59 Public Medical Institution Drug Sales by Product Type 2020 (3).....	581
Table 3.60 Public Medical Institution Drug Sales by Tender Category 2019-2020.....	582
Table 3.61 Chemical Drug & Biologicals Sales by TCs in Public Medical Institutions 2020	582
Table 3.62 Top 10 Chemical Drugs in Major Chinese Urban Public Hospitals 2020....	583
Table 3.63 Top 10 Chemical Drug Brands in Major Chinese Urban Public Hospitals 2020	583
Table 3.64 Public Medical Institution Drug Sales by Product Category 2015- 2020 (1)	584
Table 3.65 Public Medical Institution Drug Sales by Product Category 2015- H1/2020 (2)	584
Table 3.66 Public Medical Institution Drug Sales by Tender Category H1/2019-H1/2020	584

Table 3.67 Public Medical Institution Drug Sales by Channel Type H1/2019-H1/2020	584
Table 3.68 Public Medical Institution Drug Sales H1/2019-H1/2020: Domestic vs. Import	585
Table 3.69 Chemical Drug & Biologicals Sales by TCs in Public Medical Institutions H1/2020.....	585
Table 3.70 China’s Public Hospital Drug Markets 2010-2020	586
Table 3.71 Segmentation of Chinese Public Hospital Drug Sales 2011-2020.....	586
Table 3.72 Growth of Chinese Public Hospital Drug Sales by Channel Type 2017-2020	587
Table 3.73 Top 20 TCs by Drug Sales in Public Chinese Medical Institutions 2019	587
Table 3.74 Top 20 Drug Brands by Sales in Chinese Public Medical Institutions 2019	588
Table 3.75 Top 20 Drugs by Sales Value in Rep Urban Chinese Hospitals 2020.....	589
Table 3.76 Top 10 Drug Cos by Sales Value in Rep Urban Chinese Hospitals 2020	590
Table 3.77 Chinese Urban Rep Hospital Drug Market 2012-2019.....	590
Table 3.78 Chinese Urban Rep Hospital Drug Market Share by TCs 2012-2019.....	590
Table 3.79 Top 20 Drug Suppliers in Chinese Rep Urban Hospitals 2019.....	591
Table 3.80 Top Pharma Player in Ten TCs of Chinese Urban Rep Hospitals 2019.....	591
Table 3.81 Top 20 Drug Products in Chinese Urban Rep Hospitals 2019.....	592
Table 3.82 Number and Distribution of Medical Facilities in China.....	592
Table 3.83 Chinese County Public Hospital Drug Market 2011- 2020	593
Table 3.84 Share of County Hospitals in Total Public Hospital Drug Sales 2011-2019	593
Table 3.85 Chemical Drug Sales by TCs in Chinese County Public Hospitals 2019	593
Table 3.86 Top 20 Chemical Drug Brands by Sales Value in Chinese County Public Hospitals 2019	594
Table 3.87 MNC Market Share in Urban and County Level Hospitals 2009-2017.....	596
Table 3.88 Drug Consumption by Urban Public CHCs 2010-2020.....	597
Table 3.89 Drug Sales of Chinese Public Primary Healthcare Facilities 2011-2020.....	598
Table 3.90 Drug Sales Segmentation of Chinese Public Primary Healthcare Facilities 2011-2020	598

Table 3.91 Drug Consumption by Urban Public CHCs 2010-2020.....	599
Table 3.92 Share of Urban Public CHCs in Total Public Primary Healthcare Drug Consumption 2011-2019	599
Table 3.93 Market Shares by Major TCs: Hospitals vs. CHCs MAT Q4/2017	600
Table 3.94 Market Shares by City Tiers: Hospitals vs. CHCs MAT Q4/2017	600
Table 3.95 Drugs Sales in Chinese Township Health Centers 2011-2020	600
Table 3.96 Share of THCs in Total Public Primary Healthcare Drug Consumption 2011-2020.....	601
Table 3.97 Chemical Drug Sales by TCs in Chinese Township Health Centers 2018...	601
Table 3.98 Top 20 Chemical Drug Brands by Sales Value in Chinese Township Health Centers 2018.....	601
Table 3.99 Public Medical Institution Chemical Drug Sales 2015-2020.....	603
Table 3.100 Chemical Drug Sales in Rep Urban Public Hospitals 2018-H1/2020.....	603
Table 3.101 Top 20 Chemical Drug Suppliers to Rep Urban Public Hospitals H1/2020	603
Table 3.102 Top 20 Chemical Drug Products in Rep Urban Public Hospitals H1/2020	604
Table 3.103 Chemical Drug Sales by TCs in Chinese Urban Public Hospitals 2019	605
Table 3.104 Top 20 Chemical Drug Brands by Sales Value in Chinese Urban Public Hospitals 2019.....	605
Table 3.105 Chemical Drug Sales in Public Hospitals of Major Chinese Cities 2015-2019	607
Table 3.106 Sales Value of 25 Drugs under 4+7 Trial in Rep Hospital 2014-2019	607
Table 3.107 Sales Performance of 3 Drugs in the 1st Round of BMI Negotiation (CNY mln)	608
Table 3.108 Five Rounds of BMI Negotiation for Drug Product Inclusion 2016-2020	609
Table 3.109 # of Prevailing Products at BMI Negotiations 2016-2020 (Domestic vs. Import).....	610
Table 3.110 # of Prevailing Products at BMI Negotiations 2017-2020 (Chemicals vs. TCMs)	610
Table 3.111 Rep Hospital Market Growth of Prevailing Products at BMI Negotiations 2016-2019.....	610
Table 3.112 # of Prevailing Products by TC at BMI Negotiations 2016-2020	610

Table 3.113 Rep Hospital Market Growth by TC of Prevailing Products at 2017 BMI Negotiation.....	611
Table 3.114 Vol Growth of Top 5 Prevailing Products by Price Drop at BMI Negotiations 2017-2020	611
Table 3.115 Vol Growth of Bottom 5 Prevailing Products by Price Drop at BMI Negotiations 2017-2020.....	612
Table 3.116 Hospital Consumption of NDRL 2017 and 2019 Drugs in H1/2020	612
Table 3.117 Hospital Consumption of NDRL 2017 and 2019 Drugs by Product # in H1/2020.....	613
Table 3.118 Hospital Consumption of NDRL 2017 and 2019 Drugs by Value Share in H1/2020.....	613
Table 3.119 Hospital Consumption of NDRL 2017 and 2019 Drugs by DDD Share in H1/2020.....	614
Table 3.120 Number of Chinese Retail Pharmacy Outlets 2006-2020	615
Table 3.121 Overall Chinese Retail Pharmacy Sales 2013-2020*	616
Table 3.122 Structure of Chinese Retail Pharmacy Sales: Offline vs. Online 2013-2020*	616
Table 3.123 Chinese Offline Retail Pharmacy Sales by Product Category 2013-2020 (CNY bln)	617
Table 3.124 Chinese Offline Retail Pharmacy Sales by Product Category 2013-2020 (Share %)	617
Table 3.125 Chinese Retail Pharmacy Drug Sales 2011-2020 (Value).....	617
Table 3.126 Chinese Offline Retail Pharmacy Drug Sales Value 2015-2020 (Urban vs. Rural)	618
Table 3.127 Chinese Offline Retail Pharmacy Drug Sales Share 2015-2020 (Urban vs. Rural)	618
Table 3.128 Chinese Urban Offline Retail Pharmacy Drug Sales 2018-2020: Chemicals vs. TCMs.....	618
Table 3.129 Chinese Urban Offline Retail Pharmacy Drug Sales 2018-2020: Rx vs. OTC	618
Table 3.130 Top 20 Chemical Drug Brands by Sales Value in Chinese Offline Retail Pharmacies 2020	619

Table 3.131 Top 20 Company by Sales Value in Chinese Urban Offline Retail Pharmacies 2020.....	620
Table 3.132 Sale Revenue and Profit of Chinese Pharma Industry 2017-2021	621
Table 3.133 Online Rx Drug Sales on Selected Platforms 2015-2021	621
Table 3.134 Chinese Online Drug Sales 2012-2021E.....	621
Table 3.135 # of Retail Pharmacies 2011-2021.....	622
Table 3.136 Growth of Top 20 OTC Drug & Health Food Players in China Retail Pharmacy Market in MAT Q1/2021	625
Table 3.137 Top 20 Products by OTC Drug & Health Food Sales in China Retail Market in MAT Q1/2021	625
Table 3.138 Top 20 Rx Drug in China Retail Market MAT Q1/2021	626
Table 3.139 Growth of Top 20 OTC Drug & Health Food Players in Chinese Retail Pharmacy Market in MAT Q1/2020.....	628
Table 3.140 Top 20 Products by OTC Drug & Health Food Sales in China Retail Market in MAT Q1/2020	629
Table 3.141 Top 20 Rx Drug in China Retail Market MAT Q1/2020.....	629
Table 3.142 Top 20 Cos by Urban Retail Pharmacy Chemical Drug Sales H1/2020	630
Table 3.143 Top 17 Chemical Drugs by Urban Retail Pharmacy Sales H1/2020.....	631
Table 3.144 Top 11 Chemical Drug Brands by Urban Retail Pharmacy Sales H1/2020.....	632
Table 3.145 Retail Drug Consumption by Channel 2010-2020.....	632
Table 3.146 Segmentation of Chinese Retail Pharmacy Drug Sales 2011-2020	633
Table 3.147 # of Drug Brands with >CNY 100M Urban Retail Sales in 2018.....	633
Table 3.148 Top Drug Brands with >CNY 100M Urban Retail Sales and >100% Growth in 2018.....	634
Table 3.149 Chinese Retail Pharmacy Sales Value and Growth 2009-2018.....	635
Table 3.150 Composition of Chinese Retail Pharmacy Sales 2017-2018.....	635
Table 3.151 Share and Growth of Chinese Retail Pharmacy Sales by TCs	636
Table 3.152 Top 20 OTC Medicine Brands by Retail Pharmacy Sales Value 2018	637
Table 3.153 Top 20 Rx Drug Brands by Retail Pharmacy Sales Value 2018.....	637
Table 3.154 Market Share of Rx Drug in Chinese Retail Pharmacy Sales 2011-2018..	638

Table 3.155 Chinese Online Pharmacy Sales 2013-2020*	639
Table 3.156 Chinese Online Pharmacy Drug Sales Value 2011- 2020	640
Table 3.157 Chinese Online Drug B2C Market 2018-2023E: Rx vs. OTC (1).....	640
Table 3.158 Chinese Online Drug B2C Market 2018-2023E: Rx vs. OTC (2).....	641
Table 3.159 China Internet + Healthcare Market Size 2015-2023E	641
Table 3.160 NH’s Chinese CHC Market Review 2019-2020 (\$ million).....	643
Table 3.161 NH’s Chinese CHC Market Review 2019-2020 (CNY million).....	645
Table 3.162 NH’s Chinese OTC Drug Market Forecast 2019-2030 (US\$ mln).....	647
Table 3.163 NH’s Chinese OTC Drug Market Forecast 2019-2030 (CNY mln).....	647
Table 3.164 Urban Retail Pharmacy Drug Sales: OTC Vs Rx 2015-2020	648
Table 3.165 Chinese OTC Drug Sales by Terminal Markets 2020.....	648
Table 3.166 Chinese OTC Drug Market Value 2016-2019.....	649
Table 3.167 Chinese OTC Drug Market Share 2016-2019.....	649
Table 3.168 Chinese OTC Drug Market Growth 2016-2019	649
Table 3.169 Market Size of Offline Retail Pharmacies 2019	649
Table 3.170 Chinese OTC Drug Market Share by TCs 2019	650
Table 3.171 Global OTC Drug Market 2015-2020.....	650
Table 3.172 Top Ten Chinese CHC Brands by Sales Value in 2020 (US\$).....	652
Table 3.173 Top Ten Chinese CHC Brands by Sales Value in 2020 (CNY).....	653
Table 3.174 Chinese Drug Market Size by Major Segments 2014-2019.....	656
Table 3.175 Overall Hospital Drug Market in Shanghai 2019-2020	657
Table 3.176 Shanghai Drug Market Segmentation by Hospital Tier 2020	657
Table 3.177 Shanghai Drug Market Growth by Hospital Tier 2019-2020	657
Table 3.178 Shanghai Hospital Drug Market by Product Category 2020	657
Table 3.179 Shanghai Hospital Drug Market Growth by TCs 2020.....	657
Table 3.180 Chemical Drug Sales in Public Hospitals by Major Cities 2019	658
Table 3.181 Chemical Drug Sales in Beijing Public Hospitals 2015-2019	659
Table 3.182 Top 10 Chemical Drug Brands in Beijing Public Hospitals 2019	659

Table 3.183 Chemical Drug Sales in Guangzhou Public Hospitals 2015-2019.....	660
Table 3.184 Top 10 Chemical Drug Brands in Guangzhou Public Hospitals 2019	660
Table 3.185 Chemical Drug Sales in Shanghai Public Hospitals 2015-2019	660
Table 3.186 Top 10 Chemical Drug Brands in Shanghai Public Hospitals 2019.....	660
Table 3.187 Chemical Drugs Sales in Rep Public Hospitals in 16 Major Cities 2018 ..	661
Table 3.188 GDP and Population in Beijing, Shanghai & Guangzhou 2018.....	662
Table 3.189 Top 5 TCs by Public Hospital Sales in Beijing, Shanghai and Guangzhou 2018	662
Table 3.190 Top 10 Chemical Drug Brands by Sales in Beijing Public Hospitals 2018	662
Table 3.191 Top 10 Chemical Drug Brands by Sales in Shanghai Public Hospitals 2018	663
Table 3.192 Top 10 Chemical Drug Brands by Sales in Guangzhou Public Hospitals 2018	663
Table 3.193 Share of Patient Visits to County Hospitals by Province 2019	664
Table 3.194 Share of County Hospital Inpatients by Province 2019	664
Table 3.195 Shanghai Drug Market by Terminal Sales Channels 2019.....	666
Table 3.196 Quarterly Shanghai Hospital Drug Market* 2015-2019	666
Table 3.197 Shanghai Hospital Drug Market by TCs 2018-2019.....	666
Table 3.198 Shanghai Drug Market – Tier 1 Therapeutic Category Growth.....	666
Table 3.199 Top 10 Drug Suppliers to Shanghai Hospitals 2019	667
Table 3.200 Top 10 Drug Products by Sales in Shanghai Hospitals 2019	667
Table 3.201 Provincial Level Hospital Drug Markets 2017.....	667
Table 3.202 Chinese Hospitals Market Growth by City Tiers 2017	668
Table 3.203 Chinese Hospitals Market Share by City Tiers Q4/2017	668
Table 3.204 Regional Chinese Pharma Distribution Sales in 2020.....	669
Table 3.205 Regional Pharmaceutical Distributor Sales Structure 2016-2020.....	670
Table 3.206 Top 15 Regional Drug Distributors by Operating Revenues 2016.....	670
Table 3.207 Geographic Coverage of 15 Regional Drug Distributors.....	671
Table 3.208 Top 15 Regional Drug Distributors by Gross Profit Margin 2016.....	671

Table 3.209 Share and Growth of Major Chinese Provincial Retail Pharmacy Markets 2018.....	672
Table 3.210 Offline Retail Pharmacy Drug Sales by City Tiers 2017-2018.....	673
Table 3.211 Top 10 Chemical Drug TCs by Urban Retail Pharmacy Sales in North China 2016.....	674
Table 3.212 Top 10 TCM TCs by Urban Retail Pharmacy Sales in North China 2016	674
Table 3.213 Top 10 Chemical Drug TCs by Urban Retail Pharmacy Sales in East China 2016.....	674
Table 3.214 Top 10 TCM TCs by Urban Retail Pharmacy Sales in East China 2016...	675
Table 3.215 Top 10 Chemical Drug TCs by Urban Retail Pharmacy Sales in West China 2016.....	675
Table 3.216 Top 10 TCM TCs by Urban Retail Pharmacy Sales in West China 2016..	676
Table 3.217 Top 10 Chemical Drug TCs by Urban Retail Pharmacy Sales in Central South China.....	676
Table 3.218 Top 10 TCM TCs by Urban Retail Pharmacy Sales in Central South China 2016.....	676
Table 3.219 Top 15 Provinces by Share of CHC Patient Visits 2015	677
Table 3.220 Growth of Drugs Sales Value in Tier 1 Cities 2015: Hospitals VS. CHCs	678
Table 3.221 Regional Shares of Chinese BMI Spending 2018.....	678
Table 3.222 Average # of Months BMI Surplus May Last by Region 2018.....	679
Table 3.223 Top Ten Pharma Cos by Chinese Hospital and Retail Drug Sales 2019....	681
Table 3.224 Hospital Market Shares of Local, JV and Imported Drugs 2006-2019.....	682
Table 3.225 Urban Hospital Drug Sales Structure: MNCs vs. Domestics 2013-2019 ..	682
Table 3.226 Hospital Drug Sales Growth by City Tier: MNCs vs. Domestics, 2016-2019	683
Table 3.227 MNC Chinese Urban Hospital Drug Market Shares by City Tiers 2013-2019	683
Table 3.228 Healthcare Expenditure Comparisons in Ten Countries 2005-2018*	683
Table 3.229 China Revenues of MNCs in 2019	684
Table 3.230 CAGR of Top 11 MNCs Sales in Rep Chinese Hospitals 2013-2018	684

Table 3.231 Segmentation of 2019 MNC Drug Sales in China by Product Launch Time (1)	685
Table 3.232 Segmentation of 2019 MNC Drug Sales in China by Product Launch Time (2)	685
Table 3.233 China Sales Segmentation of Top 11 MNCs 2019	685
Table 3.234 Chinese Rep Hospital Market Share by Tier 2018: MNCs vs. Domestics	686
Table 3.235 Roche’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	686
Table 3.236 AstraZeneca’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	686
Table 3.237 Novartis’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	686
Table 3.238 Sanofi’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	687
Table 3.239 Eli Lilly’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	687
Table 3.240 Bayer’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	687
Table 3.241 GSK’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	687
Table 3.242 Pfizer’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	688
Table 3.243 BMS’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	688
Table 3.244 MSD’s Chinese Rep Hospital Drug Sales Segmentation by TCs 2018	688
Table 3.245 Ranking of Top 19 Pharma Cos by Sales Value in Chinese Rep Hospitals 2010-2018	688
Table 3.246 Drug Sales/Growth in Chinese Rep Hospitals 2016-2018: MNCs vs. Domestics	689
Table 3.247 Drug Sales/Growth in Chinese Rep Hospitals 2016-2018: Top 10 Players	689
Table 3.248 China Sales Growth of Top 10 Pharma Cos 2010-2020E: MNCs vs. Domestics	690
Table 3.249 # of New Drug Approvals 2016-2019: MNCs vs. Domestics	690
Table 3.250 # of New Drug Approvals of Leading Players in 2019	690
Table 3.251 Overview of National Reimbursement Drug List (NRDL) 2000-2019	691
Table 3.252 # of New/Renewed 2019 NRDL Product Listings of Leading Players	691
Table 3.253 Share of Chinese Clinical Trial Approvals by Company Type 2016-2019	692
Table 3.254 Share of Chinese Clinical Trial Approvals by TCs 2019: China vs. U.S.	692

Table 3.255 Global and China Performances of Selected MNCs in H1/2020.....	694
Table 3.256 Iressa Quarterly Sales in China Q1/2019-Q2/2020.....	694
Table 3.257 Lipitor and Novasc Quarter Sales in China Q1/2019-Q2/2020	695
Table 3.258 Snapshot of MNCs Pharma Revenues in China 2019.....	695
Table 3.259 Top Eight MNCs by China Revenue Size 2019.....	696
Table 3.260 Top Six Drug Products by Revenue in Urban Chinese Hospitals 2019.....	697
Table 3.261 Top 7 Diseases by Mortality Rate among Chinese Urban Residents.....	699
Table 3.262 Leading Causes of Death in China.....	700
Table 3.263 Growth of NCDs in China 2002-2012	701
Table 3.264 NCD Awareness, Treatment and Control Rates: China v.s. USA	701
Table 3.265 # of Newly-included Drug Products by TCs in 2017 NRDL.....	702
Table 3.266 Chinese Clinical Trials by Disease Categories	702
Table 3.267 China’s Population Structure by Age Group 1995-2040E.....	703
Table 3.268 Rear and Forward View of Chinese Drug Markets for Three Major Chronic Diseases.....	703
Table 3.269 Chinese Drug Markets for Three Major Chronic Diseases 2016-2018 (1)	703
Table 3.270 Chinese Drug Markets for Three Major Chronic Diseases 2016-2018 (2)	703
Table 3.271 Top 10 Provinces by Sales Share of Three Chronic Disease Drugs in China 2018.....	704
Table 3.272 Chinese Drug Markets for Three Major Chronic Diseases by City Tier and Terminal Markets	704
Table 3.273 Chinese Drug Markets for Three Major Chronic Diseases 2016-2018: MNCs vs. Domestics (1)	705
Table 3.274 Chinese Drug Markets for Three Major Chronic Diseases 2016-2018: MNCs vs. Domestics (2)	705
Table 3.275 Chinese Drug Markets for Three Major Chronic Diseases 2016-2018: MNCs vs. Domestics (3)	705
Table 3.276 Rear/Forward View of Chinese Antihypertensive Drug Market 2016-2023E (1).....	705
Table 3.277 Rear/Forward View of Chinese Antihypertensive Drug Market 2016-2023E (2).....	706

Table 3.278 Forecast of Chinese Antihypertensive Drug Market by Terminals 2018-2023E	706
Table 3.279 Segmentation of the Chinese Antihypertensive Drug Market 2016-2018 (1)	706
Table 3.280 Segmentation of the Chinese Antihypertensive Drug Market 2016-2018 (2)	706
Table 3.281 Average Price of Antihypertensive Drugs by Terminal Markets 2016-2018	707
Table 3.282 Sale Volume of Antihypertensive Drugs by Terminal Markets 2016-2018	707
Table 3.283 Market Share by Volume of Antihypertensive Drugs by Channels 2016-2018	707
Table 3.284 Top 10 Antihypertensive Drugs in Urban Hospitals 2018.....	707
Table 3.285 Top 10 Antihypertensive Drugs in County Hospitals 2018.....	708
Table 3.286 Top 10 Antihypertensive Drugs in CHCs 2018.....	708
Table 3.287 Rear/Forward View of Chinese Oral Hypoglycemic Drug Market 2016-2023E (1)	708
Table 3.288 Rear/Forward View of Chinese Oral Hypoglycemic Drug Market 2016-2023E (2)	709
Table 3.289 Forecast of Chinese Oral Hypoglycemic Drug Market by Terminals 2018-2023E	709
Table 3.290 Segmentation of the Chinese Hypoglycemic Drug Market 2016-2018 (1)	709
Table 3.291 Segmentation of the Chinese Hypoglycemic Drug Market 2016-2018 (2)	710
Table 3.292 Average Price of Oral Hypoglycemic Drugs by Terminal Markets 2016-2018	710
Table 3.293 Sale Volume of Oral Hypoglycemic Drugs by Terminal Markets 2016-2018	710
Table 3.294 Market Share by Volume of Oral Hypoglycemic Drugs by Terminal Markets 2016-2018.....	710
Table 3.295 Top 10 Oral Hypoglycemic Drugs in Urban Hospitals 2018	710
Table 3.296 Top 10 Oral Hypoglycemic Drugs in County Hospitals 2018	711
Table 3.297 Top 10 Oral Hypoglycemic Drugs in CHCs 2018.....	711

Table 3.298 Rear/Forward View of Chinese Lipid-lowering Drug Market 2016-2023E (1)	712
Table 3.299 Rear/Forward View of Chinese Lipid-lowering Drug Market 2016-2023E (2)	712
Table 3.300 Forecast of Chinese Lipid-lowering Drug Market by Terminals 2018-2023E	712
Table 3.301 Segmentation of the Chinese Lipid-lowering Drug Market 2016-2018 (1)	712
Table 3.302 Segmentation of the Chinese Lipid-lowering Drug Market 2016-2018 (2)	713
Table 3.303 Average Price of Lipid-lowering Drugs by Terminal Markets 2016-2018	713
Table 3.304 Sale Volume of Lipid-lowering Drugs by Terminal Markets 2016-2018 ..	713
Table 3.305 Market Share by Volume of Lipid-lowering Drugs by Terminal Markets 2016-2018.....	713
Table 3.306 Top 10 Lipid-lowering Drugs in Urban Hospitals 2018	714
Table 3.307 Top 10 Lipid-lowering Drugs in County Hospitals 2018.....	714
Table 3.308 Top 10 Lipid-lowering Drugs in CHCs 2018.....	714
Table 3.309 Major Chinese pharmas developing DPP-4 inhibitors.....	719
Table 3.310 Major Chinese pharmas developing GLP-1 agonists.....	719
Table 3.311 Major Chinese pharmas developing insulin	720
Table 3.312 Major Chinese pharmas developing SGLT-2 inhibitors.....	720
Table 3.313 Consumption of Chemical Diabetes Drugs of Major Provincial level Public Hospitals 2013-2018	721
Table 3.314 Top Ten Diabetes Drugs in Major Provincial level Public Hospitals 2018	721
Table 3.315 Shares of Top Ten Diabetes Drug Suppliers to Major Provincial level Public Hospitals 2018	722
Table 3.316 Diabetes Chemical Drug by Sales in Major Urban Public Hospitals 3Qs/2018	723
Table 3.317 Diabetes Chemical Drug by Category in Urban Public Hospitals 3Qs/2018	723
Table 3.318 Diabetes Chemical Drugs by Dosage Form in Urban Public Hospitals 3Qs/2018.....	723

Table 3.319 Top Ten Diabetes Drugs by Sales in Urban Public Hospitals 2016-3Qs/2018	724
Table 3.320 Top Ten Diabetes Drug Brands by Sales in Urban Public Hospitals 2016-3Qs/2018	724
Table 3.321 Share of Digestive Tract & Metabolic Drugs in Chinese Rx Drug Market 2016-2018.....	725
Table 3.322 Chinese Rx Drug Market Share: Cardiovascular Drugs	725
Table 3.323 Cardiovascular Chemical Drug Sales in Urban Chinese Pharmacies 2017-2019.....	725
Table 3.324 Top 20 Cardiovascular Chemical Drug Manufacturers to Urban Chinese Pharmacies 2019	726
Table 3.325 Top 20 Cardiovascular Chemical Drugs in Urban Chinese Pharmacies 2019	726
Table 3.326 Leading TCs of Cardiovascular Drug Consumption by Rep Urban Hospitals 2018.....	727
Table 3.327 Top 10 Suppliers of Cardiovasculars to Rep Urban Hospitals 2018	727
Table 3.328 Top 10 Cardiovascular Drugs by Value of Rep Urban Hospitals 2018	728
Table 3.329 Chinese Oncology Drug Market Project 2008-2018.....	730
Table 3.330 Share of Anticancers & Immuno-Regulators in Chinese Rx Drug Market 2016-2018.....	731
Table 3.331 CAGR Growth of Chinese Antiviral Drug Market 2013-2030E.....	744
Table 3.332 China Antiviral Drug Market Size 2013-2030E.....	744
Table 3.333 China Antiviral Drug Market Share by Sub-category 2018	744
Table 3.334 Cause of Respiratory Diseases in Shanghai H1/2016	746
Table 3.335 COPD Incidence Rate by Gender in Shanghai.....	746
Table 3.336 COPD Incidence Rate by Age in Shanghai	746
Table 3.337 Top 10 COPD Drugs in Shanghai Rep Hospitals.....	747
Table 3.338 PD Drug Consumption by Rep Chinese Hospitals 2013-2017	753
Table 3.339 Top 10 PD Drugs in Chinese Rep Hospitals by Share in 2017	753
Table 3.340 Statistical Summary of Chinese Senior Population.....	754

Table 3.341 Consumption of Geriatric Drugs in Major Urban Public Hospitals 2011-2014	754
Table 3.342 Approval and Reimbursement of Drugs for Listed Rare Diseases (Batch 1) in China	759
Table 3.343 22 Rare Diseases Treated Off-label by Existing Drugs on the Market	759
Table 3.344 Treatment Costs of Unreimbursed Drugs for 13 Rare Diseases	760
Table 3.345 Chinese Generic Drug Market Size 2016-2021E.....	768
Table 3.346 Generic Drug Shares in Three Major Terminal Drug Markets 2016	768
Table 3.347 Top 10 Generic Drug TCs in Chinese Rep Hospitals 2016.....	768
Table 3.348 Top 13 Generic Drug Cos with CNY 10B+ Revenue 2016	769
Table 3.349 Major Product Market Shares: Originator Drugs vs. Generics 2017.....	769
Table 3.350 Oral WM Market Shares: Originators vs. Generics/MNCs vs. Domestics 2017	770
Table 3.351 Chinese Western Medicine Market Shares MAT Q3/2018	770
Table 3.352 Top 10 Brands by Value in MAT Q3/2018 (China vs. the U.S.).....	770
Table 3.353 Public Medical Institution Drug Sales 2019-2020: Originators vs. Generics	772
Table 3.354 Drugs Sales Segmentation 2017–H1/2020: Originator vs. Generic Drugs	772
Table 3.355 Public Medical Institution Drug Sales H1/2019-H1/2020: Originators vs. Generics	772
Table 3.356 Chinese Vaccine Consumption 2005-2020E.....	774
Table 3.357 Compound Vaccines with No Local Production in China	775
Table 3.358 Polyvalent Vaccines with No Local Production in China	775
Table 3.359 Therapeutic Vaccines Launched Outside China.....	775
Table 3.360 Application Status of Therapeutic Vaccines in China 2017	776
Table 3.361 Chinese Vaccine Market Size by Value 2013-2019	778
Table 3.362 Chinese Vaccine Market Size by Volume 2013-2019	778
Table 3.363 Batch Released Vaccine Volume 2007-Q1/2019.....	778
Table 3.364 Chinese Vaccine Market Shares by Company Type 2018.....	779
Table 3.365 Top 10 Biologics by Batch Release Sales in China 2014-2018.....	779

Table 3.366 Vaccine Consumption at Rep Chinese Hospitals 2008-2017	784
Table 3.367 Chinese PPV 23 Market Shares of Producers 2017	784
Table 3.368 Chinese Hep B Vaccine Market Shares of Producers 2017.....	784
Table 3.369 Top 5 Human Rabies Vaccine Sales in Major Urban Hospitals 2008-2017	785
Table 3.370 Top 5 Cowpox Vaccine Sales in Major Urban Hospitals 2012-2017.....	785
Table 3.371 Top 5 Pseudomonas Aeruginosa Vaccine Sales in Major Urban Hospitals 2012-2017.....	785
Table 3.372 Top 5 BCG Vaccine Sales in Major Urban Public Hospitals 2012-2017 ...	785
Table 3.373 Top 5 Recombinant HepB Vaccine Sales in Major Urban Hospitals 2008-2017	786
Table 4.1 Number of Pharma Manufacturers 2013-2020.....	807
Table 4.2 Overview of All Registration Applications in 2011-2020	810
Table 4.3 Breakdown of Drug Registration Applications Concluding CDE Review 2013-2020 (1).....	810
Table 4.4 Breakdown of Drug Applications with Concluded CDE Review 2013-2020 (2)	810
Table 4.5 Breakdown of Registration Applications with Concluded CDE Review in 2020	811
Table 4.6 Breakdown of CDE Recommendations for Chemical Drug Applications in 2020	811
Table 4.7 Breakdown of CDE-concluded Chemical Drug Registration Applications 2012-2020.....	812
Table 4.8 Chemical Drug NDAs and INDs with Concluded CDE Review in 2015-2020	812
Table 4.9 CDE Approved Class 1 Chemical New Drug INDs by TCs 2020	812
Table 4.10 Breakdown of CDE Recommendations for TCM Registration Applications in 2020.....	813
Table 4.11 # of Concluded TCM Registration Applications by the CDE in 2012-2020	813
Table 4.12 Breakdown of TCM Registration NDA and IND Applications by the CDE in 2015-2020.....	814

Table 4.13 Breakdown of CDE Recommendations for Biological Product Applications in 2020.....	814
Table 4.14 # of Concluded Biological Product Registration Applications by the CDE in 2012-2020	814
Table 4.15 Breakdown of Biological Product Registration NDA and IND Applications by the CDE in 2015-2020	815
Table 4.16 # of Administrative Approvals Completed by the CDE 2018-2020	815
Table 4.17 Breakdown of CDE Administrative Approvals 2020.....	815
Table 4.18 No. of Newly Accepted Applications Subject to CDE Review 2013-2020.	816
Table 4.19 No. of Newly Accepted Applications Subject to CDE Review 2016-2020.	816
Table 4.20 Breakdown of Newly Accepted Applications Subject to CDE Review 2020	816
Table 4.21 Breakdown of CDE-Accepted Class 1 New Drug Applications 2020 (1)...	817
Table 4.22 Breakdown of CDE-Accepted Class 1 New Drug Applications 2020 (2)...	817
Table 4.23 Chemical Drug Registration Applications Accepted by CDE in 2011-2020	817
Table 4.24 Breakdown of CDE Accepted Chemical New Drug Applications 2014-2020	818
Table 4.25 TCM Registration Applications Accepted by the CDE in 2012-2020	818
Table 4.26 Biological Product Registration Applications Accepted by the CDE in 2012-2020.....	818
Table 4.27 # of Administrative Approval Applications Accepted by the CDE 2018-2020	819
Table 4.28 Breakdown of Administrative Approval Applications Accepted by the CDE 2020.....	819
Table 4.29 Breakdown of Registration Applications Granted Priority Review 2016-2019 (1).....	819
Table 4.30 Breakdown of Registration Applications Granted Priority Review 2016-2019 (2).....	820
Table 4.31 Breakdown of Registration Applications Granted Priority Review in 2020 (1)*	820
Table 4.32 Breakdown of Registration Applications Granted Priority Review in 2020 (2)*	821

Table 4.33 Breakdown of Products Granted Priority Review 2016-2020.....	821
Table 4.34 Structure of Priority Review Products 2016-2020	821
Table 4.35 # of Communication Meeting Requests and Fulfillment with CDE 2016-2020	822
Table 4.36 Breakdown of Communication Meeting Requests and Fulfillment with CDE 2020.....	822
Table 4.37 Breakdown of Communication Meeting Requests to and Fulfillment by CDE 2018-2020.....	822
Table 4.38 No. of Drug Registration Applications Accepted by CDE 2017-2020.....	823
Table 4.39 CDE-Accepted Drug Registration Applications 2019-2020 by Category (1)	823
Table 4.40 CDE-Accepted Drug Registration Applications by Category 2020 (2)	824
Table 4.41 Type of Drug Registration Applications under CDE Review 2020.....	824
Table 4.42 No. of New Drug Registration Applications Accepted by CDE 2016-2020	824
Table 4.43 Type of New Drug Registration Applications Accepted by CDE 2020	825
Table 4.44 Type of CDE-Accepted Chemical Drug Registration Applications 2020	825
Table 4.45 Type of CDE-Accepted TCM Registration Applications 2020	825
Table 4.46 Type of CDE-Accepted Biologic Registration Applications 2020.....	825
Table 4.47 Vaccine Registration Applications Accepted by CDE.....	826
Table 4.48 Antibody Accepted by CDE and Launched in 2020.....	826
Table 4.49 Recombinant Proteins Accepted by CDE and Launched in 2020	827
Table 4.50 Biologics Approved for the First Time in China H1/2020	827
Table 4.51 New Indication Approvals of Small Molecule Drugs H1/2020	827
Table 4.52 Urgently-Needed Foreign New Drugs First Approved in China H1/2020...	828
Table 4.53 # of Drug Registration Applications Accepted by CDE 2011-2019.....	828
Table 4.54 Breakdown of Registration Applications under CDE Review 2018-2019...	829
Table 4.55 Breakdown of Chemical Drug Registration Applications under CDE Review 2019 (1)	829
Table 4.56 Breakdown of Chemical Drug Registration Applications under CDE Review 2019 (2)	829

Table 4.57 # of CDE Review-concluded Applications 2019	829
Table 4.58 Breakdown of CDE Review-concluded Chemical Drug Applications 2019	830
Table 4.59 Breakdown of CDE Recommendations for Chemical Drug Applications 2019	830
Table 4.60 Number of Drug CTAs and PCTRs in China 2018-2020	831
Table 4.61 Structure of Clinical Trial Registrations by Phase 2019-2020.....	831
Table 4.62 Structure of Clinical Trial Registrations by Product Category 2020	831
Table 4.63 Top 10 Drugs by # of Clinical Trial Registrations 2020	831
Table 4.64 Drug Clinical Trial Registrations by ATC 2020.....	832
Table 4.65 Top 5 Anticancers by # of Clinical Trial Registrations 2020	832
Table 4.66 Top 5 Applicants by # of Anticancer Clinical Trial Registrations 2020	832
Table 4.67 # of GQCE Bioequivalence Studies 2016-2020	832
Table 4.68 Top 10 Applicants by # of GQCE Bioequivalence Studies 2020.....	833
Table 4.69 Top 10 Drugs # of GQCE Bioequivalence Studies 2020	833
Table 4.70 Top 10 Drug Clinical Trial Sponsors by # of Registrations 2020	833
Table 4.71 Top 10 Drug Clinical Trial Institutions by # of PCTRs 2020	834
Table 4.72 Top 10 KOLs by # of Drug Clinic Trial Registrations 2020.....	834
Table 4.73 Type of Priority Review Drug Registration Applications 2020	834
Table 4.74 Structure of Drug Applications Accepted by CDE for Priority Review	835
Table 4.75 Annual # of Drug Applications Accepted by CDE for Priority Review	836
Table 4.76 Snapshot of grounds on which priority review are granted 2016-11/2018..	836
Table 4.77 Drug Applications under Accelerated Review by the CDE 2004-2017.....	837
Table 4.78 Composition of Drug Applications under Accelerated Review by the CDE 2004-2017	837
Table 4.79 Pharma-related Regulatory Introductions in China in 2016-2020 and H1/2021	841
Table 4.80 Pharma-related Regulations and Policies Newly Issued in H1/2021 (1).....	841
Table 4.81 Pharma-related Regulations and Policies Newly Issued in H1/2021 (2).....	843
Table 4.82 Quarterly Pharma-Related Regulatory Introductions in China in 2015-2020	843

Table 4.83 Pharma-related Regulations and Policies Newly Issued in 2020 (1)	844
Table 4.84 Pharma-related Regulations and Policies Newly Issued in 2020 (2)	845
Table 4.85 Pharma-related Regulations and Policies Newly Issued in 2020 (3)	846
Table 4.86 Pharma-related Regulations and Policies Newly Issued in 2020 (4)	847
Table 4.87 # of Generic Drug Applications Accepted by CDE 2015-2018	866
Table 4.88 Share of Generic Drug Application by Class Type 2015-2018	866
Table 4.89 Top 15 Companies by Generic Drug Applications 2018	866
Table 4.90 Top 15 Companies by Generic Drug Applications 2017	867
Table 4.91 The Internal Organizational Structure and Departmental Responsibilities of Provincial Branches of NHTA	917
Table 4.92 The Internal Organizational Structure and Departmental Responsibilities of Local HSA Branches below Provincial Level	918
Table 4.93 New Classification System for Registration and Exclusivity of Chemical Drugs	942
Table 5.1 Overall Chinese Terminal Drug Market Growth and Value 2011-2020	1433
Table 5.2 Chinese Drug Market Segmentation 2020: Terminals and Sub-markets	1434
Table 5.3 China's Three Major Terminal Drug Markets 2010-2020 – Retail Value and Market Share	1434
Table 5.4 Overall Chinese Pharma Market by Terminal Market 2020 (1)	1435
Table 5.5 Overall Chinese Pharma Market by Terminal Market 2020 (2)	1435
Table 5.6 Overall Chinese Pharma Market by Terminal Market 2020 (3)	1436
Table 5.7 Overall Chinese Pharma Market 2020: Rx Drugs vs. OTC Drugs (1)	1436
Table 5.8 Overall Chinese Pharma Market 2020: Rx Drugs vs. OTC Drugs (2)	1436
Table 5.9 Top Ten Pharma Cos by Chinese Hospital and Retail Drug Sales 2020	1437
Table 5.10 Number of Facilities by Drug Sales Channel 2020	1437
Table 5.11 Size of Chinese Pharmaceutical Market 2013-2019	1438
Table 5.12 Innovative Drug Sales Value in China 2012-2018	1438
Table 5.13 China Drug Market Size and Growth 2007-2020E	1438
Table 5.14 Chinese Drug Market Share by Sales Channels 2007-2020E	1439
Table 5.15 Chinese Retail Pharmacy Quarterly Sales and Growth 2007-Q1/2020	1439

Table 5.16 Chinese Hospital Drug Sales Value 2015-MAT Q2/2021	1440
Table 5.17 Chinese Public Medical Institution Drug Sales 2011-2020	1442
Table 5.18 Public Medical Institution Drug Consumption by Facility Type 2010-2020	1443
Table 5.19 Chinese Urban Rep Hospital Drug Market 2012-2020.....	1444
Table 5.20 Chinese Retail Pharmacy Drug Market Overview 2011-2020.....	1446
Table 5.21 Size of Chinese Retail Pharmacy Market 2011-2018	1448
Table 5.22 # of Retail Pharmacy Stores in China and Their Service Population 2010-2018	1448
Table 5.23 Revenue Growth of Chemical Drug Producers 2015-2020E.....	1450
Table 5.24 Chinese Pharma Industry Performance M1-7/2019.....	1451
Table 5.25 Chinese Pharma Industry Performance 2005-2019.....	1451
Table 5.26 China Revenues of Eight Leading MNC Pharma Cos in 2020 (\$ mlns) ...	1454
Table 5.27 Global and China Performance of Eight MNCs in 3Qs/2020.....	1457
Table 5.28 Near-Term MNC Product Launch Plan in China.....	1457
Table 5.29 Global and China Performances of Selected MNCs in H1/2020.....	1458
Table 5.30 Iressa Quarterly Sales in China Q1/2019-Q2/2020.....	1458
Table 5.31 Lipitor and Novasc Quarter Sales in China Q1/2019-Q2/2020	1459
Table 5.32 Snapshot of MNCs Pharma Revenues in China 2019.....	1459
Table 5.33 Top Eight MNCs by China Revenue Size 2019.....	1460
Table 5.34 Top Six Drug Products by Revenue in Urban Chinese Hospitals 2019.....	1461
Table 5.35 29 MNC Drug Products in the 2020 NRDL	1461
Table 5.36 11 Listed Domestic Medpharm Cos with over CNY 1B in Net Profits Q1/2021	1477
Table 5.37 Top 10 Chinese Pharma Companies by Sales Revenue 3Qs/2020	1478
Table 5.38 Performance of 17 Leading A Share-listed Medpharm Cos 3Qs/2020.....	1478
Table 5.39 Sales and R&D Spending by A Share-listed Medpharm Cos 3Qs/2020....	1479
Table 5.40 Share of Sales Expense in Revenues of A Share-listed Medpharm Cos....	1479
Table 5.41 Structure of Sales Expenses A Share-listed Medpharm Cos 3Qs/2020	1479

Table 5.42 Top Ten Newly-listed Companies by Market Capitalization 2020	1480
Table 5.43 Newly-listed Chinese Chemical Drug Formulation Companies in 2020 ...	1480
Table 5.44 Newly-listed Chinese Biologic Companies in 2020.....	1481
Table 5.45 Income Distribution among the Chinese Population.....	1530
Table 5.46 Sales and R&D Spending by A Share-listed Medpharm Cos 3Qs/2020	1546
Table 5.47 Share of Sales Expense in Revenues of A Share-listed Medpharm Cos	1546
Table 5.48 Structure of Sales Expenses A Share-listed Medpharm Cos 3Qs/2020.....	1546
Table 5.49 Leading Six A Share-Listed Chinese Biopharma Cos by R&D Spending 2020	1547
Table 5.50 Sales Performance of 3 Drugs in the 1st Round of BMI Negotiation (CNY mln)	1563
Table 5.51 Summary of Chinese Pharma Events Q2/2021 and H1/2021	1576
Table 5.52 Summary of Sino-foreign Licensing Deals in H1/2021 (1)	1577
Table 5.53 Summary of Sino-foreign Licensing Deals in H1/2021 (2)	1578
Table 5.54 Summary of Sino-foreign Licensing Deals in H1/2021 (3)	1579
Table 5.55 Summary of Sino-foreign Licensing Deals in H1/2021 (4)	1580
Table 5.56 Summary of Sino-foreign Licensing Deals in H1/2021 (5)	1581
Table 5.57 Summary of Sino-foreign Licensing Deals in H1/2021 (6)	1582
Table 5.58 Summary of Sino-foreign Licensing Deals in H1/2021 (7)	1583
Table 5.59 Summary of Sino-foreign Licensing Deals in H1/2021 (8)	1584
Table 5.60 Summary of Selected JV/Strategic Alliance Deals in H1/2021 (1).....	1584
Table 5.61 Summary of Selected JV/Strategic Alliance Deals in H1/2021 (2).....	1585
Table 5.62 Summary of Selected JV/Strategic Alliance Deals in H1/2021 (3).....	1586
Table 5.63 Summary of Sino-foreign Contract Research/Collaborative R&D Agreements in H1/2021 (1).....	1586
Table 5.64 Summary of Sino-foreign Contract Research/Collaborative R&D Agreements in H1/2021 (2)	1587
Table 5.65 Summary of Sino-foreign M&A Deals in H1/2021	1587
Table 5.66 Summary of Chinese Pharma Events in 2015 – 2020	1589
Table 5.67 Summary of Sino-foreign Licensing Deals in 2020 (1)	1589

Table 5.68 Summary of Sino-foreign Licensing Deals in 2020 (2).....	1590
Table 5.69 Summary of Sino-foreign Licensing Deals in 2020 (3).....	1591
Table 5.70 Summary of Sino-foreign Licensing Deals in 2020 (4).....	1592
Table 5.71 Summary of Sino-foreign Licensing Deals in 2020 (5).....	1593
Table 5.72 Summary of Sino-foreign Licensing Deals in 2020 (6).....	1594
Table 5.73 Summary of Sino-foreign Licensing Deals in 2020 (7).....	1595
Table 5.74 Summary of Sino-foreign Licensing Deals in 2020 (8).....	1596
Table 5.75 Summary of Sino-foreign Contract Research/Collaborative R&D Agreements in 2020 (1).....	1597
Table 5.76 Summary of Sino-foreign Contract Research/Collaborative R&D Agreements in 2020 (2).....	1598
Table 5.77 Summary of Sino-foreign Contract Research/Collaborative R&D Agreements in 2020 (3).....	1599
Table 5.78 Summary of Selected JV/Strategic Alliance Deals in 2020 (1)	1599
Table 5.79 Summary of Selected JV/Strategic Alliance Deals in 2020 (2)	1600
Table 5.80 Summary of Selected JV/Strategic Alliance Deals in 2020 (3)	1601
Table 5.81 Summary of Selected JV/Strategic Alliance Deals in 2020 (4)	1602
Table 5.82 Summary of Selected JV/Strategic Alliance Deals in 2020 (5)	1603
Table 5.83 Summary of Sino-foreign M&A Deals in 2020	1603
Table 5.84 Distribution of China New Drug Licensing Deals in by Licensor Region 2020	1605
Table 5.85 Distribution of China New Drug Licensing Deals in by Licensor Type 2020	1605
Table 5.86 China New Drug In-licensing Deals over CNY 300M in 2020 (1)	1605
Table 5.87 China New Drug In-licensing Deals over CNY 300M in 2020 (2)	1605
Table 5.88 Distribution of China New Drug Licensing Deals in by R&D Status 2020	1606
Table 5.89 Distribution of China New Drug Licensing Deals by Indication 2020.....	1606
Table 5.90 Top 11 Companies by No. of China New Drug License Deals 2020.....	1607
Table 5.91 China New Drug Out-licensing Deals over CNY 300M in 2020 (1).....	1607

Table 5.92 China New Drug Out-licensing Deals over CNY 300M in 2020 (2).....	1607
Table 5.93 Ten Out-licensing Deals of China-Originated New Drugs by Deal Value (US\$ bln).....	1608
Table 5.94 Top Ten Out-licensing Deals of China-Originated New Drugs by Upfront Payment (US\$ bln).....	1608
Table 5.95 Out-licensing Deals of China-Originated New Drugs Among Domestic Firms (Small Molecule Drugs).....	1609
Table 5.96 Out-licensing Deals of China-Originated New Drugs Among Domestic Firms (Biologics).....	1610
Table 5.97 Out-licensing Deals of China-Originated New Drugs between Domestic and Foreign Firms (Small Molecule Drugs).....	1611
Table 5.98 Out-licensing Deals of China-Originated New Drugs between Domestic and Foreign Firms (Biologics).....	1611
Table 5.99 Chinese In-licensing Deals by TC in 2020.....	1612
Table 5.100 Major In-licensing Deals of Chinese Cos for New Drug Candidates in 2020.....	1612
Table 5.101 Chinese Out-licensing Deals Involving Novel Chemical Drugs in 2020.....	1614
Table 5.102 Top 15 Innovative Drug In-licensing Deals by Chinese Cos 2020.....	1615
Table 5.103 Projected Chinese Pharma Market Growth (CAGR 2018-2023).....	1629
Table 5.104 Total Chinese Pharma Market Sales Projections (2018-2023) CNY (mln).....	1629
Table 5.105 Total Chinese Pharma Market Sales Projections (2018-2023) US\$ (mln).....	1630
Table 5.106 Forecast of Chinese Drug Market Value by Terminals 2019-2021E.....	1644
Table 5.107 Chinese Retail Pharmacy Market 2020: Online vs. Offline.....	1644
Table 5.108 Domestic Innovative New Drugs Approved in China 2020.....	1645
Table 5.109 NDAs of Domestic Innovative New Drugs Accepted in 2020.....	1646
Table 5.110 A and H Share-listed Chinese Biotech Companies.....	1647
Table 5.111 China-originated New Drugs at Late-Stage Filing in the U.S. and EU....	1648
Table 5.112 Innovative Drugs of Established Chinese Pharma Cos in Late Stage Filing.....	1649

Table 5.113 Bispecific Antibodies Currently under Clinical Development in China ..	1650
Table 5.114 Major Deals Among Domestic Pharma Companies 2018-2020	1650
Table 5.115 Average Price Reduction of Innovative Drugs in BMI 2016-2020	1651
Table 6.1 Chinese Pharma Licensing Deals by Product Type 2019	1765
Table 6.2 # of Chinese Innovative Drug Licensing Deals by Registration Status 2015-2019	1765
Table 6.3 # of Chinese Innovative Drug Licensing Deals by Product Category 2019	1765
Table 6.4 # of Chinese Innovative Drug Licensing Deals by Mechanism 2019.....	1766
Table 6.5 # of Chinese Innovative Drug Licensing Deals by Therapeutic Targets 2019	1766
Table 6.6 Chinese Pharma Licensing Deals Related to Technology Platforms 2019 ..	1766
Table 6.7 Chinese Pharma Licensing Deals by Licensor/Licensee Origins	1767
Table 6.8 Chinese Innovative Drug In-Licensing Deals by TCs 2019	1767
Table 6.9 Chinese Innovative Drug In-Licensing Deals by Registration Status 2015-2019	1767
Table 6.10 Chinese Innovative Drug In-licensing Deals by Therapeutic Target 2019	1768
Table 6.11 Major Chinese Innovative Drug In-licensing Deals 2019.....	1768
Table 6.12 Chinese Startup and Transforming Cos Most Active with Licensing in 2019	1768
Table 6.13 Top 10 Licensing Deals by Upfront Payment 2019	1769
Table 6.14 # of Drug Applications Designated for Priority Review 2016-2021.....	1773
Table 6.15 Drug Applications Designated for Priority Review by TCs.....	1773
Table 6.16 Drug Applications Designated for Priority Review by Supporting Reason	1774
Table 6.17 # of Drug Applications Designated Breakthrough Therapy 2021	1774
Table 6.18 Number of Chinese Drug INDs 2010-2020	1777
Table 6.19 Success Rate of Phase III Drug Clinical Trials of Drug Candidates for Prevalent Cancers.....	1777
Table 6.20 Terminated/Suspended Chinese New Drug Projects due to Efficacy Issues	1778

Table 6.21 Terminated/Suspended Chinese New Drug New Drug Projects due to Safety Issues	1778
Table 6.22 Terminated/Suspended Chinese New Drug Projects due to Market Competitive Issues	1778
Table 6.23 Terminated/Suspended Chinese New Drug Projects due to Other Issues ..	1779
Table 6.24 # of Chinese Companies Initiating FIC R&D 2007-2021E	1783
Table 6.25 Top 25 FIC New Drug Developers in China	1783
Table 6.26 No. of Chinese INDs by Type and Share of FICs in Total	1784
Table 6.27 Breakup of Chinese FIC Projects after 2018 by Type	1784
Table 6.28 Biologic FIC New Drug Projects by Product Category	1784
Table 6.29 Development of Typical Me-Too Products in China.....	1785
Table 6.30 Typical FIC/BIC Products in China	1785
Table 6.31 # of Fundraising in China Healthcare 2014-2021	1785
Table 6.32 # of Investment Firms in China Healthcare 2014-2021	1786
Table 6.33 Cycle of Initial Financing Round 2014-2021	1786
Table 6.34 # of Projects Incubated by Investment Capital Firms 2000-2021	1786
Table 6.35 Innovative Drug Financing in China 2014-2021	1787
Table 6.36 CRO/CDMO Financing in China 2014-2021	1787
Table 6.37 Domestically-developed Class 1 New Drugs Approved by NMPA 2020 ..	1794
Table 6.38 Class I New Drugs Approved by Type in China 2018-H1/2020	1795
Table 6.39 Class I New Drugs Approved in China by TCs 2018-H1/2020	1795
Table 6.40 Class I New Drugs Approved in China 2018-H1/2020	1796
Table 6.41 # of Class 1 New Drugs Accepted by CDE 2016-2017	1797
Table 6.42 CDE-Accepted Class 1 New Drug Applications by TCs 2017	1798
Table 6.43 CDE-Accepted Class 1 Anticancer Applications by Mechanism 2017.....	1798
Table 6.44 Applicant Ranking by # of Class 1 CDE-Accepted New Drug Applications 2017.....	1798
Table 6.45 Class 1 New Drugs Approvals in 2003-2015	1799
Table 6.46 Class 1 New Drug Applicants by Ownership 2003-2015.....	1799

Table 6.47 Class 1 New Drug Applicants by Company Size 2003-2015	1800
Table 6.48 Class 1 New Drug Applicants by Stock Listing 2003-2015	1800
Table 6.49 Class 1 New Drug Approvals by # of Producers 2003-2015	1800
Table 6.50 Approved Class 1 New Drugs by Indications 2003-2015.....	1800
Table 6.51 No. of Recorded New Drug Projects in China in 2016-2020 and H1/2021	1801
Table 6.52 No. of Recorded Novel New Drug Developer in China in 2020-2021	1801
Table 6.53 Chinese New Drug Projects by R&D Phase in 2012-2020 and H1/2021 ..	1801
Table 6.54 Summary of Chinese New Drug Projects Recorded in H1/2021 (1)	1802
Table 6.55 Summary of Chinese New Drug Projects Recorded in H1/2021 (2)	1803
Table 6.56 Number of Recorded Novel New Drug Projects in China in 2015-2020 ..	1804
Table 6.57 Number of Recorded Novel New Drug Developer in China in 2020	1804
Table 6.58 Chinese New Drug Projects by R&D Phase in 2010-2020.....	1804
Table 6.59 Summary of Chinese New Drug Projects Recorded in 2020 (1)	1805
Table 6.60 Summary of Chinese New Drug Projects Recorded in 2020 (2)	1806
Table 6.61 Summary of Chinese New Drug Projects Recorded in 2020 (3)	1807
Table 6.62 Summary of Chinese New Drug Projects Recorded in 2020 (4)	1808
Table 6.63 Imported IND Chemicals Accepted by CDE 2016-2020.....	1808
Table 6.64 Imported IND Chemical Drugs Accepted by CDE 2020.....	1809
Table 6.65 29 MNC Drug Products Listed in the 2020 NRDL	1812
Table 6.66 Nine China-originated New Drugs under BLA/NDA and Approved in the U.S.	1813
Table 6.67 # of Innovative Drugs Approved in China*	1820
Table 6.68 Launch Lag between China and Global First Launch.....	1820
Table 6.69 # of NRDL Listed Molecules (2004–2019)	1820
Table 6.70 Magnitude of Price Reduction (%)	1820
Table 6.71 Breakdown of NRDL-negotiation Drugs by TA, Western Drugs Only	1821
Table 6.72 2015-2019E Revenue Growth for VBP* Impacted LOE Originators	1821
Table 6.73 A Brief History of MNCs Commercial Performance in China	1821

Table 6.74 Chinese CROs/CMDOs Listed in Mainland China, HK and Taiwan	1873
Table 6.75 Chinese Pharmaceutical CRO Market Size 2011-2021E	1882
Table 6.76 Four CRO Companies in Shanghai Stock Market 2016-2017	1883
Table 7.1 Number of Pharma Distribution License Holders 2013-2020.....	1999
Table 7.2 Structure of Chinese Retail Pharmacy Sector 2006-2020	2000
Table 7.3 Chinese Drug Distribution Sector Performance 2011-2020.....	2000
Table 7.4 Chinese Pharma Distributor Sales by Terminal Markets 2020	2001
Table 7.5 Composition of Chinese Pharmaceutical Distributor Sales in 2016-2020 ...	2002
Table 7.6 Chinese Pharmaceutical Distributor Sales in 2020	2002
Table 7.7 Chinese Pharma Distributor Segmentation by Ownership 2020.....	2002
Table 7.8 Regional Chinese Pharma Distribution Sales in 2020.....	2003
Table 7.9 Regional Pharmaceutical Distributor Sales Structure 2016-2020	2004
Table 7.10 Top 100 Chinese Pharma Distributors and Top 100 Retail Companies Sales 2016-2020.....	2005
Table 7.11 E-Commerce Composition of Chinese Drug Distributor Sales 2020.....	2006
Table 7.12 Composition of B2B/B2C Sales by Chinese Drug Distributors 2020.....	2006
Table 7.13 Online Learning Time of Chinese Physicians at Different Rankings.....	2049

LIST OF CHARTS

Chart 1.1 Core Business Revenues of Broad Chinese Pharma Industry 2006 – 2019E	144
Chart 1.2 Pretax Net Profitability Trend of the Chinese Pharma Industry 2000-2019..	144
Chart 1.3 R&D Centers of RDPAC Members by Research Stage in China	188
Chart 1.4 R&D Centers of RDPAC Members by Function in China	188
Chart 1.5 Locations of R&D Centers of RDPAC Members in China.....	189
Chart 2.1 Per capital Healthcare Expenditures 2016 (\$): China vs. Other Countries....	292
Chart 2.2 Medical Institutions Inpatient Beds in China 2009-2020	304
Chart 2.3 Number of Medical Institutions in China 2009-2020	304
Chart 2.4 Healthcare Professionals in China 2009-2020	306
Chart 2.5 Outpatient Visits in China 2009-2020.....	308
Chart 2.6 Inpatients of Medical Institutions in China 2009-2020	309
Chart 2.7 Healthcare Spending by Funding Source 1980-2020 (%)	379
Chart 3.1 Growth of Healthcare Expenditures in China 2000-2020.....	507
Chart 3.2 Growth of Per Capita Healthcare Expenditures in China 1990-2020.....	507
Chart 3.3 Market Share Trend of County Level Hospitals in China 2014-2020	596
Chart 4.1 Administrative Structure of Drug Regulation in China	903
Chart 4.2 Compulsory License Application Process.....	1234
Chart 4.3 The Model for Realizing Minimum Drug Resale Profit Margin in China...	1331
Chart 6.1 Drugs Granted Priority Review in China by Sponsor Company Country (03/2017-01/2021)	1771
Chart 6.2 Local Companies Dominate Biosimilar Market in China.....	1818
Chart 7.1 Structure of the Chinese Pharmaceutical Distribution System in the Old Days	1941
Chart 7.2 Approval Process of Hospital Drug Purchase	1975
Chart 7.3 Hospital Market Potential Assessment Process	1980
Chart 7.4 Pharmaceutical Distribution Channels in the Urban Areas.....	2009
Chart 7.5 Pharmaceutical Distribution through Retail Pharmacies	2010

Chart 7.6 Pharmaceutical Distribution in Sub-urban and Rural Areas (3rd Terminal Market)	2011
Chart 7.7 Dominant Distribution Models Used by MNCs in China	2017

TABLE OF ABBREVIATIONS

ADR – Adverse Drug Reaction	GDP – Gross Domestic Products
AmCham – American Chamber of Commerce	GLP – Good Laboratory Practices
API – Active Pharmaceutical Ingredients	GMP – Good Manufacturing Practices
APP – Administrative Protection of Pharmaceuticals	GSP – Good Supply Practices
ANDA – Abbreviated New Drug Application	IFPMA – International Federation of Pharmaceutical Manufacturer Associations
BMI – Basic Medical Insurance	JV – Joint Venture
CAGR – Compound Annual Growth Rate	M&A – Merger and Acquisition
CCCIEMHP – China Chamber of Commerce for Import & Export of Medicines and Health Products	MIIT – Ministry of Industry and Information Technology
CAPC – China Association of Pharmaceutical Commerce	MOFCOM or MOC – Ministry of Commerce
CFDA – China Food and Drug Administration (predecessor of NMPA)	MOF – Ministry of Finance
ChP – Chinese Pharmacopoeia	MOH – Ministry of Health
CMH – China Monitor Health	MoHRSS – Ministry of Human Resources and Social Security
CNCM – China National Corporation of Medicines	MNCs – Multinational pharmaceutical companies (<i>in the context of this guide</i>)
CNIPA – China National Intellectual Property Administration	MR / PSR – Medical Representative/ Pharmaceutical Sales Representative
CNY – Chinese Yuan	NBS – National Bureau of Statistics
CPA – Chinese Pharmaceutical Association	NCGHSR – National Coordination Group for Healthcare System Reform
CPIIC – China Pharmaceutical Industry Information Center	NDRC – National Development and Reform Commission
CRO – Contract Research Organization	NH – Nicholas Hall & Co.
DRG – Diagnosis Related Groups	NHC – National Health Commission, successor of NHFPC
ED – Erectile Dysfunction	NHFPC – National Health and Family Planning Commission, predecessor of NHC
FDA/USFDA – U.S. Food and Drug Administration	NRCMS – New Rural Cooperative Medical System
FDI – Foreign Direct Investment	NMPA – National Medical Products Administration (formerly CFDA)
FIEs – Foreign Invested Enterprises	NHSA – National Healthcare Security Administration
FTCMs – Formulated TCMs	OECD – Organization for Economic Co-
GCP – Good Clinical Practices	

operation and Development	SMEI – Southern Medicine Economic Institute under the CFDA
OTC – Over the Counter	SOE – State Owed Enterprise
PHIIC – China Pharmaceutical Industry Information Center	SPAC – State Pharmaceutical Administration of China, predecessor of SDA
PRC –People’s Republic of China	STD – Sexually Transmitted Disease
PSR/MR – Pharmaceutical Sales Representative/Medical Representative	TC – Therapeutic Class
QA – Quality Assurance	TCM – Traditional Chinese Medicine
QC – Quality Control	UEBMI – Urban Employee BMI
R&D – Research and Development	URBMI – Urban Resident BMI
RDPAC – R&D-based Pharmaceutical Association Committee in China	URRBMI – Urban and Rural Resident BMI (URBMI+NRCMS)
SATCM – State Administration of Traditional Chinese Medicine	USTR – US Trade Representative
SDA – State Drug Administration, predecessor of SFDA	VAT – Value Added Tax
SFDA – State Food and Drug Administration of China (predecessor of CFDA)	VBP – Volume-based Procurement
SAMR – State Administration for Market Regulation, governing body of NMPA	VC – Venture Capital
SIPO – State Intellectual Property Office	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 NHA 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 NHTA 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 NHTA, 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, NHTA 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 NHTA signed a MOU in September 2020 to establish an information exchange mechanism for commercial bribes 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 year, 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.