

China Pharmaceutical Guide

中国医药市场指南

14th Edition (2019)

Written by:

James J. Shen, MBA

Unrivaled China Healthcare Intelligenece Since 1991

Published by WiCON International Group

WiCON International Group LLC

311 Sayre Drive, Princeton, NJ 08540, USA

Tel: +1 609 903 8881 Fax: +1 801 751 5728

Email: info@pharmachinaonline.com Internet: www.pharmachinaonline.com

China Office

Suite 17D, Building B, Oriental Kenzo Plaza

48 Dongzhimenwai Dajie, Dongcheng District, Beijing 100027, China

Tel: +86 10 8447 6010 Fax: +86 10 8447 6110

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 © 2017 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

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 30-year career to pharmaceutical businesses in China.



James Shen has rich operational and senior level management experience on China's healthcare businesses in the capacities of a senior consultant to multinational pharmaceutical companies, a manager of joint venture projects and companies, a business development executive, an entrepreneur, and most recently a publisher.

James Shen started his career in the pharmaceutical industry in 1987 when he joined Beijing Ciba-Geigy Pharmaceutical Ltd. (now Beijing Novartis) as Assistant to the General Manager. While he studied MBA in England in various periods of 1980s, he worked as an editorial consultant for Scrip/PJB Publications, IMS and Financial Times Business Information on China's healthcare news.

In 1991, he founded WiCON International Group in the USA to provide strategic consulting and competitive intelligence to international healthcare companies in order to assist and facilitate their market entry into China. He has worked with many large and mid-size international pharmaceutical companies on a diverse range of projects including entry strategy development, strategic alliances and joint ventures, marketing and distribution agreements, product registration and clinical trials, licensing and technology transfer, API sourcing, and M&A due diligence.

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

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

In early 2006, following a restructure of WiCON's businesses, James Shen founded **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 Beijing with frequent visits to the U.S., Europe and Japan. He continues to be active in strategic consulting with multinational pharmaceutical companies at headquarter and regional head office levels, as well as selective entrepreneurial and VC/PE investment projects in the Chinese healthcare sector.

PREFACE

Despite the enormous business opportunities and growth prospects offered by China's healthcare sector, I've witnessed and experienced countless regulatory and business environmental changes, which has frequently caused painful business difficulties, frustrations and downfalls, in my past 30 years of work in the sector as a consultant, manager and entrepreneur.

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

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

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

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

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

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

Group accumulated since 1991.

About *China Pharmaceutical Guide 2017 (12th Edition)*

The *China Pharmaceutical Guide 2017 (12th 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 2016/1H2017, 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/pharmaceutical related policies, laws and regulations.

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

- ☞ Hundreds of pages of new data, information, analysis and case studies.
- ☞ Thorough summaries and analysis of the latest healthcare reform, drug pricing & reimbursement and hospital tender purchase policies.
- ☞ Comprehensive industry, market and foreign trade data as well as health statistics are updated with the 2016 (full year) and available figures for the first half of 2017.
- ☞ Expanded coverage on e-commerce and digital marketing opportunities, the primary healthcare sector, OTC and consumer healthcare sector, high growth market segments, regional hospital markets, and the pharma distribution sector,
- ☞ Updated coverage of the Chinese biosimilars/biologics market prospects and regulatory outlook.

- ☞ Updated coverage of emerging legal issues (including latest Chinese government crackdown on corruption in healthcare, FCPA/compliance and liability issues) and drug-related IP and trademark concerns.
- ☞ Comprehensive top line data, research findings and observations from our collaborative partners such as IMS Health, Kantar Health, Nicholas Hall, ZS Associates, Rubicon Strategy Group and RDPAC, as well as other reputable sources including the Chinese Pharmaceutical Association, SMEI and Sinohealth.
- ☞ All regulatory changes in 2016/H12017 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-2017.
- ☞ Focused coverage of China's ongoing efforts to revamp its drug regulatory regime through amendments of the *Drug Administration Law*, its latest proposal and preparations to overhaul the drug pricing mechanism, deepening reform of its drug registration and evaluation regime, new policies to support drug innovation and high clinical value generics, and its initiative to re-evaluate all generic drugs with bioequivalence studies.
- ☞ An updated section covering proposed new drug-related laws and regulations under drafting process with selective previews of the draft versions.
- ☞ Extensive review and analysis of China's drug registration applications and approvals as well as Chinese drug innovation trends in recent years.
- ☞ Comprehensive review of Sino-foreign M&A, joint venture, strategic alliance, licensing, research partnerships, co-marketing, and new drug research events in 2016 and H1/2017.
- ☞ Expanded coverage on MNC strategies in China with healthcare reform in the backdrop, intellectual property/patent law amendments, data exclusivity, patent litigation, drug regulations, pharma marketing and distribution strategies, drug consumption patterns, the Chinese R&D and outsourcing sector, clinical studies/practices, healthcare reform, community healthcare sector, essential drug policy, regional drug consumption patterns, and the vaccine and API sectors.
- ☞ Numerous new case studies are added.

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

James J. Shen

July 30, 2017

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.....	15
LIST OF CHARTS.....	29
TABLE OF ABBREVIATIONS	31
EXECUTIVE SUMMARY	33
PART I OVERVIEW OF THE CHINESE PHARMACEUTICAL SECTOR.....	43
Chapter I-1 China’s Broad Business Environment.....	45
1.1 Fast Economic Growth and Change.....	45
1.2 Integration into the World Economy	46
1.3 Economic Reform	47
1.4 WTO Entry Brought Further Reform and Regulatory Changes.....	48
1.5 Demographic Trends and Challenges.....	51
1.6 Rising R&D Investments and Patent Applications	58
1.7 Foreign Investment: Structure, Trends & Outlook.....	60
1.8 A Bird’s Eye View of the Contemporary Chinese Economy	66
1.9 China’s Economy: The New Normal and the Virtuous Circle	70
1.10 Foreign Firms Need New Strategies For China's 'New Normal'	72
1.11 Business Climate and Outlook – Surveys of Foreign Companies in China	74
1.12 Foreign MNCs Fear Unfair Chinese Law Enforcement.....	81
Chapter I-2 Background: The Chinese Pharmaceutical Sector.....	84
2.1 Introduction.....	84
2.2 Government Guidelines for Pharmaceutical Industry Development.....	91
2.3 Pharmaceutical Sector Reform As A Part of Healthcare Reform	100
Chapter I-3 Overview: The Chinese Pharmaceutical Industry	105
3.1 Overview.....	105
3.2 The Pharmaceutical Formulation Sector.....	111
3.3 The Bulk Drug/Active Pharmaceutical Ingredient and Excipient Sector.....	115
3.4 The Biopharmaceutical Sector	130
3.5 The Pharmaceutical Distribution Sector	140
3.6 The Human Vaccine Sector.....	149
3.7 Pharmaceutical R&D in China – Domestic Chinese Companies.....	156
3.8 Pharmaceutical R&D in China – Foreign Companies.....	164

3.9	Pharmaceutical Outsourcing Sector (R&D and Manufacturing)	173
3.10	Emerging Trends of Chinese New Drug R&D	177
3.11	M&A and Venture Capital Investment in the Pharmaceutical Industry	183
3.12	Leading Pharmaceutical Companies in China	195
3.13	Leading Pharmaceutical Distributors	208
3.14	Leading Retail Pharmacy Chains in China	210
3.15	Overview of A-Share Listed Chinese Biopharma Companies 2016	213
Chapter I-4 Foreign Investment in The Pharma Industry		216
4.1	China's Foreign Investment Regulatory Framework	216
4.2	Major Tax Categories for FIEs and Foreigners	227
4.3	Forms of Foreign Investment in the Pharma Sector	230
4.4	Encouraged, Restricted and Banned Areas for Foreign Investment in the Pharma Industry	231
4.5	Growth of Foreign Investment in the Pharma Sector	234
4.6	Contemporary Trends, Issues and Strategic Considerations for Foreign Investment in the Pharmaceutical Industry	241
4.7	Three Holistic Advices to Pharma MNCs in China	255
Chapter I-5 The Ethical Pharmaceutical Market		258
5.1	Market Size	258
5.2	Market Prospects and Future Outlook	261
5.3	Special Characteristics of the Chinese Ethical Pharmaceutical Market	264
5.4	The Hospital Drug Market	265
5.5	The Rise of Retail Pharmacy Sector	268
5.6	Rural Chinese Market for Ethical Drugs	276
5.7	Rising Importance of the Primary Healthcare Drug Market	279
5.8	Chinese Biologics Market Growth Expected to Accelerate	280
Chapter I-6 The Chinese Vaccine Market		285
6.1	Chinese Vaccine Market Landscape	285
6.2	Snapshot of Hospital Vaccine Sales in 22 Chinese Cities	291
6.3	Market Outlook of the Chinese Human Vaccine Market	293
6.4	Asia-Pacific Influenza Vaccines Market to Surpass \$1.7B by 2022	294
Chapter I-7 The OTC Pharmaceutical Market		296
7.1	Overview of the Chinese OTC Market	296
7.2	Regulatory Progress on OTC Drugs	299
7.3	Chinese OTC Drug Market under Rapid Transformation	301
7.4	Enthusiastic Pharmaceutical Industry Seeks to Expand OTC Drug Sales	302
7.5	Drug Companies Foray into Consumer Healthcare to Counter Pharma Pitfalls	304
7.6	Healthcare Reform Casts Shadow on Future of the Retail Pharmacy Sector	305
7.7	CFDA Considers Ban of OTC Drug Ads on Mass Media	305

Chapter I-8 Pharmaceutical Import and Export	308
8.1 Background.....	308
8.2 Present State of China’s International Trade of Medicines and Health Products	309
8.3 Custom Duties on Drug Import.....	312
8.4 Trends and Outlook.....	313
PART II HEALTHCARE PROVISION AND FINANCING	315
Chapter II-1 Overview	317
1.1 Improving Healthcare Provision	317
1.2 Falling Death Rate and Rising Life Expectancy	319
1.3 Composition of the Chinese Population.....	321
1.4 Ageing in China: The Implications for Healthcare	323
1.5 Economic Burden from Chronic Diseases May Slowdown China’s Growth.....	325
1.6 2015 Annual Health and Family Planning Sector Development Report	327
1.7 Health China 2020 Strategic Research Report.....	330
1.8 The National Planning Guideline for Healthcare Service System (2015–2020).....	332
1.9 Healthy China 2030 Plan	335
Chapter II-2 Structure and Composition of Medical Provision.....	337
2.1 Composition of the Chinese Medical Sector.....	337
2.2 Grade Structure of Chinese Medical Institutions	341
2.3 Regional Distribution of Healthcare Resources	342
2.4 Distribution of Healthcare Resources by Medical Specialty.....	347
2.5 Human Resources in China’s Healthcare Industry	348
2.6 China Seeks to Establish a General Practitioner System by 2020.....	349
2.7 Government Encourages the Formation of Medical Service Consortiums	351
2.8 Chinese Government Seeks to Boost Private Healthcare.....	352
2.9 China’s Telemedicine Industry Gets Ready To Take Off.....	353
2.10 China’s Mobile Healthcare Sees Sharp Growth.....	357
2.11 Internet Economy to Save China CNY 610B Healthcare Expenditures Annually by 2025 ..	358
Chapter II-3 Healthcare Reform	360
3.1 A Review of China’s Healthcare System Reform in the Past Three Decades	360
3.2 Chinese Leadership Mapped A New Blueprint of Healthcare Reform	365
3.3 The Healthcare Reform Plan in the 13th FYP (2016-2020).....	367
3.4 Major Healthcare Reform Tasks in 2017	374
Chapter II-4 Healthcare Financing and Insurance Programs	381
4.1 Healthcare Financing in China.....	381
4.2 Urban Employee Basic Medical Insurance (UEBMI).....	389
4.3 Urban Resident Basic Medical Insurance and New Rural Cooperative Medical Scheme	391
4.4 Critical Illness Insurance Coverage for Urban and Rural Residents	394
4.5 Work-related Injury Insurance Program.....	395

4.6	Medical Assistance Program for Civil Servants.....	396
4.7	Maternity Insurance	397
4.8	Medical Assistance Program for the Poor.....	398
4.9	Commercial Health Insurance.....	400
4.10	Universal Coverage of Chinese Population by Basic Medical Insurance	405
4.11	MOHRSS Issues Internet+ Action Plan, Citing BMI Settlement by Social Security Card via Payment Services.....	406
Chapter II-5 Drug Reimbursement.....		407
5.1	Drug Reimbursement under BMI, WRI and MI Programs	407
5.2	A Thorough Summary of the MoHRSS Notice for Publication of the 2017 NRDL under BMI, WRI and MI Programs.....	409
5.3	Snapshot of Newly-added Western Medicines in 2017 NDRL.....	411
5.4	Analysis of 2017 NRDL's New Product Additions.....	412
5.5	Snapshot of MNC Winners of New 2017 NRDL Listing	413
Chapter II-6 Measures of Healthcare Cost-containment		415
6.1	Price Control.....	416
6.2	Centralized Hospital Drug Purchase Tenders.....	419
6.3	The National Essential Drug System	438
6.4	National Formulary and Clinical Guidelines	446
6.5	Clinical Pathway/DRGs.....	447
6.6	National Drug Price Negotiation	450
6.7	Other Cost-containment Measures.....	451
6.8	Tiered Medical Service System	455
PART III DISEASE AND DRUG CONSUMPTION PATTERNS.....		457
Chapter III-1 Growth of Drug Consumption and Demand		459
1.1	Sharp Growth in Drug Consumption and Healthcare Expenditures	459
1.2	The State of Health of the Chinese Population	463
1.3	Health Awareness and Literacy.....	464
1.4	Demographic Convergence and the Coming Chinese Healthcare Explosion	465
1.5	Medical and Public Health Services	467
Chapter III-2 Popular Diseases and Morbidity.....		468
2.1	Leading Diseases in Recent Years	468
2.2	Leading Causes of Death	472
2.3	An Extensive Overview of Chronic and Epidemic Diseases in China.....	475
2.4	Recent Trends with Cancer Challenges in China.....	492
2.5	China's Cancer Research Advances, Closing In with the U.S.....	500
2.6	Prevalent Health Problems to Senior Citizens in China.....	501
2.7	Chinese in Good Health Longer Than People in Other G20 Countries	502
2.8	Medium and Long Term Plan for Prevention and Treatment of Chronic Diseases.....	503

Chapter III-3 Medical Institution Attendance and Expenses.....	505
3.1 Composition of Medical Care System in China.....	505
3.2 Hospital Attendance	506
3.3 Healthcare Expenditures and Medical Expenses	512
Chapter III-4 Drug Consumption Patterns in Medical Institutions	514
4.1 Patterns of the Chinese Hospital Drug Market.....	514
4.2 Hospital Drug Consumption of Chemical Drugs	525
4.3 Drug Consumption in Chinese County Level Hospitals	526
4.4 Drug Consumption of Urban Community Healthcare Centers	539
4.5 Drug Consumption in Rural Townshuip Health Centers.....	546
Chapter III-5 Retail Drug Consumption Patterns	552
5.1 Overview of the Chinese Pharmaceutical Retail Sales	552
5.2 Consumption Patterns of Retail Pharmacy Sales of Medicine and Health Products.....	554
5.3 Structure of Chinese B2C Online Pharmacy Market	564
Chapter III-6 Consumption Patterns of OTC Drugs	569
6.1 Structure of Chinese OTC Drug Market	569
6.2 Leading Chinese OTC Companies and Brands.....	576
6.3 How to Succeed in China's Challenging OTC Environment	581
6.4 China OTC Market Has Growth Potential despite Regulatory Uncertainty	584
Chapter III-7 Consumption Patterns of Formulated Traditional Chinese Medicines	589
7.1 IMS Data.....	589
7.2 SMEI Data	593
7.3 Sinohealth Data.....	600
Chapter III-8 Regional Drug Consumption Patterns	602
8.1 Gap Between Cities and Rural Areas	602
8.2 Regional Hospital Markets for Drug Products	604
8.3 Hospital Drug Sales Champions in 22 Chinese Cities/Regions in 2016	610
8.4 Regional Markets by Pharmaceutical Distributor Sales	611
8.5 Regional Retail Pharmacy Markets for Drug Products	614
8.6 Regional OTC Drug Markets	616
8.7 Regional Primary Healthcare Drug Markets	618
Chapter III-9 Market Shares of Local, JV and Imported Drugs.....	622
9.1 Hospital Market – Domestic vs. MNC Drugs	622
9.2 Retail Pharmacy/OTC Market – Domestic Companies vs. JV/Foreign Players	632
9.3 Future Trends and Outlook	632
Chapter III-10 High Growth Market Segments	635
10.1 Chinese Oncology Drug Market	636

10.2	The Chinese Diabetes Drug Market.....	645
10.3	The Chinese Cardiovascular Drug Market.....	652
10.4	The Chinese Hepatitis Drug Market	654
10.5	Chinese Asthma and COPD Drugs Markets Poised for Steady Growth	658
10.6	The Chinese Drug Market for Mental Disorders Has Huge Potential	660
10.7	Prospects of Chinese Pediatric Drug Market	663
10.8	Emerging Orphan Drug Market Is Hope for Millions of Chinese with Rare Diseases	664
10.9	Chinese Geriatric Drug Market Offers Great Potential.....	666
10.10	Alzheimer's Is China's Biggest Future Health Problem - And Biggest Healthcare Industry Opportunity.....	667
10.11	China, The World's Second Largest Clinical Nutrition Market	671
VOLUME 2 CHINESE PHARMACEUTICAL IP AND REGULATORY GUIDE		
.....		675
TABLE OF CONTENTS		677
LIST OF TABLES		681
LIST OF CHARTS		683
TABLE OF ABBREVIATIONS		685
PART IV CHINESE PHARMACEUTICAL REGULATORY AND IP GUIDE .687		
Chapter IV-1 Overview		689
1.1	Drug Regulation Statistics	689
1.2	Overview of Drug Evaluation and Registration in 2016 and Q1/2017	692
1.3	Adverse Drug Reaction and Drug Abuse Reporting	703
1.4	Review of New Chinese Pharmaceutical/Healthcare Regulations in 2016 and Early 2017....	704
1.5	Major Drug-related Policies, Regulations and Laws under Drafting Process.....	709
1.6	CFDA to Complete Legal Framework for Food and Drug Regulation by 2020	713
1.7	Drug Regulatory Reform Direction in 2017	713
1.8	Reform of China's Drug Evaluation and Approval System	714
1.9	CFDA's Plan to Phase in Bioequivalence Study on Generic Drugs.....	723
Chapter IV-2 Important Laws and Regulations		726
2.1	The Drug Administration Law of the People's Republic of China.....	726
2.2	Regulations for Implementation of the Drug Administration Law of the PRC.....	730
2.3	Major Regulations under the Drug Administration Law of PRC.....	734
2.4	Other Drug Related Laws and Regulations.....	737
Chapter IV-3 Major Government Agencies and Industry Associations in The Pharma Field		740
3.1	The China Food and Drug Administration (CFDA)	741
3.2	The Center for Drug Evaluation under the CFDA	750
3.3	National Development and Reform Commission (NDRC).....	752

3.4	The National Health and Family Planning Commission (NHFPC)	756
3.5	Ministry of Human Resources and Social Security (MOHRSS).....	764
3.6	Ministry of Industry and Information Technology (MIIT).....	765
3.7	Ministry of Commerce (MOFCOM or MOC)	766
3.8	State-owned Assets Supervision and Administration Commission (SASAC)	766
3.9	State Administration of Traditional Chinese Medicine (SATCM)	767
3.10	Pharmaceutical Industry Associations in China	768

Chapter IV-4 Drug Regulatory Framework in China (1) -Drug Registration Regime 773

4.1	Overview.....	773
4.2	General Principles of Provisions for Registration of Drug Products	784
4.3	Clinical Research for Drug Registration	787
4.4	Rules, Standards and Technical Guidelines for Drug Research/Registration.....	788
4.5	Multi-Regional Clinical Trials (MRCT)	791
4.6	Acceptance of Foreign Preclinical Study Data	793
4.7	Rules for Special Approval of Drug Registration	793
4.8	New Drug Surveillance Period	796
4.9	Registration of Copy/Generic Drugs and Their Quality/Efficacy Equivalence Studies.....	796
4.10	Registration of Import Drugs	806
4.11	Re-Registration of Imported Drugs.....	810
4.12	Registration of Biosimilars	811
4.13	Registration of OTC Drugs	812
4.14	Registration of Drug Related Products, Foods for Medical Purpose and Health Foods	812
4.15	Supplemental Requirements for Registration of Traditional Chinese Medicines	816
4.16	Applications and Approvals for Supplemental Registrations.....	816
4.17	Drug Registration Reconsideration	817
4.18	Post Approval Changes to Pharmaceuticals	818
4.19	Onsite Verification for Drug Registration	819
4.20	The Drug Evaluation Regime	820
4.21	Chinese Pharmacopoeia (ChP).....	821
4.22	GLP/Preclinical Research and GCP/Clinical Research.....	822
4.23	China Pilots Drug Marketing Authorization Holder (MAH) System.....	830
4.24	Interpretations for Application of Criminal Laws for Faking Drug and Medical Device Registration Data	836

Chapter IV-5 Drug Regulatory Framework in China (2) – Others837

5.1	Pharmaceutical Manufacturer Licensing.....	837
5.2	Contract Manufacture/OEM	839
5.3	Pharmaceutical Manufacturing and GMP Certification	845
5.4	Regulation of Pharmaceutical Excipients	850
5.5	Drug Labeling and Packaging	853
5.6	Pharmaceutical Distribution Licensing	859
5.7	Pharmaceutical and Vaccine Distribution/GSP	862

5.8 Drug and Excipient Import Process	871
5.9 Pharmaceutical Regulatory Inspections and Enforcements	874
5.10 Classified Control of Drug Products	876
5.11 Drug Advertising.....	880
5.12 Drug Pricing and Price Control.....	887
5.13 Post-marketing Surveillance/ADR Reporting/Tracing	894
5.14 Counterfeit, Fake and Sub-standard Drugs	901
5.15 Control of Narcotic, Psychotropic and Radioactive Drugs	908
5.16 Internet Information Service and Online Sales of Drug Products	914
5.17 Drug Prescription/Rational Drug Use/Clinical Practices	918
5.18 Pharmaceutical Technology Transfer / Administrative Protection / IP	929
5.19 Anti-corruption/Compliance/Black Listing	933
5.20 Drug Donations.....	943
5.21 International Regulatory Cooperation.....	952
5.22 Others.....	959
Chapter IV-6 Intellectual Property Rights and Legal Issues	962
6.1 Pharmaceutical Patent Protection	969
6.2 Administrative Protection of Pharmaceuticals (APP).....	992
6.3 Data Exclusivity.....	994
6.4 Patent and Trademark Registration.....	997
6.5 Patent and IP Strategies for China	1005
6.6 Protecting and Policing IPRs in China.....	1007
6.7 Administrative Enforcement of Patents in China.....	1008
6.8 Pharmaceutical Patent Litigation in China.....	1011
6.9 Importance of Patents in Chinese Pharmaceutical Tendering	1016
6.10 Trade Secret Protection.....	1019
6.11 Counterfeit Drugs.....	1021
6.12 Judicial Interpretations of Law Applications over Drug Safety	1024
6.13 The Tort Liability Law: Impacts on Pharma	1031
6.14 Compliance and Corruption Risks	1035
6.15 Antitrust/Antimonopoly.....	1052
6.16 Merger & Acquisitions.....	1072
6.17 Big Data Policy and Legal Issues in the Healthcare Industry	1079
6.18 A Guide to the Two Invoices System in Chinese Pharmaceuticals Distribution.....	1086
VOLUME 3 ANNUAL REVIEW, TRENDS, OPPORTUNITIES & STRATEGIC CONSIDERATIONS.....	1091
TABLE OF CONTENTS	1093
LIST OF TABLES	1097
LIST OF CHARTS.....	1100
TABLE OF ABBREVIATIONS	1101

PART V ANNUAL REVIEW AND OUTLOOK OF THE CHINESE PHAMACEUTICAL INUSTRY AND MARKET	1103
Chapter V-1 The Broad Chinese Economy: Review and Outlook	1105
Chapter V-2 Annual Review of the Chinese Pharmaceutical Industry and Market..	1110
2.1 Data Overview: Chinese Pharmaceutical Market Landscape	1110
2.2 Data Overview: Pharmaceutical Industry Performance	1117
2.3 Review of Regulatory Developments in 2016 and H1/2017.....	1122
2.4 Healthcare Reform Stumbles on amid a Matrix of Government Policies	1137
2.5 Pharma Industry In The Process of Revamping Its Business Model to Fit with the New Business Environment.....	1151
2.6 Old IP flaws remained as new issues spring up amid regulatory reform and antimonopoly enforcements.....	1168
Chapter V-3 Review of Chinese Pharma M&A, Licensing and Collaborative R&D Deals in 2016 and 1H/2017	1173
Chapter V-4 What Does the Future Hold for China's Healthcare Economy?	1194
4.1 What to Expect in the Year of “Trump Rooster”?	1194
4.2 Analysis: China’s Healthcare Reforms, A Blessing or A Threat?.....	1196
4.3 More Challenges Ahead, Despite Unchanged Long Term Prospects.....	1197
4.4 13FYP Paints a Gloomy Picture for Healthcare MNCs	1209
4.5 China Pledges to Speed Up Approvals of Foreign Drugs	1213
4.6 China-U.S. Biopharma Players Look on Bright Side for 2017	1214
4.7 What If the New Normal of China Healthcare Is About Domestic Self-Reliance and Export Ambitions?.....	1216
4.8 Three Holistic Advice to Pharma MNCs in China	1220
4.9 Top 10 Predictions on Implications of Healthcare IT in China.....	1222
PART VI CONTEMPORARY TRENDS, OPPORTUNITIES AND STRATEGIC CONSIDERATIONS	1225
Chapter VI-1 Introduction	1227
Chapter VI-2 Market Dynamics and Strategic Considerations	1229
2.1 Impacts of Slowing Chinese Economy on the Country’s Healthcare Plans	1229
2.2 Healthcare Reform in China May Be A Double-Edged Sword For Foreign Companies	1231
2.3 What Should We Know about the Merger of China’s Urban and Rural Resident Basic Medical Insurance Schemes?	1233
2.4 Embracing China's Brave New Pharmaceutical World	1235
2.5 How To Think About China's Special Economic Zones As A Foreign Pharmaceutical, Medical Device, or Hospital Company	1239
2.6 Hard to Swallow: Emerging Markets Get Tougher for Drugmakers.....	1241
2.7 What Happens When Multinationals Need The China Market More Than China Needs FDI?	1242

2.8	New Guidelines to Make China A More Drug-Friendly Market.....	1244
2.9	Cross-Sector Collaboration to Enhance Market Access for Pharmaceutical Companies in Asia: Six Steps to Make It Work	1247
2.10	China Fast Tracks Merck's Cancer Drug For Approval, But There's A Catch	1250
2.11	Will Apple's Business Model Work in Pharmaceuticals?.....	1252
2.12	The View of China from Headquarters	1255
2.13	Big Pharma Facing Roadblock in China.....	1257
2.14	Are You Ready for the Lower Tier Market?	1259
2.15	Fostering a Sustainable Ecosystem for "Healthy China 2030" - Promoting a Quantity-to- Quality Transition in China's Drug Innovation	1260
2.16	Leading Chinese Pharma Companies Eyes The Medical Service Sector.....	1262
2.17	Why Chinese Drugmakers Are Looking Overseas	1265
2.18	Review of Off-label Drug Usage in Chinese Hospitals	1267
2.19	Physician-Patient Relations and Health Literacy in China	1268
2.20	China Healthcare Advertising: Failure to Learn	1270
2.21	Growing Problem of Counterfeit Drugs.....	1271
2.22	What Is Venture Capital Up to in China's Life Science Space?.....	1272
2.23	Regulatory Changes in China to Impact Development & Manufacturing Strategies.....	1275
2.24	How Patient Do Chinese Patients Need To Be for Innovative New Drugs?.....	1277
2.25	China's Life Science Innovative Development Policies.....	1279
2.26	Strategic Domains in The U.S.-China Life Science Sector.....	1281
2.27	Can Technology Really Solve China's Healthcare Crisis?.....	1283
2.28	Pharma MNCs are on the Defensive. Are They Thinking Clearly?	1284
2.29	China's Healthcare Reforms, Who Will Survive?	1287
2.30	Generic Consistency Evaluation in China: The Coming Paradigm Shift in Drug Pricing and Patent Cliff.....	1288
2.31	Maybe MNC Pharma Shouldn't Be Scared of the Chinese Government	1290
Chapter VI-3 Promising Opportunities of the Present and Future.....		1294
3.1	Chinese Healthcare Expenditures to Triple by 2020 Despite Challenges	1294
3.2	Commercial Models in China's Pharma Sector Must Change	1297
3.3	Time to Rethink about Your OTC/Consumer Healthcare Strategies in China	1298
3.4	Two Way Traffic for Chinese Drug Licensing	1299
3.5	Chinese Market Offers New Life to Many Drugs.....	1301
3.6	MNCs Boost Drug Research and Clinical Trials for Diseases Prevalent in China and Other Asian Markets	1303
3.7	Changing R&D and Manufacturing Strategies For MNCs In China	1305
3.8	Impact of GSK Crisis and China's Law Enforcement Bias on Foreign Business Enthusiam	1307
3.9	Review of Indigenous Drug Innovation in China	1312
3.10	Review of Class 1 New Drug Approvals between 2003 and 2015	1314
3.11	Review of Anticancer Drug Registration Applications in China 2008-2014	1316
3.12	Review of New Drugs on Special Approval Path 2004-2015.....	1318
3.13	Review of Drug Registration Applications on Three Fast Tracks 2011-2014.....	1321

3.14	Review of New Drugs Under Development in China in 2016 and H1/2017	1322
3.15	Applying "Innovation Arbitrage" to Develop Novel Medicines in China.....	1326
3.16	China's Private Health Insurance: Navigating Uncharted Waters	1328
3.17	The Transformation and Future of China's Biomedical Innovation	1331
3.18	China to Become Life Science Powerhouse by 2020.....	1333
3.19	McKinsey: What Industry Experts Told Us About Pharma Innovation in China.....	1337
3.20	Pharmaceuticals: China Wishes to Transform Into A Hub for Innovation – Is It Possible?	1339
3.21	Inefficient Innovation in China	1342
3.22	Understanding China's Marketing Authorization Holder Pilot Plan in Selected Regions ..	1343
3.23	China Embraces Precision Medicine on a Massive Scale	1344
3.24	Building a Translational Medicine Powerhouse in China	1346
3.25	How Telemedicine Might Reshape Pharmacies in China	1351
3.26	Winning In China's HCV Travails	1352
Chapter VI-4 Trends and Prospects in Pharma Outsourcing		1358
4.1	CMO/Manufacturing Outsourcing in China and Asia.....	1358
4.2	Will China Lose Its Cost-Competitiveness in Pharma Manufacturing?.....	1367
4.3	Chinese CRO Market Estimated to Grow 20% Annually Before 2018	1370
4.4	Trends and Prospects of Clinical Research in China.....	1371
4.5	SCPRR Survey Expects Growing Clinical Trials in China.....	1376
4.6	Potential Compliance Risks in Clinical Research Outsourcing to China.....	1377
4.7	The Next Hotspots for CMO/CRO Growth in China.....	1381
4.8	Asia: Preferred Destination For Clinical Trials.....	1382
4.9	APAC Is the Fastest Growing Market for CRO Industry.....	1388
VOLUME 4 SALES & MARKETING, ENTRY STRATEGIES AND CASE STUDIES		1393
TABLE OF CONTENTS.....		1395
LIST OF TABLES.....		1403
LIST OF CHARTS.....		1404
TABLE OF ABBREVIATIONS.....		1405
PART VII PHARMACEUTICAL SALES, MARKETING AND DISTRIBUTION		1407
Chapter VII-1 History and Overview.....		1409
1.1	Pharmaceutical Sales and Distribution in China Before Early 1980s	1409
1.2	The Breaking Up of the Old System	1410
1.3	The Present State of the Pharmaceutical Marketing, Sales and Distribution System in China – An Overview.....	1411
Chapter VII-2 Major Promotional Practices and Government Affairs		1417
2.1	National and Local Drug Reimbursement Lists	1417

2.2	Pricing of Drug Products	1422
2.3	Centralized Hospital Drug Purchase Tenders.....	1424
2.4	Product Launches.....	1426
2.5	Clinical Research	1427
2.6	Public Relations	1428
2.7	Lobbying for Industrial Policies and Regulations.....	1428
2.8	Building a Better Government Affairs Function in China	1429
2.9	Only 12.1% of the Doctors Are Satisfied with the Domestic Academic Meetings	1436
2.10	Measuring Pharma's Success by Customer Reputation and Loyalty	1442
2.11	Snapshot of Chinese Pharmaceutical Marketing and Digital Communication Channels....	1446
Chapter VII-3 Marketing and Sales of Ethical Drugs in Urban Hospitals.....		1448
3.1	Mainstream Hospital Marketing and Sales Models	1448
3.2	The Hospital Drug Purchase Approval Process	1450
3.3	Hospital Drug Purchase Channels	1451
3.4	Hospital Marketing/Sales Organization and Execution	1452
3.5	Key Factors in Hospital Marketing and Sales.....	1453
3.6	Developing Effective Market Coverage and Sales Force Strategies in China	1454
3.7	Shifting from Network Marketing to Evidence Based Medicine in China	1457
3.8	More Chinese Pharma Cos Cuts Sales Force and Switch to Agency Sales.....	1459
Chapter VII-4 Marketing and Sales of Ethical Drugs through Urban Retail Pharmacies		1461
4.1	Channels of Retail Pharmacy Sales and Distribution	1461
4.2	Process and Key Components of Retail Pharmacy Sales.....	1462
4.3	Key Factors in Sales of Ethical Drugs through Retail Pharmacies	1462
4.4	Case in Point: Pfizer's Retail Pharmacy Sales Efforts in China	1463
Chapter VII-5 Sales & Marketing of OTC Drug Products in Cities		1465
5.1	Channels of OTC Drug Sales.....	1465
5.2	Process and Key Components of OTC Drug Sales.....	1466
5.3	Key Factors in OTC Drug Sales	1467
Chapter VII-6 Sales, Marketing and Distribution of Drugs in the "Third Terminal Market"		1469
6.1	Pharmaceutical Sales & Distribution Channels to the "Third Terminal Market".....	1469
6.2	Sales and Marketing Strategies for the "Third Terminal Market"	1471
6.3	Special Characteristics of the "Third Terminal Market"	1472
Chapter VII-7 Pharmaceutical Distribution		1473
7.1	Overview	1473
7.2	Important Regulatory Requirements on Pharmaceutical Distribution	1475
7.3	Pharmaceutical Distribution Channels in China	1476
7.4	GSP Requirements for Pharmaceutical Distributors.....	1479

7.5	Logistics in Pharmaceutical Distribution	1479
7.6	Opening of the Chinese Pharmaceutical Distribution Sector	1481
7.7	Recent Trends and Outlook in Pharmaceutical Distribution	1482
7.8	Chinese Pharmaceutical Distribution Landscape and Models	1484
7.9	Building Distributor Channel Management Capabilities in China.....	1487
7.10	How the Distribution Challenge for Pharma is Going to Change in China	1492
7.11	The Challenges of Managing China's Highly Fragmented Distributor Networks	1495
7.12	Fitch: Further Consolidation of China's Drug Distribution Sector Inevitable.....	1497
7.13	Margin Pressure and Consolidation for China's Pharma Distributors	1498
7.14	New Two-Invoice System in Pharma Distribution Launched in 2017	1499
Chapter VII-8 e-Commerce and Digital Marketing Opportunities for Pharma Companies		1502
8.1	China Preparing for a Digitized Healthcare Landscape	1502
8.2	China Issues Guidance Clarifying Core Tasks and Deadlines for Application of the Country's Telemedicine System	1503
8.3	Data Overview of Chinese Pharma e-Commerce Market.....	1504
8.4	BCG: Emerging Trends and Drivers of Pharma e-Commerce in China.....	1505
8.5	Online Healthcare An Emerging Trend in China	1507
8.6	Cracking the China Conundrum & "Robo-reps".....	1507
8.7	Survey: 33% of Chinese Pharma Marketers Will Spend 20%+ on Digital Channels	1509
8.8	Kantar Health: Analysis of Digital Health in China.....	1510
8.9	Indegene's Chinese HCP Channel Preference Survey	1512
8.10	China Healthcare Multi Channel Marketing? OK, But Where?.....	1512
8.11	Mobile Health APP Seeks to Provide New Solutions to China Healthcare.....	1514
8.12	Chinese Digital Healthcare Sector To Worth \$110B in 2020	1519
8.13	Mobile Medical Healthcare Trends in China	1520
8.14	What's Influencing Digital Health Growth in China?.....	1523
8.15	Balancing Act: China's Online Healthcare System Needs Both Innovation and Regulation	1526
8.16	China to Grow Big on e-Healthcare Data	1528
8.17	BMI: Flourishing Telecare in China Means Opportunities for MNCs	1531
PART VIII MARKET ENTRY STRATEGIES AND EXECUTION.....		1533
Chapter VIII-1 Preparations for a Market Entry Strategy.....		1535
1.1	The Need for a Market Entry Strategy	1535
1.2	Long Term Perspective	1535
1.3	Information Sources.....	1536
1.4	Getting Expert Help	1539
1.5	Market Research	1539
1.6	Selecting the Right Products	1540
1.7	China's Evolving Pharma Partnering Landscape: The Right Partner Profile	1541
1.8	What Healthcare Companies Looking To Get Into China Must Know.....	1545
1.9	Five Elements to Consider When Choosing the Next Emerging Market to Enter	1547

Chapter VIII-2 Strategic Approaches for Market Entry	1550
2.1 Direct Export of Finished Products.....	1550
2.2 Sino-foreign Joint Ventures.....	1552
2.3 Solely Foreign-owned Companies in China	1554
2.4 Licensing and Technology Transfer	1554
2.5 Merger & Acquisition (M&A).....	1556
Chapter VIII-3 Execution of The Market Entry Strategy	1558
3.1 Product Registration	1558
3.2 New Drug Clinical Trials and Patient Recruitment in China	1560
3.3 Latest Regulatory Developments on Ethical Review in Chinese Clinical Trials	1562
3.4 Selection of a Local Distributor for Imported Drugs	1564
3.5 Selection of a Chinese Partner for Joint Venture.....	1565
3.6 Product Launch.....	1566
3.7 Promotional Activities and Advertising	1567
Chapter VIII-4 Challenges and Realities for Operating in China.....	1568
4.1 The Importance of Patience	1568
4.2 The Value of Relationship.....	1568
4.3 Dealing with Chinese Style Laws	1569
4.4 The Ethical Challenges of Doing Business in China's Healthcare Economy	1569
4.5 Commercial Briberies Seen as a Leading Risk as Chinese and Foreign Governments Step Up Enforcements	1571
4.6 Behind China's Corruption Crackdown: Whistleblowers	1573
4.7 Compliance in China: Ongoing Regulatory and Operational Challenges.....	1576
4.8 Staff Turnover and Talent Retention A Growing Problem	1579
4.9 Drawing Pharmaceutical Talents from the West	1581
4.10 Choosing Your General Manager for China.....	1582
4.11 Managing Sino-Foreign Joint Ventures in China	1585
4.12 Recruiting R&D Leaders in China and India.....	1591
4.13 Recruiting Medical Executives in China	1595
4.14 Managing Clinical Trials in China	1597
4.15 Resourcing Clinical Research Programs in China	1598
4.16 Survey: Clinical Research Experience, Practice and Attitudes of Chinese Physicians	1601
4.17 Why Your NDA Does Not Work For China.....	1603
PART IX MINI CASE STUDIES	1605
Chapter IX-1 China Experiences of Foreign Drug Companies	1607
1.1 Quest PharmaTech's Ill-fated China Venture	1607
1.2 Ranbaxy's Successful Entry and Surprising Exit of the Chinese Market.....	1608
1.3 Zuelig Pharma China/Cardinal Health China – A Successful Case and Business Model for China's Pharmaceutical Distribution Sector.....	1611
1.4 West Pharmaceutical Services - Tapping into China's Growing Healthcare Industry.....	1614

1.5	Novo Nordisk China - Focusing on Diabetes.....	1616
1.6	Abbott Succeeds in China by Focusing on Nutrition Business.....	1619
1.7	Bayer's Big Bet on China.....	1620
1.8	Bayer Troubled by Integration of Acquired OTC Business in China.....	1621
1.9	Roche's Unique, Global Strategy for China.....	1622
1.10	Helping Establish Private Health Insurance for Cancer in China – A Roche Story.....	1625
1.11	A Decade Old Drug Launch In China With Important Insights Today - BMS's Experience with Baraclude in China.....	1626
1.12	Ipsen Outlines Strategies for Continued Growth in China - The Success Story of a Mid-size Company.....	1631
1.13	SciClone Pharmaceuticals: Building a Product Portfolio Optimized for China's Evolving Pharmaceutical Market.....	1633
1.14	Leveraging U.S. Resources and Chinese Partnership for Drug Development and Commercialization.....	1638
1.15	With a Band of Biotech Collaborators, RuiYi Sets Sail Developing New Biologics for China	1640
1.16	Why Did One of the World's Largest Generic Drug Makers Exit China?.....	1642
1.17	CleveXel's Collaboration with Guilin Pharma for Development of Artesunate Injection... 1645	
1.18	Lessons from Glaxosmithkline's Record \$492 Million Bribery Fine in China.....	1649
1.19	One Multinational's Lessons Learned in China.....	1651
1.20	MSD and Nanjing Simcere Set to Go Their Own Ways.....	1653
1.21	Merck Finds Shortcut for Anticancer Keytruda into China via Medical Tourism.....	1655
1.22	Merck's Gardasil preps for head-to-head with GlaxoSmithKline's Cervarix in China, with big sales targets ahead.....	1656
1.23	Pfizer Builds Viagra Success in China Despite Fierce Competition and Generics.....	1657
1.24	Pfizer Eyes Huge Potential in Online Sales of Its Health Products in China.....	1659
1.25	Eli Lilly Launches LEAP to Expand Lower Tier Market Access in China.....	1660
1.26	Roche Looks to Grow and Change with China's Ever-evolving Healthcare Industry.....	1661
1.27	Sanofi to Center China Business Strategy on Primary Healthcare in the Next Five Years .	1664
1.28	Despite Strong Albumin Sales, CSL Complains of Barriers in China Business.....	1665
1.29	Kobayashi Pharma: China Business Growth without China Presence.....	1666
Chapter IX-2 R&D and Outsourcing Case Studies.....		1669
2.1	Birth of A New Novel Anticancer, Made in China.....	1669
2.2	China Becomes Center of Startup CROs for Basic Research.....	1670
2.3	Huya Bioscience - Tapping into China for Novel Drug Candidates.....	1676
2.4	LEAD Therapeutics: A Unique US-China Drug Discovery Model.....	1677
2.5	BeiGene Strives to Become China's Genentech.....	1679
2.6	Two Emerging Companies Leverage the Strength of Both China and the U.S. for Growth	1681
2.7	Chinese Innovation: BGI's Code for Success.....	1684
2.8	Human Genomics in China: 10-Year Endeavor.....	1688
2.9	China Learns the Lesson of Vaccine R&D Bubble - The Story of Chongqing Brewery's in Development of Its Novel HepB Vaccine.....	1694

2.10	Research Partnership between BMS and Simcere: The Right Chemistry amid a Global Paradim Shift of Drug R&D	1696
2.11	China's Academic "Black Market" Fooled Canadian Medical Journal	1701
2.12	A Setback For Chinese Drug R&D	1703
2.13	USFDA Found China Data Irregularities for Key Study of Pfizer and BMS's Eliquis	1707
2.14	How Chinese Suppliers to Global Drug Firms Hide Bad Test Results	1708
2.15	TCM Gets a Modern Look.....	1710
2.16	Chinese Companies Make Progress on New Drugs from TCM Herbs	1712
2.17	A Better Pill from China - Chinese Pharma Firms Target the Global Market.....	1714
2.18	Novartis CEO on Why the Firm Just Opened a Major R&D Facility in China	1715
2.19	Pfizer to Use GE's Mobile Biotech Factory to Make Next-Generation Drugs in China.....	1717
Chapter IX-3 Human Resource Management Case Studies		1720
3.1	AstraZeneca China: Continued Mission on People	1720
3.2	Novartis China: The Learning Strategy	1721
3.3	Trends in Managing Pharmaceutical R&D and Medical Affairs Professionals	1723
Chapter IX-4 Legal Case Studies: IPR/Counterfeits/AML/Others.....		1728
4.1	Sankyo vs. Beijing Wansheng: First Lawsuit over Process Patent for Preparing Pharmaceutical Composites	1728
4.2	Pfizer vs. 12 Local Drug Companies: Landmark Lawsuit over Viagra Patent.....	1729
4.3	Eli Lilly vs. Beijing Ganli - Battle over Insulin	1731
4.4	Boehringer Ingelheim vs. Chaitai Tianqing over Tiotropium Bromide	1732
4.5	Legal Battle between Sanofi and Jiangsu Hengrui over Docetaxel	1733
4.6	Merck vs. Henan Topfond over Chinese Patent for Finasteride.....	1734
4.7	Aurisco Challenges Gilead's Chinese Patent for Viread	1735
4.8	Fake Drug Sting Operation – GSK Experience	1736
4.9	Legal and Ethical Implications of ELAD Clinical Trial Death.....	1737
4.10	Ruling over Liabilities of Distributors and Hospital in Fake Armillarisni-A Inj. Case.....	1739
4.11	Novartis Sued and Challenged for Deaths Linked to Its Hepatitis B Drug Sebivo	1740
4.12	Illegal and Off-Label Use of Roche's Avastin Led to Serious ADRs in Shanghai	1742
4.13	Off-label Use of Bayer Healthcare's XARELTO under Challenge in China.....	1743
4.14	Review of the 11-Year Trademark Fight between Roche and Southwest Pharma	1745
4.15	Merck & Co. Loses Trademark Fight against Tianjin Zhongxin Pharma	1748
4.16	Pfizer Loses Final Battle for Chinese Trademark of Viagra	1748
4.17	Johnson & Johnson Loses Trademark Lawsuit against SAIC's Trademark Review Board	1749
4.18	Bayer Settles Six-Year Trademark Infringement Lawsuit with Henan Baier Pharma	1749
4.19	The Rio Tinto Case Lays New Ground for PR of Foreign Companies in China	1750
4.20	Siemens Sued in the U.S. by Former Employee over Briberies in China	1753
4.21	China's Anti-Japanese Boycott Extended to Pharmaceuticals.....	1754
4.22	The Impact of Restricted Data-flows on China's Digital Healthcare Solutions	1756
4.23	Insight Into PRB Decisions on Pharma/Biotech Inventions Around 2015.....	1758
4.24	SIPO Invalidates Gilead Sciences' Viread Patent in China	1761

4.25	China Rejects Patent for Gilead's Expensive Hepatitis C Drug	1762
4.26	I-MAK Challenges Gilead's Remaining Chinese Patents of HCV Drug Sofosbuvir	1764
4.27	Bayer Loses Avelox (Moxifloxacin) Patent Battle in China	1765
4.28	Eli Lilly vs. Changzhou Watson: China's Supreme Court Sides with Local Firm After Court Designated Technical Investigations	1766
4.29	Three Supreme Court Cases On Pharmaceutical Patents	1766
4.30	Review of China's High Profile Investigation of GSK for Corruption	1769
4.31	GSK Sued by Couple It Hired to Investigate Whistleblower in 2013	1785
4.32	The "Dignified" Drug-Dealer – A Case for Thought over Patient Access to Medicines, Parallel Import, Compulsory Licensing and Drug Pricing	1786
4.33	Pfizer Fined by Shanghai Government for Irregular Pharmacy Display Fees	1789
4.34	Other Anti-Monopoly Enforcement Cases	1790
4.35	FCPA Compliance Cases and Other Related Foreign Lawsuits	1796
Chapter IX-5 Success and Failure Stories of Domestic Companies.....		1801
5.1	BGI: The Kung Fu Panda of the Genomic World	1801
5.2	China's Bid To Be A DNA Superpower	1804
5.3	3SBio – The Success Story of a Chinese Biogeneric Company	1807
5.4	Shanghai Sunway Biotech Co. Ltd. – The Success Story of a Chinese Gene Therapy Drug Company	1811
5.5	SinoVac Biotech – The Story of a Chinese Vaccine Developer	1813
5.6	Zhejiang Hisun Pharmaceutical Ltd. – A Showcase for International Business Transformation of Chinese Pharma Companies	1815
5.7	Jiangsu Hengrui Pharmaceutical – What Does the Future Hold for China's Largest Oncology Drug Firm?.....	1819
5.8	Tongjitang Chinese Medicines Company – The Tale of a Fallen Wall Street Darling and One of the Earliest "China Concept" Drug Stocks.....	1822
5.9	Shenogen Pharma Blends East and West	1824
5.10	GenePharma - The Story of a Small Niche Chinese Biotech Company.....	1827
5.11	Luqa Pharmaceuticals – Expatriate-founded Chinese Pharma Startup with a Strategy of Tailoring Products for China through Partnerships.....	1829
5.12	The Rise and Fall of Simcere Pharmaceutical as a US-listed Company	1832
5.13	Fosun Pharma Expands Global Business Via M&As and Innovative R&D	1833
5.14	Backed by China, Ambrx No Longer Dependent on Partnerships with MNCs	1836
5.15	China's Tech Tycoons' Healthcare Dreams Aren't Coming True.....	1837
5.16	Ali Health's Reversal of Fortune on the Back of Soaring Online Pharmacy Sales.....	1840
APPENDICES		1843
Appendix I Drug Administration Law of PRC.....		1845
Appendix II Regulations for Implementation of the Drug Administration Law of PRC		1864
Appendix III Regulations on Administrative Protection for Pharmaceuticals.....		1882

Appendix IV Provisions for Drug Registration.....	1886
Appendix V Special Review and Approval Procedure for Drug Registration.....	1917
Appendix VI Administrative Reconsideration Measures of CFDA	1923
Appendix VII Provisions for Drug Insert Sheets and Labels.....	1929
Appendix VIII Provisions for Supervision of Drug Distribution.....	1934
Appendix IX Provisions for Drug Advertisement Examination	1940

LIST OF TABLES

Table 1.1 Number of Pharmaceutical Businesses in China Since 1997	105
Table 1.2 Chinese Pharmaceutical Industry Revenues by Subsectors in 2016.....	108
Table 1.3 Chinese Pharmaceutical Industry Net Profits by Subsectors in 2016.....	108
Table 1.4 Core Revenues and Profit of Chinese Pharma Industry 2008-2017E.....	110
Table 1.5 Growth of the Chinese API/Bulk Drug Sector 2002-2016	116
Table 1.6 China-based Pharma Companies with U.S. DMFs	119
Table 1.7 Summary of U.S. DMFs Filed Products Manufactured in China	119
Table 1.8 Top 15 China-based DMF Holders with Ten or More Active DMFs.....	119
Table 1.9 Chinese Pharma Cos Passing USFDA Inspections (NAI) 2013-3Qs/2015 ...	120
Table 1.10 Chinese Foreign Trade of Biochemical Drugs 2007-2016 (US\$ mln).....	133
Table 1.11 Biologic Registration Applications Accepted by the CDE in 2012-2016	133
Table 1.12 Breakdown of CDE Recommendations for Biologic Applications in 2016	134
Table 1.13 Number of Concluded Biologic Registration Applications by the CDE in 2012-2016	134
Table 1.14 Number of Pharma Distribution License Holders 2013- 2016	140
Table 1.15 Structure of Chinese Retail Pharmacy Sector 2006-2016.....	140
Table 1.16 Chinese Drug Distribution Industry Performance 2011-2016	141
Table 1.17 Composition of Chinese Pharmaceutical Distributor Sales in 2016	142
Table 1.18 Chinese Retail Pharmacy Market Segmentation in 2016.....	142
Table 1.19 Chinese Pharma Distributor Segmentation by Ownership 2016	143
Table 1.20 Structure of Top 100 Chinese Pharma Distributors in H1/2016	146
Table 1.21 Top 20 Chinese Listed Distributors by Sales Revenues in H1/2016	147
Table 1.22 Top 20 Chinese Listed Distributors by Profit in H1/2016	147
Table 1.23 Top 20 Chinese Listed Distributors by Expenses in H1/2016	148
Table 1.24 Top 10 Domestically-listed Pharma Cos by R&D Investment 2016	161
Table 1.25 Top 20 Chinese Pharma Companies by R&D Capability 2016	161
Table 1.26 China Pharma Companies Ranking by R&D Investment 2015/2016.....	163
Table 1.27 R&D Centers of RDPAC Members in China.....	166

Table 1.28 Eight MNCs with Over 40 Chinese Drug Registration Submissions 2016..	172
Table 1.29 Selected Outbound Sino-Foreign Licensing Deals 2015 - 2016	178
Table 1.30 China's Pharma/Healthcare M&A Value 2005-2016	188
Table 1.31 Top Ten M&As by Value in Chinese Pharma/Healthcare Sector 2016	188
Table 1.32 Chinese Pharma Companies M&A Deals in Oversea 2003-2016.....	190
Table 1.33 Oversea M&As by Chinese Pharma Companies 2016.....	193
Table 1.34 Selected Innovative Drugs In-licensed by Domestic Pharma Companies 2016	194
Table 1.35 Top 20 China Pharma Companies by Sales in 2016.....	195
Table 1.36 Revenue Distribution of the Top 100 Chinese Pharma Cos 2005-2015.....	196
Table 1.37 Revenue Size of the 100th Chinese Pharma Company in 2005-2015.....	196
Table 1.38 Share of Top 100 in Total Chinese Pharma Industry Sales 2005-2015	197
Table 1.39 Regional Distribution of Top 100 Chinese Pharma Cos by Sales 2005-2015	197
Table 1.40 Subsectors of Top 100 Chinese Pharma Cos by in 2005-2015	197
Table 1.41 Publicly-listed Firms in Top 100 Chinese Pharma Cos by Sales 2009-2015	198
Table 1.42 Revenue Distribution of Top 100 Chinese Pharma Companies 2015	198
Table 1.43 Revenue Distribution of Top 100 Chinese Pharma Cos 2005-2015.....	198
Table 1.44 Top 16 Chinese Pharma Companies by Revenue 2015	199
Table 1.45 Top 20 Domestically-listed Pharma Companies by Capitalization (06/2017)	200
Table 1.46 Top 17 A-Share Listed Pharma Companies by Net Profits in 2016.....	201
Table 1.47 Top 20 Chinese Pharma Companies by R&D Pipelines 2016	201
Table 1.48 Top 10 Chinese Private-held Pharma Cos by Investment Value 2016	202
Table 1.49 Top 10 Chinese Pharma Growth Companies 2016.....	202
Table 1.50 Top 20 Domestically Listed Chinese Pharma Companies H1/2016	203
Table 1.51 Profit Margin of Chinese API Subsector 2010-2015.....	203
Table 1.52 Top 10 Listed API Companies by Net Profit 2015	204
Table 1.53 Profit Margin of Chinese Pharma Formulation Subsector 2010-2015.....	204

Table 1.54 Top 10 Listed Pharma Formulation Companies by Net Profit 2015.....	204
Table 1.55 Profit Margin of Chinese Biologics Subsector 2010-2015	205
Table 1.56 Top 10 Listed Biologics Companies by Net Profit 2015	205
Table 1.57 R&D Spending of Top 14 Listed Pharma Cos by Sales in 2016	206
Table 1.58 Top 30 Listed Chinese Pharma Companies by R&D Spending in 2016.....	206
Table 1.59 China Pharma Companies in Top 500 Chinese Companies 2016.....	208
Table 1.60 Seven Domestically-listed Regional Pharmaceutical Distributors 2016	209
Table 1.61 Top 20 Chinese Distributors by Sales Revenues in 2015	210
Table 1.62 Top 20 Chinese Retail Pharmacy Chains by Sales Revenues in 2015	211
Table 1.63 Top 20 Chinese Retail Pharmacy Chains by 2015 Sales.....	212
Table 1.64 Capitalization Landscape of A-Share Listed Biopharma Companies 2016.	213
Table 1.65 Top 10 A-Share Listed Biopharma Companies by Capitalization 2016	213
Table 1.66 New Foreign Investments in Chinese Pharma Industry 2013	235
Table 1.67 First Ten Sino-Foreign Pharmaceutical Joint Ventures in China	236
Table 1.68 Foreign Investment in the Chinese Pharmaceutical Industry in the 1990s ..	236
Table 1.69 Pharma Foreign Investments in China between 2000 and 2006	237
Table 1.70 Top 10 Pharma MNCs in China by Investment	238
Table 1.71 China Sales Performance of 22 MNCs H1/2015-H1/2016.....	251
Table 1.72 AZ's China Hospital Drug Sales Composition by Core Products H1/2016.	252
Table 1.73 MSD's China Hospital Drug Sales Composition by Core Products H1/2016	252
Table 1.74 Sanofi's China Hospital Drug Sales Composition by Core Products H1/2016	252
Table 1.75 Takeda's China Hospital Drug Sales Composition by Core Products H1/2016	252
Table 1.76 Allergan's China Hospital Drug Sales Composition by Core Products H1/2016	253
Table 1.77 Merck Group's China Hospital Drug Sales Composition by Core Products H1/2016.....	253
Table 1.78 China Sales Growth of Pharma MNCs Q3/2016	253

Table 1.79 Rx Drugs Sales Value of Three Channels in 2015.....	259
Table 1.80 Rx Drugs Share and Growth by TCs in 2015.....	259
Table 1.81 Share of Rx Formulated TCMs in Overall Drug Sales 2014-2015	260
Table 1.82 Share of Chronic Disease Rx Drugs by Channel in Tier 1 Cities 2015.....	260
Table 1.83 MNC Shares in Chronic Disease Rx Drug Sales in Tier 1 Cities 2015.....	261
Table 1.84 China Pharma Market Size by Sector 2011-2020E.....	262
Table 1.85 China Biologic Product Market 2015-2016E.....	281
Table 1.86 Top Ten Biologic Products (By Value) in China 2015	281
Table 1.87 Top Ten Biologic Product Suppliers (By Value) in China 2015.....	281
Table 1.88 Chinese Biologics Market Structure by TCs 2014.....	282
Table 1.89 Chinese Biologics Market Structure by Chemical Identities 2014	283
Table 1.90 Urban Biologics Market Structure by Disease Areas 2014.....	283
Table 1.91 Top 10 Biologics Companies in China 2014.....	284
Table 1.92 Top 10 Domestic Biologics Companies in China 2014.....	284
Table 1.93 Chinese Sales of SIP Pediatric Vaccines 2006-2016.....	287
Table 1.94 Chinese Vaccine Market 2006-2014.....	289
Table 1.95 Vaccine Consumption at Rep Chinese Hospitals 2010-2015	292
Table 1.96 Chinese Vaccine Market Structure 2014	292
Table 1.97 Chinese Hep B Vaccine Market Shares of Producers H1/2015.....	292
Table 1.98 Chinese Hep A Vaccine Market Shares of Producers H1/2015.....	292
Table 1.99 Chinese PPV 23 Market Shares of Producers H1/2015	293
Table 1.100 Chinese OTC Drug Market 2012-2015	297
Table 1.101 Structure of Chinese OTC Drug Market 2015	297
Table 1.102 Growth of OTC Drug Market Segments in 2013-2015.....	298
Table 1.103 Chinese Retail Pharmacy Market Growth Drivers 2015.....	298
Table 1.104 Chinese OTC Drug Market Segmentation 2013-2015	299
Table 1.105 Chinese Foreign Trade of Medicines and Health Products in 2016.....	310
Table 1.106 Top 10 Chinese Pharma Formulations Exporters in 2016.....	311

Table 2.1 Improvement of Medical Provision in China.....	317
Table 2.2 Comparisons of Healthcare Provision by China vs. Other Countries (1)	318
Table 2.3 Comparisons of Healthcare Provision by China vs. Other Countries (2)	318
Table 2.4 Comparisons of Healthcare Provision by China vs. Other Countries (3)	319
Table 2.5 Birth, Death and Population Natural Growth Rate	320
Table 2.6 Rising Life Expectancy of the Chinese Population	320
Table 2.7 Composition of the Chinese Population by Urban/Rural Division and Sex ..	321
Table 2.8 Composition of the Chinese Population by Age	322
Table 2.9 Composition of the Chinese Population by Education	323
Table 2.10 Medical Institutions by Specialties and Affiliations	338
Table 2.11 Inpatient Beds of Medical Institutions by Specialties and Affiliations	339
Table 2.12 Medical Institutions by Ownership Type	340
Table 2.13 Inpatient Beds of Medical Institutions by Ownership Type.....	340
Table 2.14 Inpatient Beds of Medical Institutions by Hospital Grade.....	341
Table 2.15 Number of Medical Institutions by Grade in 2012	341
Table 2.16 Number of Medical Institutions by Grade 2013-H1/2016.....	342
Table 2.17 Growth (%) of Medical Institutions by Grade 2013-H1/2016.....	342
Table 2.18 Regional Population Distribution in China 1990-2014.....	342
Table 2.19 Regional Distribution of Medical Institutions in Q1/2017	343
Table 2.20 Regional Distribution of Medical Institutions and Inpatient Beds in 2014 .	344
Table 2.21 Regional Distribution of Healthcare Professionals in 2014.....	345
Table 2.22 Distribution of Inpatient Beds by Medical Specialty 2005-2012	347
Table 2.23 Distribution of Physicians by Medical Specialty 2000-2012.....	347
Table 2.24 Healthcare Personnel in China 1990-2015.....	348
Table 2.25 Distribution of Healthcare Professionals in Cities and Counties 1990-2015	349
Table 2.26 Key Healthcare Reform Goals for 2017	368
Table 2.27 Key Healthcare Reform Goals by 2020	368
Table 2.28 Makeup of Healthcare Expenditures in China between 1980 and 2015	384

Table 2.29 Income and Outlays of Urban BMI Program M1-9/2016	387
Table 2.30 Income and Outlays of Urban BMI Program 2011-2016.....	387
Table 2.31 Urban BMI Fund Surplus 2011-2016.....	388
Table 2.32 Number of Enrollees of Urban/Rural BMI Programs 2011-2015	388
Table 2.33 China's Population Structure by Age 1982-2020	388
Table 2.34 Current Structure of Patient Visits and Expense in Urban BMI 2014.....	389
Table 2.35 Structure of Inpatient Expenses 2010-2014	389
Table 2.36 Coverage/Finance of New Rural Cooperative Medical System (NRCMS) .	392
Table 2.37 Overview of Medical Assistance Coverage in Urban & Rural Areas	399
Table 2.38 Coverage of Chinese Population by Basic Medical Insurance (Mln)	405
Table 2.39 Coverage and Finance of Urban BMI Programs	406
Table 2.40 New Added Western Medicines by TC in 2017 NDRL	411
Table 2.41 Newly Added Cardiovascular Drugs by Sub-TCs in 2017 NDRL.....	412
Table 2.42 WM Product Composition by TC: 2017 NRDL vs. 2009 NRDL	412
Table 2.43 CAGR Growth of Chinese Hospital Drug Market by TCs 2010-2013: All Drugs vs. Newly Added Drugs of 2009 NRDL	413
Table 2.44 New NDRL Products Made by Foreign Companies	414
Table 2.45 NEDL Product Definition Change: 2012 Ed. vs. 2009 Ed.....	440
Table 2.46 NEDL Structural Changes: 2012 Ed. vs. 2009 Ed.	441
Table 2.47 NEDL Changes by WM Therapeutic Classes: 2012 Ed. vs. 2009 Ed.....	441
Table 2.48 NEDL Changes by TCM Therapeutic Classes: 2012 Ed. vs. 2009 Ed.....	442
Tabel 2.49 112 Newly Added Drugs (Chemical Drugs and Biologicals) in NEDL 2012 Ed.	442
Table 2.50 Chemical Drugs with Newly Added/Reduced Routes/Forms in NEDL 2012	443
Table 3.1 Growth of Drug Consumption in China 2001-2016.....	459
Table 3.2 Growth of Healthcare Expenditures in China 1980-2015	460
Table 3.3 Rising Share of Per Capita Drug Expenditures in Healthcare.....	463
Table 3.4 Leading Diseases by Two-week Morbidity in 2003.....	469

Table 3.5 Leading Diseases by Two-week Morbidity in 2008	469
Table 3.6 Morbidity Rate of Chronic Diseases in 2003 and 2008	470
Table 3.7 Trend of Leading 10 Diseases among Inpatients of Urban Hospitals.....	471
Table 3.8 Leading 10 Diseases among Inpatients of County Level Hospitals.....	471
Table 3.9 Leading Causes of Death in Certain Regions of China in 2012	473
Table 3.10 Leading Causes of Death among Chinese Males in 2012.....	473
Table 3.11 Leading Causes of Death among Chinese Females in 2012	474
Table 3.12 Five-Year Cancer Prevalence in China (2011).....	493
Table 3.13 Breakdown of Cancer Survival Patients: Age Groups (2011).....	493
Table 3.14 Breakdown of Cancer Survival Patients: Male vs. Female (2011)	494
Table 3.15 Breakdown of Cancer Survival Patients: Urban vs. Rural (2011)	495
Table 3.16 Composition of Medical Care Providers in China 1950-2015.....	505
Table 3.17 Composition of Medical Care Providers in China 2016-2017.....	506
Table 3.18 # of Outpatient Visits and Inpatients in Medical Institutions 1980-2015	506
Table 3.19 Outpatient Visits and Inpatients by Medical Institution Type 2013-2015 ...	508
Table 3.20 Outpatient Visits and Inpatients by Medical Institution Type in Q1/2016... 508	
Table 3.21 Regional Distribution of Outpatient Visits and Inpatients in Q1/2016	509
Table 3.22 # of Outpatient Visits and Inpatients by Medical Specialties in 2012	510
Table 3.23 # of Outpatient & Emergencies Visits by Medical Specialties 2011-2012 ..	510
Table 3.24 Average Days of Hospitalization 1985-2012	511
Table 3.25 Occupancy Rate and Average Days of Hospitalization by Hospital Type 2013-2015	511
Table 3.26 Regional Distribution of Medical Institutions and Inpatient Beds in 2016 .	512
Table 3.27 Overall Healthcare Expenditures in China 2013-2015	512
Table 3.28 Composition of Healthcare Expenditures in China 2013-2015	513
Table 3.29 Inpatient Healthcare Expenditures in China 2013-H1/2016	513
Table 3.30 Segmentation of Top 100 Chinese Pharma Companies 2016	515
Table 3.31 Top 20 Chinese Pharmaceutical Cos by Sales Value 2016	515
Table 3.32 Top 10 Drug Suppliers to Chinese Hospitals Q4/2016	516

Table 3.33 Top 20 Domestic Western Medicines in Chinese Hospitals 2016.....	516
Table 3.34 Top 10 Drug Products in Chinese Hospitals Q4/2016.....	518
Table 3.35 Top 10 TCs in Chinese Hospitals 2016.....	518
Table 3.36 Medical Institution Drug Consumption by Facility Type 2010-H1/2017	519
Table 3.37 Medical Institution Drug Consumption by Facility Type 2007-2016	520
Table 3.38 Top 20 Pharma Cos by Hospital Drug Sales Value 2016	521
Table 3.39 Shares of Top Ten Pharma Suppliers by Therapeutic Categories in 2016 ...	521
Table 3.40 Drugs Consumption by Rep Hospitals in Major Cities 2011-2016.....	522
Table 3.41 Top 10 TCs by Sales in Rep Hospitals in Major Cities 2016.....	522
Table 3.42 Top 10 Pharma Suppliers to Rep Urban Hospitals by Sales 2015-2016	523
Table 3.43 Top 20 Pharma Suppliers to Rep Urban Hospitals by Sales 2016	523
Table 3.44 Top 20 Products in Rep Urban Hospitals by Sales 2016.....	524
Table 3.45 Chemical Drugs in Chinese Urban Public Hospitals 2015.....	525
Table 3.46 Chemical Drugs by TCs in Chinese Urban Public Hospitals 2013-2015.....	525
Table 3.47 Top 10 Chemical Drugs in Urban Public Hospitals 2015	526
Table 3.48 Top 10 Chemical Drug Suppliers to Urban Hospitals by Value 2015	526
Table 3.49 Growth of County Level Hospital Drug Market in Six Provinces 2015	527
Table 3.50 Shares of County Level Hospital Drug Market in Six Provinces 2015.....	527
Table 3.51 MNC Market Share in Urban and County Level Hospitals 2009-2015	528
Table 3.52 Top 10 TCs in Chinese County Level Hospitals M10/2015.....	529
Table 3.53 Top 10 Drug Suppliers to Chinese County Level Hospitals M10/2015.....	530
Table 3.54 Shares of MNC/Local Cos in County Level Hospitals of Six Provinces M10/2015	530
Table 3.55 Top 10 Drug Suppliers to County Level Hospitals in Six Provinces M10/2015	531
Table 3.56 Top 10 Products in County Level Hospitals M10/2015	532
Table 3.57 TC Composition of County Level Hospital Drug Market 2014-2015E.....	532
Table 3.58 TC Composition of Chinese County Level Hospital Drug Market 2014-2015E: WMs vs. TCMs	533

Table 3.59 Top 20 WMs of Chinese County Level Hospitals 2014-2015E.....	533
Table 3.60 Top 20 WM Brands of Chinese County Level Hospitals 2014-2015E	534
Table 3.61 Top 20 FTCMs of Chinese County Level Hospitals 2014-2015E	535
Table 3.62 Top 20 FTCM Brands of Chinese County Level Hospitals 2014-2015E	536
Table 3.63 Top 20 WM Suppliers to County Level Hospitals 2014-2015E	537
Table 3.64 Top 20 FTCM Suppliers to County Level Hospitals 2014-2015E.....	538
Table 3.65 Number and Distribution of Medical Facilities in China 2014.....	538
Table 3.66 Chinese County Public Hospitals Market 2011- H1/2017	539
Table 3.67 Drug Consumption by Urban Public CHCs 2010- H1/2017.....	539
Table 3.68 Drug Sales and Market Shares of CHCs in Six Cities 2016	540
Table 3.69 Top Five TCs in CHCs and Hospitals of Six Tier 1 & 2 Cities 2016.....	540
Table 3.70 Top 15 Provinces by Patient Visit Share in CHCs 2015	540
Table 3.71 Growth of Drugs Sales Value in Tier 1 Cities 2015: Hospitals VS. CHCs..	541
Table 3.72 Top 5 TCs by Sales Value 2015: Hospitals vs. CHCs	541
Table 3.73 Top 10 Suppliers to Tier 1 City CHCs by Sales Value 2015.....	542
Table 3.74 Top 10 Products in Tier 1 City CHCs by Sales Value 2015.....	542
Table 3.75 TC Composition of Urban CHC Drug Consumption 2014-2015	543
Table 3.76 TC Composition of Urban CHC Drug Consumption 2014-2015: WMs vs. TCMs	543
Table 3.77 Top 20 WMs in Urban CHCs 2014-2015.....	544
Table 3.78 Top 20 WM Brands in Urban CHCs 2014-2015.....	544
Table 3.79 Top 20 FTCMs in Urban CHCs 2014-2015	545
Table 3.80 Top 20 FTCM Brands in Urban CHCs 2014-2015	546
Table 3.81 Drug Consumption by Rural Township Health Centers 2010-H1/2017	546
Table 3.82 TC Composition of Drug Consumption by Chinese Township Health Centers 2014-2015	547
Table 3.83 TC Composition of Drug Consumption by Chinese Township Health Centers 2014-2015: WMs vs. TCMs.....	547
Table 3.84 Top 20 WMs of Chinese Township Health Centers 2014-2015.....	548

Table 3.85 Top 20 WMs of Chinese Township Health Centers 2014-2015	549
Table 3.86 Top 20 FTCMs of Chinese Township Health Centers 2014-2015E.....	549
Table 3.87 Top 20 FTCM Brands of Chinese Township Health Centers 2014-2015.....	550
Table 3.88 Number of Chinese Retail Pharmacy Outlets 2012-2015	552
Table 3.89 Top 20 OTC Drug & Health Food Cos in Chinese Retail Pharmacy Market Q4/2016.....	554
Table 3.90 Top 20 OTC Drug & Health Products by Retail Pharmacy Sales Q4/2016.....	555
Table 3.91 Composition of Chinese Retail Pharmacy Drug Sales Q4/2016.....	556
Table 3.92 Retail Drug Consumption by Facility Type 2010- H1/2017	557
Table 3.93 Top 10 TCs by Retail Sales in 22 Major Chinese Cities 2013-H1/2016.....	557
Table 3.94 Top 10 TCs by Market Shares in 22 Major Chinese Cities H1/2016.....	558
Table 3.95 Top 10 Chemical Drug TCs by Urban Retail Pharmacy Sales.....	558
Table 3.96 Top 10 Branded Chemical Drugs by Retail Pharmacy Sales in Tier 1 Cities 2015.....	559
Table 3.97 Top 10 Branded Chemical Drugs by Retail Pharmacy Sales in Tier 2 Cities 2015.....	559
Table 3.98 Top 10 Branded Chemical Drugs by Retail Pharmacy Sales in Tier 3 Cities 2015.....	560
Table 3.99 Top 10 Branded Chemical Drugs by Retail Pharmacy Sales in Tier 4 Cities 2015.....	560
Table 3.100 Top 20 Western Medicines by Retail Sales 2016	562
Table 3.101 Chinese Retail Pharmacy Market 2009-2015: Non-Drugs vs. Drugs	562
Table 3.102 Composition of Chinese Retail Market Sales of Non-drugs 2011-2015	563
Table 3.103 Chinese Retail Pharmacy Drug Sales 2011-2015: WMs vs. TCMs	563
Table 3.104 Chinese Retail Pharmacy Sales 2011-2015: OTC vs. Rx.....	563
Table 3.105 Chinese Retail Pharmacy Market Segmentation in 2016.....	564
Table 3.106 Chinese Online Pharmacy Market and Forecast 2011-2017	565
Table 3.107 Chinese Online Pharmacy Drug Sales Value 2011- H1/2017	565
Table 3.108 Top Ten Online Pharmacies by Sales Value 2015	565
Table 3.109 Consumer Age Distribution of TMall Pharmacy Platform.....	566

Table 3.110 Sales Composition of TMall Pharmacy Platform 2015	566
Table 3.111 Top 10 Brands on TMall Pharmacy Platform 2015.....	566
Table 3.112 Gross Profit Margins and Expense Ratio of Pharma B2C Sector 2015	567
Table 3.113 Expenditure Composition of Chinese Pharma B2C Sector 2015.....	567
Table 3.114 Overall and Online Chinese Drug Sales 2014-2020	567
Table 3.115 Overview of Chinese OTC Drug Market 2015-2016 (CNY).....	569
Table 3.116 Overview of Chinese OTC Drug Market 2015-2016 (US\$).....	571
Table 3.117 Chinese OTC Drug Market Forecast 2016-2026	573
Table 3.118 Shares of OTC and Rx Products in Chinese Drug Terminal Sales 2015 ...	574
Table 3.119 Structure of Chinese OTC Drug Terminal Market 2014-2015.....	574
Table 3.120 Share of OTC Drugs in Terminal Markets of 3 Cities* 2014-2015.....	575
Table 3.121 Structure of OTC Drug Sales in Different Tiers of Retail Pharmacy 2015	575
Table 3.122 Number of Retail Pharmacies 2013-2015	575
Table 3.123 Number of Retail Pharmacies by Level 2015	575
Table 3.124 Top 10 TCs by Chinese Retail Pharmacy OTC Drug Sales 2015.....	576
Table 3.125 Top 10 OTC Drug Brands and Suppliers by Retail Pharmacy Sales 2015	577
Table 3.126 Top 10 OTC Suppliers to Chinese Retail Pharmacies 2015	577
Table 3.127 Top 20 OTC & Health Food Players in China Retail Pharmacy Market 2015	578
Table 3.128 Top 20 OTC & Health Products in China Retail Market 2015	578
Table 3.129 China's Top 5 OTC Chemical Drug Brands in 2015.....	579
Table 3.130 Top 10 Formulated TCMs by Chinese Hospital Sales (May 2013).....	590
Table 3.131 Composition of Chinese Pharma Market 2012: TCMs vs. WMs	591
Table 3.132 Hospital Market Share of Formulated TCMs by TCs 2012.....	591
Table 3.133 Market Share of Formulated TCMs by Hospital Tier 2012	592
Table 3.134 Formulated TCMs under NRDL 2000 Ed. & 2009 Ed.	592
Table 3.135 Share of Formulated TCMs in Total NRDL Reimbursement 2010	592
Table 3.136 Share of NEDL FTCMs in Chinese FTCM Sales Value by TCs in 2012 ..	592
Table 3.137 Composition of Urban Hospital TCM Consumption 2015	593

Table 3.138 Chinese Public Hospital Formulated TCM Market by TCs in 2015	594
Table 3.139 Structure of TCM Consumption by TCs in Public Hospitals 2015	594
Table 3.140 Top 20 TCM Drugs in Urban Public Hospitals 2015	595
Table 3.141 Top 20 TCM Drugs in County Level Public Hospitals 2015	595
Table 3.142 Top 20 TCM Drugs in Community Health Service Centers 2015	596
Table 3.143 Top 20 TCM Drugs in Township Health Centers 2015	597
Table 3.144 Top 20 TCM Suppliers by Sales to Urban Public Hospitals 2015	597
Table 3.145 Top 20 TCM Suppliers by Sales to County Level Public Hospitals 2015	598
Table 3.146 Top 20 TCM Suppliers by Sales to Community Health Service Centers 2015	599
Table 3.147 Top 20 TCM Suppliers by Sales to Township Health Centers 2015	599
Table 3.148 Changing Hospital TCM Drug Consumption Patterns Since 2006.....	600
Table 3.149 Chinese TCM Market Segmentation 2013-2015.....	601
Table 3.150 Chinese Drug Market Size by Major Segments 2014-2016.....	603
Table 3.151 Growth of Chinese Hospital Drug Sales by City Tiers 2016	604
Table 3.152 MNC Share of Hospital Drug Markets in 24 Provinces/Regions	604
Table 3.153 Growth of Chinese Hospital Drug Sales by City Level in 2014-2016.....	605
Table 3.154 2015 Hospital Drug Sales Growth in 24 Provinces.....	606
Table 3.155 Structure of Provincial Level Hospital Drug Markets in China 3Qs/2015	607
Table 3.156 Growth of Provincial Level Hospital Drug Markets	608
Table 3.157 Growth of Rx Drug Sales Value in Rep Shanghai Hospitals 2016.....	609
Table 3.158 Rx Drug Sales Value by TCs in Rep Shanghai Hospitals 2016	609
Table 3.159 Top 10 Pharma Suppliers to Rep Shanghai Hospitals 2016.....	610
Table 3.160 Drug Sales Champions in Rep Public Hospitals of 22 Cities 2016.....	610
Table 3.161 Regional Chinese Pharma Distribution Sales in 2016.....	611
Table 3.162 Regional Pharmaceutical Distributor Sales Structure 2016	612
Table 3.163 Top 15 Regional Drug Distributors by Operating Revenues 2016.....	613
Table 3.164 Geographic Coverage of 15 Regional Drug Distributors.....	613
Table 3.165 Top 15 Regional Drug Distributors by Gross Profit Margin 2016.....	614

Table 3.166 Regional Distribution of Chinese Retail Pharmacy Outlets 2014.....	614
Table 3.167 Number of Urban Retail Pharmacies by City Tiers 2012 & 2014	615
Table 3.168 Growth of Urban Retail Pharmacy Sales by City Tier 2015.....	615
Table 3.169 Retail Pharmacy Market Segmentation by Level 2015.....	616
Table 3.170 Retail Pharmacy Market Segmentation by Level 2015.....	616
Table 3.171 Leading Provincial Level Retail Pharmacy Markets	616
Table 3.172 Chinese Retail OTC Drug Consumption Value by City Tier 2012	618
Table 3.173 Top 10 TCs by Share of Rx Value & No. in Shanghai Rep CHCs 2013....	619
Table 3.174 Top 10 Sub TCs by Rx Value Share & Growth in Shanghai CHCs 2013..	620
Table 3.175 Top 10 Drugs by Rx Value Share and Growth in Shanghai Rep CHCs 2013	620
Table 3.176 Top 10 NEDL Products in Shanghai Rep CHCs in 2013.....	621
Table 3.177 Segmentation of All Pharmaceutical Companies in China 2016	623
Table 3.178 Hospital Market Shares of Local, JV and Imported Drugs 2006-2016.....	623
Table 3.179 China Urban Hospital Drug Structure: MNCs vs. Domestic 2012-2016..	623
Table 3.180 Hospital Drug Sales Growth (%) in 2014-2016: Domestic vs. MNCs.....	623
Table 3.181 Chinese Hospital Drug Sales Growth Drivers 2014-2015	624
Table 3.182 Hospital Drug Sales in 24 Provinces 2015: Domestic vs. MNCs	624
Table 3.183 Growth of County Level Hospital Drug Market in Six Provinces 2015: Domestic vs. MNCs	625
Table 3.184 Shares of County Level Hospital Drug Market in Six Provinces 2015: Domestic vs. MNCs	626
Table 3.185 Chinese Drug Market Segmentation 2013-15: MNCs vs. Domestic (1)..	627
Table 3.186 Chinese Drug Market Segmentation 2013-15: MNCs vs. Domestic (2)..	627
Table 3.187 Drug Sales Champions in Rep Public Hospitals of 22 Cities 2016	627
Table 3.188 Drug Sales Champions by TCs in Rep Urban Public Hospitals 2016	628
Table 3.189 Drug Consumption of Leading TCs in Level 3 General Hospitals 2015: Domestic vs. JVs vs. Foreign Cos.....	630
Table 3.190 Drug Consumption of Leading TCs in Level 2 General Hospitals 2015: Domestic vs. JVs vs. Foreign Cos.....	630

Table 3.191 Supplier Structure of Level 3 General Hospitals 2015.....	630
Table 3.192 Supplier Structure of Level 2 General Hospitals 2015.....	630
Table 3.193 Leading Suppliers of Major TCs in Level 3 General Hospitals 2015	631
Table 3.194 Leading Suppliers of Major TCs in Level 2 General Hospitals 2015	631
Table 3.195 Top 7 Diseases by Mortality Rate Among China Urban Residents 2014...	635
Table 3.196 Top Ten Anticancers by Rep Hospital Consumption in 3Qs/2015	636
Table 3.197 Rep Hospital Consumption of Anticancers and Immuno-suppressants in Major Cities 2007-2015E	636
Table 3.198 Anticancer Drug Market Trend by Sub-TCs in Rep Hospitals 2013-14	637
Table 3.199 Rep Hospital Consumption of Small Molecule Target-oriented Anticancers in Major Cities 2006-2015E	637
Table 3.200 Icotinib Rep Hospital Consumption in Major Cities 2011-2015.....	638
Table 3.201 Imatinib Rep Hospital Consumption in Major Cities 2007-2014	638
Table 3.202 Small Molecule Target-oriented TKIs Drugs Approved by CFDA.....	638
Table 3.203 20 Approved Target-oriented Anticancers Approved by the CFDA.....	639
Table 3.204 Cancer Immunotherapy Drug Consumption by Urban Rep Hospitals 2016	640
Table 3.205 Cancer Immunotherapy Drug Consumption by Urban Rep Hospitals 2006-2016	641
Table 3.206 Target-oriented Micromolecule Anticancers (Tinibs) on Chinese Market .	641
Table 3.207 Top Four Tinibs by Urban Rep Hospital Consumption 2007-2016E.....	641
Table 3.208 Top Four Imatinib Brands by Rep Urban Public Hospitals 2016.....	642
Table 3.209 Chinese Market of Digestive System and Metabolism Drugs 2014-2016 .	649
Table 3.210 Chinese Market of Digestive System and Metabolism Drugs	649
Table 3.211 Top 10 Suppliers of Digestive System and Metabolism Drugs	649
Table 3.212 Top 10 Digestive System & Metabolism Chemical Drugs by Share 2015	650
Table 3.213 Top 10 Digestive System and Metabolism Biologics by Share 2015	650
Table 3.214 China Insulin Market 2015	651
Table 3.215 Leading Players of Insulin & Analogues in China 2015	651
Table 3.216 Cardiovascular Drugs Consumption in Rep Hospitals of 22 Cities	652

Table 3.217 Hypertensive Sales in Hospitals of Major Chinese cities 2012-2016.....	653
Table 3.218 Hypertensive Sales Value by TCs in Major City Hospitals 2012-2016.....	653
Table 3.219 Hypertensive Submarket Shares in Major City Hospitals 2012-2016.....	653
Table 3.220 Top 10 Hypertensive Drugs in Hospitals of Major Chinese Cities 2016...	654
Table 3.221 Rep Hospital Consumption of Hepatic Drugs in Major Cities 3Qs/2015..	654
Table 3.222 Rep Hospital Consumption of Hepatic Drugs in Major Cities 2011-2015	654
Table 3.223 Top 10 Hepatic Drugs by Rep Hospital Consumption in 3Qs/2015	655
Table 3.224 Top 10 Rep Hospital Suppliers of Hepatic Drugs in 3Qs/2015	655
Table 3.225 Cause of Respiratory Diseases in Shanghai H1/2016.....	659
Table 3.226 COPD Incidence Rate by Gender in Shanghai	659
Table 3.227 COPD Incidence Rate by Age in Shanghai.....	660
Table 3.228 Top 10 COPD Drugs in Shanghai Rep Hospitals.....	660
Table 3.229 Antidepressant Consumption in Rep Urban Hospitals of Major Cities 2009-2016	661
Table 3.230 Top 10 Antidepressant by Value in Rep Hospitals of Major Cities 3Qs/2016	662
Table 3.231 Antidepressant Market Landscape in Rep Hospitals of Major Cities 3Qs/2016	662
Table 3.232 Top Antidepressant Suppliers in Rep Major City Hospitals 3Qs/2016.....	662
Table 3.233 Statistical Summary of Chinese Senior Population	666
Table 3.234 Consumption of Geriatric Drugs in Major City Public Hospitals 2011-2014	666
Table 4.1 Number of Pharma Manufacturers 2013-2016	690
Table 4.2 Number of Pharma Distribution License Holders 2013-2016	690
Table 4.3 Number of Retail Pharmacy Chain Companies 2011 – 2016	690
Table 4.4 Number of Retail Pharmacy Stores 2011 – 2016.....	690
Table 4.5 Number of Protected TCM Products 2013- 2016	691
Table 4.6 No. of Drug Applications with Completed CDE Review 2012-2016*	692
Table 4.7 No. of CDE Accepted Drug Applications 2009-2016*	692
Table 4.8 # of CDE Accepted Chemical Drug Applications 2010-2016	693

Table 4.9 # of CDE Accepted Therapeutic Biologics Applications in 2016	693
Table 4.10 Breakdown of Drug Marketing Approvals in 2012-2016	693
Table 4.11 Breakdown of Drug Clinical Approvals in 2012-2016.....	694
Table 4.12 No. of Withdrawn Drug Applications 2012-2016*	694
Table 4.13 No. of Rejected Drug Applications 2012-2016*	694
Table 4.14 Overview of All Registration Applications in 2011-2016.....	695
Table 4.15 Drug Registration Applications Completed by CDE 2013-16 (1)	695
Table 4.16 Drug Registration Applications Completed by CDE 2013-16 (2)	695
Table 4.17 Number of New Registration Applications Accepted by CDE 2013-2016..	696
Table 4.18 Drug Registration Applications under Priority Review 2016 (1).....	696
Table 4.19 Drug Registration Applications under Priority Review 2016 (2).....	696
Table 4.20 Priority Review Applications Recommended for Approvals in 2016	696
Table 4.21 Drug Registration Applications under CDE Review in 2016.....	697
Table 4.22 Chemical Drug Registration Applications Accepted by CDE in 2011-16....	699
Table 4.23 Biological Registration Applications Accepted by CDE in 2012-16	699
Table 4.24 TCM Registration Applications Accepted by the CDE in 2012-16	699
Table 4.25 Registration Applications with Completed CDE Review in 2016	700
Table 4.26 CDE Recommendations for Chemical Drug Applications in 2016.....	700
Table 4.27 Number of Completed Chemical Drug Registration Applications by CDE 2012-2016	701
Table 4.28 CDE Accepted Chemical Drug Applications in 2016	701
Table 4.29 CDE Accepted Drug Applications 2013-2016	701
Table 4.30 CDE Recommendations for Biological Product Applications in 2016	702
Table 4.31 Number of Concluded Biological Product Registration Applications by CDE in 2012-2016	702
Table 4.32 CDE Recommendations for TCM Registration Applications in 2016.....	702
Table 4.33 # of Concluded TCM Registration Applications by the CDE in 2012-16....	703
Table 4.34 Pharma-related Regulatory Introductions 2013-2016 and H1/2017	704
Table 4.35 Pharma-related Regulations and Policies Newly Issued in H1/2017	705

Table 4.36 Quarterly Pharma-Related Regulatory Introductions 2012-2016	706
Table 4.37 New Pharma-Related Regulations and Policies Issued in 2016 (1).....	707
Table 4.38 New Pharma-Related Regulations and Policies Issued in 2016 (2).....	708
Table 4.39 New Pharma-Related Regulations and Policies Issued in 2016 (3).....	709
Table 4.40 New Classification System for Registration and Exclusivity of Chemical Drugs	774
Table 4.41 Overview of Drug Application Submissions from MAH Trial Areas*	835
Table 5.1 Chinese Drug Terminal Markets 2010-H1/2017(1)	1110
Table 5.2 Chinese Drug Terminal Markets 2010- H1/2017 (2)	1111
Table 5.3 Growth of Chinese Pharmaceutical Market by Channels in 2013-2016.....	1111
Table 5.4 CAGR Growth of Chinese Drug Terminal Markets 2012-2018E.....	1111
Table 5.5 Chinese Drug Terminal Market Structure 2012-2018E	1112
Table 5.6 Chinese Hospital Drug Market 2011-2016	1112
Table 5.7 Chinese Drugs Market Segmentation 2009-2016 by Value (CNY bln).....	1114
Table 5.8 Chinese Drugs Market Segmentation 2010-2016 by Growth (%).....	1115
Table 5.9 Chinese Drugs Market Segmentation 2009-2016 by Market Share (%)	1115
Table 5.10 Chinese Drug Market Segmentation 2013-2015 by Value: OTC vs. RX ..	1115
Table 5.11 Chinese Drug Market Segmentation 2013-2015 by Market Share: OTC vs. RX	1116
Table 5.12 Chinese Drug Market Segmentation 2013-2015 by Value: Chemical Drugs vs. FTCMs	1116
Table 5.13 Chinese Drug Market Segmentation 2013-2015 by Market Share: Chemical Drugs vs. FTCMs.....	1116
Table 5.14 Revenues and Profits of Chinese Pharma Industry 2010-2016E	1118
Table 5.15 Growth of Chinese Pharma Industrial Value Added vs. GDP.....	1119
Table 5.16 Chinese Pharmaceutical Distributor Sales 2011-2016.....	1119
Table 5.17 Chinese Pharma Distributor Sales by Terminal Markets 2016	1120
Table 5.18 Summary of Chinese Pharma Events 2013-2016 and H1/2017.....	1173
Table 5.19 Summary of Sino-foreign Licensing Deals in H1/2017 (1).....	1174
Table 5.20 Summary of Sino-foreign Licensing Deals in H1/2017 (2).....	1175

Table 5.21 Summary of Selected JV/Strategic Alliance Deals in H1/2017 (1).....	1175
Table 5.22 Summary of Sino-foreign M&A Deals in H1/2017	1176
Table 5.23 Summary of Sino-foreign CR/Collaborative R&D Agreements in H1/2017	1177
Table 5.24 Summary of Chinese Pharma Events in 2012 - 2016.....	1178
Table 5.25 Summary of Sino-foreign Licensing Deals in 2016 (1)	1179
Table 5.26 Summary of Sino-foreign Licensing Deals in 2016 (2)	1180
Table 5.27 Summary of Sino-foreign Licensing Deals in 2016 (3)	1181
Table 5.28 Summary of Sino-foreign Licensing Deals in 2016 (4)	1182
Table 5.29 Summary of Sino-foreign M&A Deals in 2016 (1).....	1182
Table 5.30 Summary of Sino-foreign M&A Deals in 2016 (2).....	1184
Table 5.31 Summary of Selected Sino-foreign JV/Strategic Alliance Deals in 2016 (1)	1185
Table 5.32 Summary of Selected Sino-foreign JV/Strategic Alliance Deals in 2016 (2)	1186
Table 5.33 Summary of Selected Sino-foreign JV/Strategic Alliance Deals in 2016 (3)	1187
Table 5.34 Summary of Sino-foreign CR/Collaborative R&D Agreements in 2016... ..	1187
Table 5.35 Number of Recorded Novel New Drug Projects in China in 2012 - 2016.	1189
Table 5.36 Chinese New Drug Projects by R&D Phase in 2010 - 2016	1189
Table 5.37 Summary of Chinese New Drug Projects Recorded in 2016 (1)	1190
Table 5.38 Summary of Chinese New Drug Projects Recorded in 2016 (2)	1191
Table 5.39 Quarterly Pharma-Related Regulatory Introductions in China in 2012 - 2016	1191
Table 5.40 New Pharma-Related Regulations and Policies Issued in 2016 (1)	1192
Table 5.41 New Pharma-Related Regulations and Policies Issued in 2016 (2)	1193
Table 5.42 IMS Forecast of Chinese Pharma Market in 2011-2020	1200
Table 5.43 Chinese Drug Market Size and Growth 2009-2017E.....	1202
Table 6.1 Selected Outbound Sino-Foreign Licensing Deals in 2015 and 2016.....	1300

Table 6.2 Indigenously-developed Class I New Chemical Drugs (Production License) 2006-2013	1312
Table 6.3 Indigenously-developed Class I New Biologics (Production License) 2006-2013	1313
Table 6.4 Indigenously-developed Class I New Drugs (New Drug Certificates) 2006-2013	1313
Table 6.5 Time Required for Registration of Class 1.1 New Drugs in China.....	1314
Table 6.6 Class 1 New Drugs Approvals in 2003-2015	1314
Table 6.7 Class 1 New Drug Applicants by Ownership 2003-2015	1315
Table 6.8 Class 1 New Drug Applicants by Company Size 2003-2015	1315
Table 6.9 Class 1 New Drug Applicants by Stock Listing 2003-2015	1315
Table 6.10 Class 1 New Drug Approvals by # of Producers 2003-2015	1315
Table 6.11 Approved Class 1 New Drugs by Indications 2003-2015	1316
Table 6.12 Total New Anti-cancer Chemical Drugs Applications in China 2014	1316
Table 6.13 Class 1.1 & 3.1 New Anti-cancer Chemical Drugs Applications in China 2014	1317
Table 6.14 New Class 1.1 Anti-cancers Drugs Applications in China 2014.....	1317
Table 6.15 Applications for New Tinib Class of Anticancers in China 2014	1318
Table 6.16 Drug Applications on Special Approval Path 2004-2015	1318
Table 6.17 Drug Applications on Special Approval Path 2004-2015: Local vs. Import	1319
Table 6.18 Structure of Drug Applications on Special Approval Path 2004-2015	1319
Table 6.19 Drug Applications on Special Approval Path by Indications 2015.....	1320
Table 6.20 Top Applicants by # of Drug Applications on Special Approval Path in 2015	1320
Table 6.21 Drug Registration Applications on Fast Tracks 2011-2014: Domestic vs. Import.....	1322
Table 6.22 Applications on Fast Drug Registration Tracks 2011-2014: Top Applicants	1322
Table 6.23 Number of Recorded New Drug Projects in China in 2013-2016 and H1/2017	1323

Table 6.24 Chinese New Drug Projects by R&D Phase in 2012-2016 and H1/2017 ..	1323
Table 6.25 Summary of Chinese New Drug Projects Recorded in H1/2017	1323
Table 6.26 Number of Recorded Novel New Drug Projects in China in 2012 - 2016.	1324
Table 6.27 Chinese New Drug Projects by R&D Phase in 2010 - 2016	1325
Table 6.28 Summary of Chinese New Drug Projects Recorded in 2016 (1)	1325
Table 6.29 Summary of Chinese New Drug Projects Recorded in 2016 (2)	1326
Table 7.1 Major Pharma Marketing Spending by Channels in China 2016.....	1447
Table 7.2 Chinese Pharma B2C Market Size and Forecast 2011-2017.....	1504
Table 7.3 E-Commerce Composition of Chinese Drug Distributor Sales 2016.....	1505
Table 7.4 Composition of B2B Sales by Chinese Drug Distributors 2016	1505
Table 7.5 Composition of B2C Sales by Chinese Drug Distributors 2016	1505
Table 7.6 Anticipation of Mobile Health Development in China	1515
Table 7.7 Mobile Health Will Change the Way People Acquire Medical Info	1515
Table 7.8 Purposes of Mobile Health Purchases	1516
Table 7.9 Anticipated Leading Application Centers of Mobile Health Products	1516
Table 7.10 Leading Issues of Mobile Health Products.....	1516
Table 7.11 Perceived Reasonable Pricing of Mobile Health Hardware	1517
Table 7.12 Feedbacks on Existing Prices of Mobile Health Products	1517
Table 7.13 Mobile Health APP Downloads by Respondents in 2014	1517
Table 7.14 Reasonable Fee Structure of Mobile Health APPs	1518
Table 7.15 Chinese Mobile Healthcare User Population 2011-2015E.....	1518
Table 7.16 Penetration of Mobile Healthcare APPs in Chinese Mobile Netizens 2011-2015	1518
Table 7.17 Users Demand Preference for Mobile Healthcare APPs	1518
Table 8.1 Types of Clinical Research Participated by Respondents	1601
Table 8.2 # of Clinical Trials Participated by Respondents	1602
Table 8.3 Understanding of WMA's Helsinki Declaration.....	1602
Table 8.4 Relevant Clinical Research Experience of Respondents.....	1602
Table 8.5 Origins of Clinical Research Knowledge of Respondents	1602

Table 8.6 Benefits of Clinical Research Perceived by Respondents..... 1602
Table 8.7 Barriers of Clinical Research Faced by Respondents 1603

LIST OF CHARTS

Chart 1.1 Core Business Revenues of Broad Chinese Pharma Industry 2006 – 2016...	107
Chart 1.2 Gross Output Value of Broad Chinese Pharmaceutical Industry 2006 – 2015	107
Chart 1.3 Pretax Profit Margin Trend of the Chinese Pharma Industry 1997-2016.....	109
Chart 1.4 China in Global API Market 2011-2020	117
Chart 1.5 Revenues of Chinese Biologic Product Subsector 2006-2016.....	132
Chart 1.6 Net Profit of Chinese Biologic Products Subsector 2006-2016.....	132
Chart 1.7 Profit Margins of the Chinese Pharma Distribution Sector Since 2002.....	144
Chart 1.8 R&D Centers of RDPAC Members by Research Stage in China	167
Chart 1.9 R&D Centers of RDPAC Members by Function in China.....	168
Chart 1.10 Locations of R&D Centers of RDPAC Members in China	168
Chart 1.11 Chinese Market Access by New Drugs – 1 Year After Launch.....	169
Chart 1.12 Chinese Market Access by New Drugs – 2 Years after Launch.....	170
Chart 1.13 Number of Chinese Retail Pharmacy Stores 2006-2016.....	269
Chart 1.14 Number of Chinese Retail Pharmacy Chains 2006-2016.....	269
Chart 1.15 Number of Outlets Owned by Chinese Retail Pharmacy Chains Since 2006	270
Chart 1.16 Number of Independent Chinese Retail Pharmacy Stores Since 2006	270
Chart 1.17 Structure of Retail Pharmacy Outlets Since 2006.....	271
Chart 1.18 Growth of Chinese Retail Pharmacy Sales Since 2000.....	272
Chart 1.19 Shares of Retail Drug Sales Channels Since 2001	272
Chart 1.20 Chinese Sales of SIP Pediatric Vaccines 2006-2016.....	287
Chart 1.21 Chinese Sales of Adult Vaccines 2006-2016.....	287
Chart 1.22 Chinese Vaccine Market Size 2010-2019E	288
Chart 1.23 Chinese Foreign Trade of MHPs 2008-2016.....	310
Chart 2.1 Healthcare Spending by Funding Source 1980-2015 (CNY bln).....	386
Chart 3.1 Growth of Healthcare Expenditures in China Since 2000	461
Chart 3.2 Growth of Per Capita Healthcare Expenditures in China Since 1990.....	461

Chart 3.3 Composition of Healthcare Expenditures in China Since 2000.....	462
Chart 3.4 Market Share Trend of County Level Hospitals in China 2014-2020	528
Chart 3.5 Distribution of County Level Hospitals by Drug Sales (Per Hospital) 2014.	529
Chart 3.6 Chinese OTC Drug Consumption Value by City Tier and Sales Channel 2012	617
Chart 3.7 Chinese Retail OTC Drug Consumption Value by Cities 2012.....	618
Chart 3.8 Rx Drug Growth in Various Levels of Shanghai Rep Medical Facilities 2013	619
Chart 4.1 Number of Drug New Registration Applications Accepted by CDE 2009-2016	697
Chart 4.2 Chemical Drug Registration Applications Accepted by the CDE in 2011-2016	698
Chart 4.3 Administrative Structure of Food and Drug Regulation in China	743
Chart 4.4 CFDA Organizational Chart.....	744
Chart 4.5 Application and Approval Procedures for Clinical Trials	788
Chart 4.6 Application and Approval Procedure for Imported Drugs (1)	807
Chart 4.7 Application and Approval Procedure for Imported Drugs (2)	808
Chart 4.8 Supplemental Application and Approval Procedure for Imported Drugs (1)	808
Chart 4.9 Supplemental Application and Approval Procedure for Imported Drugs (2)	809
Chart 4.10 Compulsory License Application Process.....	987
Chart 4.11 The model for realizing minimum drug resale profit margin in China	1069
Chart 6.1 Pharmaceutical Industry's Expenditure on R&D.....	1340
Chart 6.2 Supply Structure of Chinese Drug Manufacturers 2008/2014.....	1341
Chart 6.3 Government Spending on R&D	1341
Chart 7.1 Structure of the Chinese Pharmaceutical Distribution System in the Old Days	1409
Chart 7.2 Hospital Distribution of the Respondents	1436
Chart 7.3 Professional Title Distribution of the Respondents.....	1437
Chart 7.4 No. of Conferences in Average Attended Annually (last two years).....	1437
Chart 7.5 Lengthen of Optimal Duration for an Academic Conference	1438

Chart 7.6 Which Sponsors of Academic Conferences Are Most Trusted by You?	1438
Chart 7.7 What Types of Meetings Do You Prefer to Attend?	1439
Chart 7.8 The Major Purpose of Attending an Academic Event	1439
Chart 7.9 Registration Fee Paid to Attend an Academic Conference?.....	1440
Chart 7.10 Evaluation on Overall Situation of Domestic Academic Conferences.....	1442
Chart 7.11 Any Areas for Improvement? (Check all that apply).....	1442
Chart 7.12 Top 10 Companies in Academic Marketing (All Physicians)	1443
Chart 7.13 Top 10 Companies in Academic Marketing (Endocrinologists)	1444
Chart 7.14 Top 10 Companies in Academic Marketing (Oncologists)	1444
Chart 7.15 Online/Digital Platforms Attractive to Chinese Physicians	1445
Chart 7.16 Top Five High Customer Loyalty Scores (All Physicians)	1445
Chart 7.17 Top Five High Customer Loyalty Scores (Oncologists)	1446
Chart 7.18 Approval Process of Hospital Drug Purchase	1451
Chart 7.19 Hospital Market Potential Assessment Process.....	1455
Chart 7.20 Pharmaceutical Distribution Channels in the Urban Areas	1477
Chart 7.21 Pharmaceutical Distribution through Retail Pharmacies.....	1478
Chart 7.22 Pharmaceutical Distribution in Sub-urban and Rural Areas (3rd Terminal Market).....	1479
Chart 7.23 Dominant Distribution Models Used by MNCs in China	1485

TABLE OF ABBREVIATIONS

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

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

EXECUTIVE SUMMARY

2016 was a turbulent year for the broad Chinese economy. For the year ahead, China's Central Economic Work Conference has made "seeking progress while maintaining stability" the main theme for economic work, pledging to push for substantial progress in supply-side structural reform. The forecasting department at the State Information Center (SIC) predicts that the country's economic growth could slow to 6.5% this year from about 6.7% in 2016.

Meanwhile, things between Washington and Beijing have been on the rope since Trump won the presidential election. There will be broad impacts of Trump Presidency on the pharmaceutical industry and related China business. Trump slammed the U.S. pharmaceutical industry for producing drugs overseas even before taking office. Pharmaceutical factories in India and China, in particular, may be tempting targets, given that they've repeatedly been called out for safety and quality violations, from lying to inspectors to leaving bird droppings and black mold on the factory floor.

Trump also has a tough stance toward trade with China, which is well founded although it could be a double-edged sword for pharma MNCs. A tougher U.S. trade policy will help improve Chinese market access and IP protection of big pharma companies in general, but an all-out trade war between the two countries may result in Chinese retaliations which could very well negatively affect pharma MNC business there.

Each year there are more uncertainties surrounding China healthcare and 2017 is no exception. The pharmaceutical industry in China is facing an overhaul of its business model, fast changing marketplace and repeated assaults of its bottomlines. Indeed, there will be no more middle road for anyone, as the *Fengshui* masters say about the Chinese New Year of Rooster. Those unfit will be wiped out and those surviving will embrace a turbulent new world, which is for sure much bigger but not necessarily as profitable. What will be the name of new game? Volume over margin, perhaps?

The Chinese pharmaceutical industry revenue growth rebounded slightly in 2016 to above 10% despite shadows of numerous challenges stemmed from the troubled Chinese economy, regulatory shakeups, cost containment measures and healthcare reform turbulences, according to the *China Pharmaceutical Guide 2017 (12th Edition)* quoting official data.

The industry's core revenues and net profits are estimated to have risen 10.3% and 15.6% respectively in 2016, suggests a recent presentation by Minli Lu, Chief Consultant of China National Pharmaceutical Industry Information Center (CPIIC).

On the other hand, SMEI data shows the size of the Chinese drug market to be CNY 1,497.4 billion in 2016 at retail price level, up 8.28% year on year. The pace of growth has been falling consecutively in recent years affected by stringent drug cost containment measures, according to LIN Jianning, President of Southern Medicine Economic Institute under the CFDA (SMEI). Among the total, the size of hospital drug market, retail pharmacy drug market and primary healthcare drug market are projected to be CNY

1,024.0 billion (+7.60%), CNY 337.5 billion (+8.49%) and CNY 135.9 billion (+13.16%) respectively.

The Chinese drug market had just exceeded CNY 1 trillion in 2016, according to QuintilesIMS. Rx Western medicines dominated the hospital drug market with nearly 80% market share, while TCM market share was quite significant in the retail and the third terminal drug markets. The Chinese hospital drug sales were up 8.1% in the same year, reaching CNY 698 billion.

Ethical and OTC Western medicines as well as formulated TCMs witnessed high growth in the third terminal drug market in the year as a result of tiered medical system reform. The growth of Rx TCMs was particularly fast.

The growth of retail drug sales slowed in 2016, said QuintilesIMS, which predicts major changes with the Chinese retail drug market landscape in 2017. In retail pharmacies, Rx drug products of large MNCs experienced strong performance in 2016. 44% of retail pharmacy sales came from Rx drugs in 2016.

The sales of OTC drugs and health foods of Chinese retail pharmacy sector reached CNY 77.4 billion in 2016, up only 2.8%, continuing a slowing growth trend due to slower price rise and negative volume growth, according to IMS PharmaTrend, which monitors retail pharmacies in 41 Tier 1/2 thru 4 representative Chinese cities. Price surges remained main driver of growth with sales volume down persistently.

Among the total, sales of OTC drugs in the period were CNY 64.7 billion in 2016, up 3.7% year on year. Formulated TCMs as a subclass of OTC drugs surged 4.2%, accounting for over 66% of total OTC drug sales. However, growth rate of chemical drugs and health foods in the period were slowed to only 2.0%.

Most notably for pharmaceutical retail sales, according to SMEI, the Chinese online pharmacy drug market surged 50% to CNY 4.8 billion in 2016. The growth of this market is expected to see more explosive growth as the Chinese government liberalize its regulation.

CFDA makes marked advances with drug regulatory system reform as uncertainties continue with drug pricing reform

First and foremost, the State Council issued its #666 order in March 2016 to amend a number of administrative regulations including *the Implementation Regulation of the Drug Administration Law of PRC*. The amendment is necessary to facilitate the earlier amendment of the *Drug Administration Law of PRC* in April 2015. Meanwhile, the CFDA continues to prepare another amendment of the law to facilitate its ongoing drug regulatory reform.

Later in the year, the agency issued a new document, *Implementation Opinions for Fully Strengthening Legal Infrastructural Building for Food and Drug Regulation*, on August 16. Under the document, the CFDA pledged to complete development of the framework of laws and regulations for foods, drugs, medical devices and cosmetics before 2020. Specifically, the agency said it plans to submit a draft amendment of the *Drug Administration Law of PRC* to the State Council before the end of 2016. Nonetheless,

the pledge had not materialized by the end of January 2017.

The *PRC Law on Traditional Chinese Medicine* also found its way through China's top legislature, the Standing Committee National People's Congress, in late 2016 and it will become effective in July 2017 to give traditional Chinese medicine (TCM) a bigger role in the healthcare system.

Meanwhile, following a year of drug evaluation and approval system reform, the CFDA said at the *2017 National Food and Drug Regulatory Working Conference* in January that it has successfully established the drug evaluation project managing system, clinical value-oriented team review system, reviewer and applicant communication system, expert consultation committee system, open validation system for major disputes among reviewers and applicants, review and approval information publication system and priority review system.

The drug application backlog has been reduced to 8,863 at the end of 2016 from 22,000 at the peak in 2015, the agency disclosed. The review for clinical trial of chemical drugs and vaccines, as well as all types of applications for TCM and minority medicine registration are now under processing subject to regular official timeline requirements. Priority review status has been granted to 146 innovative drugs, drugs under urgent clinical needs, off-patent generic drugs and first-to-copy generic drugs.

On the front of drug pricing, the NDRC returned to the drug pricing theme in 2016 under a different flag. There are signs that the government is beginning to back-paddle for at least some renewed control over drug prices through antitrust enforcements.

As to the proposed uniform BMI drug payment standards, the MOHRSS has submitted its final draft for "*Guiding Opinions for Basic Medical Insurance Drug Payment Standard Development Rules (Interim)*" in November 2016 to the State Council for approval. The initial draft for comments was also not publicized, but Chinese reporters gained access to the document and reported the following components of it: 1) an essential principle of the document is to rationalize drug use, improve drug consumption behaviors and motivate designated medical institutions on the basis of securing medical service quality; 2) for drugs not passing quality equivalence appraisals and those with large quality gaps, differentiated BMI drug payment standards can be set for the same drugs produced by different manufacturers; 3) medical institutions are allowed to sell drugs at prices above the uniform BMI drug payment standards; 4) If the actual drug prices of medical institutions are lower than their respective uniform BMI payment standards, they will continue to be paid by the BMI in accordance with payment standards, while co-pay of BMI participants will still be calculated on the basis of actual prices; and 5) the uniform BMI drug payment standards are set on the basis of generic drug names in principle.

Healthcare reform stumbles on amid a matrix of government policies

By early 2017, the NHFPC claimed victories for deepening healthcare reform, elevating healthcare service quality and public satisfaction, boosting capability for public health and healthcare emergency response, and implementing the national two-child policy in

2016.

Information from the agency shows that more than 1,560 urban public hospitals have already removed drug sales margins and eliminated the model of compensating medical services with drug sales profits. It said the income structure of public hospitals continued to optimize in 2016 and medical expenditure growth was effectively controlled.

Compared with 2013, the shares of government and social funding went up by 0.8 and 3.1 percentage points while that of personal out-of-pocket funding was down by 3.9 percentage points in 2015, according to the latest information release by the NHFPC. As China's commercial health insurance sector is still tiny, it is fair to conclude that the Chinese BMI system has absorbed most of the healthcare expenditure growth and a significant drop of personal out-of-pocket share. Without sharply increased government subsidies and personal premium contributions, the question remains with the sustainability of Chinese BMI system under fast rising healthcare expenditures? Will the last straw of relentless cost cutting be enough to save the day?

On a more positive note, the share of healthcare spending in Chinese GDP rose to 6.0% in 2015 from 5.6% in 2013. Even though this figure is still very low compared with developed countries which are much less populated, progress in this direction is encouraging and the endpoint is about funding to meet the true demands of China's 1.4 billion people for good quality healthcare services.

Though China has achieved a number of milestones in healthcare advancement over the past three decades, further reforms are urgently needed, said a new report by WHO, the World Bank and the Chinese government. Escalating health care costs are set to place an unsustainable burden on citizens, underlining the need for drastic reforms, according to the study. "China needs to deepen its health reform to avoid the risk of creating a high-cost-low-value health system as observed in some high-income countries," the report underlines. "Business as usual, without reform, would result in growth of total health expenditure from 5.6% of GDP in 2015 to 9.1% in 2035, an average increase of 8.4% per year in real terms."

Meanwhile, China's healthcare reform may have a new direction under the direct leadership of President Xi Jinping in the wake of a top-level national health conference and approval of a new blueprint *Healthy China 2030* in July. Xi's Central Leaders Group for Comprehensively Deepening Reform mapped a new blueprint of healthcare reform and he put the "tiered medical service system" (TMS) on top of the five essential healthcare systems which are to become the foundation of Chinese healthcare reform. In the spirit of this new blueprint, the NHFPC held press release conferences in September 2016 to showcase healthcare reform experiences of various local governments, citing in particular their reform efforts to build the TMS, restrict excessive growth of big hospitals and elevate service capacity of primary healthcare facilities.

To begin the New Year on a high note, the State Council introduced China's *13th Five Year Plan for Healthcare Reform (2016-2020)* in early 2017, outlining the reform path forward in the next five years. The essential principles of this plan are laid out as follows: 1) Putting the health of people in the center as priority for development. The ultimate

goals are to ensure fair access, public benefits and welfare nature of basic medical services; 2) Securing basic and primary healthcare with solid infrastructure. Basic healthcare system should be provided to all residents as a public product; 3) Combining the leadership role of government and the role of market forces; 4) Persisting on supply side reform to separate government from institutions, ownership from management, medical services from drug sales, as well as for-profit from non-profit healthcare institutions; 5) Sticking to coordinated reform of medical service, health insurance and pharmaceutical sectors; and 6) Spotlighting key reforms, demonstrating reform trial outcomes and proceeding the reform orderly.

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

Despite superficial slogans and touted ambitions of the Chinese government, the healthcare reform has been hijacked by cost containment and gone astray from the pledged path of improving efficiency and fixing structural flaws.

With tax and other revenues drying up and under increasing threat of BMI system deficit amid a slowing Chinese economy, local governments are pressured by both the central government and the public to do more for healthcare with less financial resources. As local governments assaulted the pharma industry above the table with wave after wave of cost containment measures, public hospitals also squeezed drug companies under the table for funds through a variety of schemes.

Pushed to the corner, the Chinese pharmaceutical industry is now at the brink of business bottomlines. Under pressures of escalating anti-corruption campaigns, increasingly sophisticated cost containment measures as well as policy shifts in drug pricing and reimbursements, both domestic and multinational drug companies had no choice but to recalibrate their strategies and business models in order to meet the challenges of the Chinese healthcare business today.

The Chinese economy and the reform of its healthcare system are once again at crossroads. Pharma companies, local or foreign, must change to remain competitive and fit with the market.

Nonetheless, many drug company executives are still bullish about China's long-term growth prospects. As the government improves access to healthcare, the country's pharmaceutical market is projected by QuintilesIMS to maintain growth at slower single-digit rate. But the short-term picture is proving difficult, with reforms in the hospital sector affecting physician prescriptions and price pressures growing for most drugs.

Old IP flaws remained as new issues spring up amid regulatory reform and antimonopoly enforcements

The U.S. Trade Representative (USTR) recently issued its *2016 Report to Congress on China's Compliance with WTO*, which comprehensively reviews the magnitude of China's continuing compliance problems related to intellectual property rights, including such issues related to the pharmaceutical sector, after 15 years of WTO accession.

Our case for the following contemporary IP concerns in relation to the Chinese pharmaceutical sector is built on the basis of this report.

IP and market access related issues

- ☞ Patent protection is an area of serious concern of foreign pharmaceutical stakeholders. In particular, SIPO examination guidelines governing information disclosure requirements for pharmaceutical patent applications have been revised through a series of amendments making these guidelines more restrictive.
- ☞ *Data exclusivity* - There has been persistent concern over the extent to which China provides effective protection against unfair commercial use of, and unauthorized disclosure of, undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. However, Chinese law does not include an appropriate definition of the term “new chemical entity” for purposes of identifying test or other data entitled to protection.
- ☞ *Delay in new drug approvals and drug regulatory reform* - This additional area of concern in the pharmaceuticals sector involves the long delays in China’s review of applications for permission to market new and innovative pharmaceutical products in China and for these products to be placed on approved reimbursement lists. While China is committed to take several specific steps to streamline and speed up its regulatory review and approval systems, there are growing concerns that some of the steps contemplated by China to implement reforms to address the regulatory delays would serve to promote domestic Chinese enterprises at the expense of foreign enterprises and foreign-invested enterprises in China.
- ☞ *Drug distribution* - Despite overall progress in this area, many other restrictions affecting the pharmaceuticals sector continue to make it difficult for foreign pharmaceutical companies to realize the full benefits of China’s WTO distribution commitments.
- ☞ *Price control* - China continued to maintain price controls in 2016 on several products and services including pharmaceuticals.
- ☞ *Counterfeit drugs and API/bulk drug regulation* - Although rights holders report increased enforcement efforts by Chinese government authorities, counterfeiting in China remains widespread. Despite sustained engagement by the United States, China still needs to improve its regulation of the manufacture of APIs to prevent their use in counterfeit and substandard medications..
- ☞ *Anti-monopoly Law enforcement* - The implementation of China’s Anti-monopoly Law by Chinese regulatory authorities poses multiple challenges. One key concern relates to how the Anti-monopoly Law will be applied to state-owned enterprises. Another concern relates to the procedural fairness of Anti-monopoly Law investigations. U.S. industry has expressed concern about insufficient predictability, fairness and transparency in the investigative processes of the NDRC, including the agency’s pressure to “cooperate” in the face of

unspecified allegations.

More Challenges in the New Year, Despite Unchanged Long Term Prospects

Unfortunately Chinese pharma inherited in 2016 most old devils overshadowing the sector in prior years with no new fixes found and new challenges kept pouring in. It is almost certain that the industry will face an even more challenging time in 2017.

The trend of irrational cost containment is expected to intensify further this year, with the central government upholding the radical healthcare reform experiment in Sanming City of Fujian Province as a model for national replication. The Sanming experiment, which is set in the background of local BMI system in heavy deficits, is known for its ruthless cost containment measures, excessive emphasis on drug prices and harsh hospital reform moves. It is also the first local BMI system paying suppliers of originator drugs and local generics at uniform low prices. Besides, three more cut-throat cost containment policies, namely 1,001 additional clinical pathways, disease group-based fee standards and two-invoice system for public hospital drug procurement, were mandated for implementation in public hospitals in 2017.

Local governments are set to put more cost containment pressure on pharmaceutical companies, as they try to keep the public and central government happy and the books of BMI programs balanced in a time of fiscal crisis amid a slowing economy. On the other hand, the pharmaceutical industry will continue to be confronted by a host of other challenges including continued uncertainties of the broad Chinese economy, non-stop drug regulatory and healthcare reform turbulences, more stringent compliance requirements, and risks associated with constantly changing pharmaceutical business environment.

Chinese pharmaceutical industry experts have summed up 11 emerging trends for the Chinese pharmaceutical market in 2017 as follows:

- ☞ Further consolidation of the Chinese pharmaceutical market is expected following implementation of the two-invoice policy. Industry consolidation in both pharmaceutical manufacturing and distribution subsectors will intensify further as profit margin of prescription drugs narrow. Many pharmaceutical companies will turn to the OTC drug market for better opportunities.
- ☞ Ex-hospital pharmaceutical market will become the new battleground of pharma companies with intensive competition, as hospital drug sales become increasingly restrictive under deepening healthcare reform which is set to uphold the cost containment centered-Sanming model as template.
- ☞ Sales outsourcing or contract sales organizations (CSOs) will become more and more popular to the pharmaceutical industry. Although the model is favored more by smaller companies, even larger players may utilize it for some of their non-core products.
- ☞ More major OTC companies with dedicated sales force may diversify into consumer healthcare business.

- ☞ Pharmaceutical companies will continue penetration of the primary healthcare drug market as the reform of tiered medical service system picks up speed.
- ☞ Backed by a string of recent government policies supporting development of TCM and China's adoption of the TCM Law, clinical applications of TCM appropriate technologies will grow substantially.
- ☞ TCM clinics and hospitals will become increasingly popular as medicine sales outlets on government policy support and they will quickly emerge into the fourth terminal market for drug products, a new opportunity land for those well prepared to take advantage of it.
- ☞ Retail pharmacy chains are expected to attract by venture capitalists and private equity investors, given the rising prospects of pharmaceutical retail market under the new healthcare business environment.
- ☞ The business of contract hospital pharmacy management will become more attractive to brand name drug companies as healthcare reform deepens and social capital participation in select public hospitals increases.
- ☞ Retail pharmacies are expected to diversify into supermarket styled retailing of consumer healthcare and daily commodities in order to boost revenues and profitability.
- ☞ Pharma e-Commerce, especially B2C online pharmacy market segment, is set to see explosive growth following latest regulatory liberalization to withdraw Type B and C licenses for B2B and B2C online drug sales.

The short and intermediate term outlook of Chinese pharmaceutical market is going to be tough and blurred, but long term prospects remain hopeful for and warrant patience of those with sustaining power. Conversely, let's also remember that most Chinese pharma industry observers still agree that the Chinese healthcare market will keep on growing in the foreseeable future, albeit at a slower rate and with lower profitability.

China is projected to maintain its place as the second largest pharmaceutical market, trailing only the United States. The U.S. is projected to account for 53% of forecasted growth over the next five years (through 2021) while China will continue as the second largest market, a position it has held since 2012, contributing 12% of growth, according to a recent QuintilesIMS study. Growth of drug spending in developed markets will be driven by original brands while pharmerging markets will continue to be fueled by non-original products (i.e. generics) that make up an average 91% of volume and 78% of spending.

The study suggests that overall lower economic growth is triggering slower expansion for medicine use in pharmerging markets, including China. Leading pharmerging markets have seen real growth in GDP slow 1 to 4 percentage points over the past decade, according to the study, which has corresponded to a reduction in medicine volume growth, from an average of 7% annually over the past five years (2011–2016) to a 4% forecast through 2021. China, in particular, will see a decline in annual volume growth from 17% to 4% over the same period. Overall, volume growth continues to be

driven by non-original products that account for 91% of the volume in pharmerging markets. The outlook for spending growth across these pharmerging markets is expected to moderate from the 10% CAGR seen over the past five years (2011–2016) to 6% to 9% through 2021.

China is the largest pharmerging market. In 2016, China's pharmaceutical market was valued at nearly \$117 billion and is projected to reach approximately between \$140 billion and \$170 billion by 2021, according to QuintilesIMS. CAGR growth (as measured in constant US dollars) in China's pharmaceutical market in the period of 2011–2016 was approximately 12.4% but is projected to slow to 5% to 8% in the period of 2016–2021.