ABOUT THE AUTHOR / PUBLISHER

WiCON | China Pharmaceutical Guide is authored, edited and published by James J. Shen, a veteran of the Chinese healthcare industry and market, who has dedicated his entire 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, IQVIA and Financial Times Business Information on China’s healthcare news.

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

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

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

In early 2006, following a restructure of WiCON’s businesses, James Shen founded WiCON | Pharma China, the highly-respected English media and business intelligence service on China’s pharmaceutical industry and market which is subscribed by almost all multinational pharmaceutical companies, CROs, consulting companies and investment banking firms active in China.

James Shen was educated in China, Europe and the USA at university and postgraduate levels, and received an MBA from the University of Exeter (UK) in 1990.
He is now based in 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 31 years of work in the sector as a consultant, manager and entrepreneur.

The ever-changing legal and market environments in China healthcare present the single biggest challenge to companies and executives operating in the sector. 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 31 years of operating in almost every aspect of China’s pharmaceutical business into a publication, which will serve as a one-stop reference to anyone seeking to enter or operate in the Chinese pharmaceutical market. As of our 2007 edition, we have been adding a rising number of commentaries and contributions from many other leading pharma industry executives and experts.

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

This Guide is written based on my past experience, interviews with relevant industry experts and government officials, articles from 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.


The WiCON | China Pharmaceutical Guide 2018 (13th 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 contemporary 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 2017 (full year) and available figures for the first half of 2018.

☞ 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 IQVIA, 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 2017/H12018 are updated to present a clear and most up-to-date picture of the Chinese drug regulatory framework with summaries and analysis of all pharmaceutical related regulations in effect by mid-2018.

Focused coverage of China’s ongoing efforts to revamp its drug regulatory regime through amendments of the Drug Administration Law, 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 2017 and H1/2018.

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, 2018
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 ...... 47

Chapter I-1  China’s Broad Business Environment .......................................... 49

1.1 Fast Economic Growth and Change ............................................................. 49
1.2 Integration into the World Economy ............................................................ 50
1.3 Economic Reform ...................................................................................... 51
1.4 WTO Entry Brought Further Reform and Regulatory Changes ................... 53
1.5 Demographic Trends and Challenges ....................................................... 56
1.6 Rising R&D Investments and Patent Applications ..................................... 64
1.7 Foreign Investment: Structure, Trends & Outlook .................................... 67
1.8 A Bird’s Eye View of the Contemporary Chinese Economy ....................... 75
1.9 China’s Economy: The New Normal and the Virtuous Circle .................... 79
1.10 Foreign Firms Need New Strategies for China’s ‘New Normal’ ................. 81
1.11 Why the Death of Manufacturing in China Means A Positive Economic Outlook ..... 83
1.12 Business Climate and Outlook – Surveys of Foreign Companies in China ...... 85
1.13 Action Program on Protection of IP Rights of Foreign-Invested Enterprises ... 94

Chapter I-2  Background: The Chinese Pharmaceutical Sector .................... 99

2.1 Introduction .................................................................................................. 99
2.2 Government Guidelines for Pharmaceutical Industry Development ........... 106
2.3 Pharmaceutical Sector Reform As A Part of Healthcare Reform .................. 116

Chapter I-3  Overview: The Chinese Pharmaceutical Industry .................... 125

3.1 Overview ................................................................................................... 125
3.2 The Pharmaceutical Formulation Sector .................................................... 128
3.3 The Bulk Drug/Active Pharmaceutical Ingredient and Excipient Sector ........ 133
3.4 The Biopharmaceutical Sector ................................................................... 146
3.5 The Human Vaccine Sector ....................................................................... 160
3.6 The Pharmaceutical Distribution Sector .................................................... 168
Chapter I-4 Foreign Investment in The Pharma Industry .............................................................. 227
  4.1 China’s Foreign Investment Regulatory Framework ..................................................... 227
  4.2 Major Tax Categories for FIEs and Foreigners ............................................................ 237
  4.3 Forms of Foreign Investment in the Pharma Sector ....................................................... 240
  4.4 Encouraged, Restricted and Banned Areas for Foreign Investment in the Pharma Industry .............................................................. 241
  4.5 Growth of Foreign Investment in the Pharma Sector .................................................... 247
  4.6 Contemporary Trends, Issues and Strategic Considerations for Foreign Investment in the Pharmaceutical Industry .............................................................. 253
  4.7 Three Holistic Advices to Pharma MNCs in China ....................................................... 266
  4.8 MNC Pharma Cos Face ‘Triple Threats’ in China ......................................................... 268
  4.9 China Performance of Foreign Pharmaceutical Companies ......................................... 269

Chapter I-5 The Ethical Pharmaceutical Market ................................................................. 271
  5.1 Market Size .................................................................................................................. 271
  5.2 Market Prospects and Future Outlook ........................................................................ 274
  5.3 Special Characteristics of the Chinese Ethical Pharmaceutical Market ...................... 277
  5.4 The Hospital Drug Market ......................................................................................... 278
  5.5 The Rise of Retail Pharmacy Sector .......................................................................... 281
  5.6 Rural Chinese Market for Ethical Drugs ..................................................................... 290
  5.7 Rising Importance of the Primary Healthcare Drug Market ...................................... 292
  5.8 Chinese Biologic Market Growth Expected to Accelerate ......................................... 294

Chapter I-6 The Chinese Vaccine Market ....................................................................... 303
  6.1 Chinese Vaccine Market Landscape ........................................................................... 303
  6.2 Vaccine Consumption by Major Urban Chinese Hospitals .......................................... 309
  6.3 Market Outlook of the Chinese Human Vaccine Market ............................................ 309
  6.4 Asia-Pacific Influenza Vaccines Market to Surpass $1.7B by 2022 .......................... 314

Chapter I-7 The OTC Pharmaceutical Market ................................................................. 315
  7.1 Overview of the Chinese OTC Market ....................................................................... 315
  7.2 Regulatory Progress on OTC Drugs ........................................................................... 317
  7.3 Chinese OTC Drug Market under Rapid Transformation ......................................... 319
7.4 Enthusiastic Pharmaceutical Industry Seeks to Expand OTC Drug Sales
7.5 Drug Companies Foray into Consumer Healthcare to Counter Pharma Pitfalls
7.6 Healthcare Reform Casts Shadow on Future of the Retail Pharmacy Sector
7.7 CFDA Considers Ban of OTC Drug Ads on Mass Media

Chapter I-8 Pharmaceutical Import and Export
8.1 Background
8.2 Present State of China’s International Trade of Medicines and Health Products
8.3 Custom Duties on Drug Import
8.4 ANDA Approvals Boost Chinese Pharma's Global Ambitions
8.5 Trends and Outlook

PART II HEALTHCARE PROVISION AND FINANCING

Chapter II-1 Overview
1.1 Improving Healthcare Provision
1.2 Falling Death Rate and Rising Life Expectancy
1.3 Composition of the Chinese Population
1.4 Ageing in China: The Implications for Healthcare
1.5 Economic Burden from Chronic Diseases May Slowdown China’s Growth
1.6 2016 Annual Health and Family Planning Sector Development Report
1.7 Health China 2020 Strategic Research Report
1.9 Healthy China 2030 Plan
1.10 China’s Healthcare Crisis: Both Rich and Poor Travel Abroad

Chapter II-2 Structure and Composition of Medical Provision
2.1 Composition of the Chinese Medical Sector
2.2 Grade Structure of Chinese Medical Institutions
2.3 Regional Distribution of Healthcare Resources
2.4 Distribution of Healthcare Resources by Medical Specialty
2.5 Human Resources in China’s Healthcare Industry
2.6 China Seeks to Establish a General Practitioner System by 2020
2.7 Government Encourages the Formation of Medical Service Consortiums
2.8 Chinese Government Seeks to Boost Private Healthcare
2.9 China's Telemedicine Industry To Take Off on Official Policy for Internet+Healthcare
2.10 China’s Mobile Healthcare Sees Sharp Growth
2.11 Internet Economy to Save China CNY 610B Healthcare Expenditures Annually by 2025

Chapter II-3 Healthcare Reform
3.1 A Review of China’s Healthcare System Reform in the Past Three Decades
3.2 Chinese Leadership Mapped A New Blueprint of Healthcare Reform
3.3 The Healthcare Reform Plan in the 13th FYP (2016-2020)
3.4 Major Healthcare Reform Achievements in 2017 and Direction for 2018
Chapter II-4 Healthcare Financing and Insurance Programs

4.1 BMI Enrollment and Healthcare Financing in China ........................................ 407
4.2 Urban Employee Basic Medical Insurance (UEBMI) ........................................ 415
4.3 Urban Resident BMI Program and New Rural Cooperative Medical Scheme .... 416
4.4 Critical Illness Insurance Coverage for Urban and Rural Residents .................. 419
4.5 Work-related Injury Insurance Program .......................................................... 421
4.6 Medical Assistance Program for Civil Servants ............................................. 422
4.7 Maternity Insurance ....................................................................................... 423
4.8 Medical Assistance Program for the Poor ..................................................... 424
4.9 Commercial Health Insurance ..................................................................... 426
4.10 Universal Coverage of Chinese Population by Basic Medical Insurance ....... 432
4.11 MOHRSS Issues Internet+ Action Plan ....................................................... 433
4.12 The New Boss on the Block: State Medical Insurance Administration (SMIA) .. 433

Chapter II-5 Drug Reimbursement

5.1 Drug Reimbursement under BMI, WRI and MI Programs ............................ 435
5.2 A Thorough Summary of the MoHRSS Notice for Publication of the 2017 NRDL .. 437
5.3 Snapshot of Newly-added Western Medicines in 2017 NRDL ....................... 439
5.4 Analysis of 2017 NRDL’s New Product Additions ....................................... 440
5.5 Snapshot of MNC Winners of New 2017 NRDL Listing ............................... 441
5.6 Considerations of Latest NRDL Revision and Future Outlook ..................... 443
5.7 Rationalized Medicine Drug List of the Chinese Military (RMDL) .................. 443

Chapter II-6 Measures of Healthcare Cost-containment

6.1 Price Control ................................................................................................. 446
6.2 Centralized Hospital Drug Purchase Tenders ............................................. 450
6.3 The National Essential Drug System ............................................................ 469
6.4 National Formulary and Clinical Guidelines ............................................... 477
6.5 Clinical Pathway/DRGs ............................................................................... 478
6.6 National Drug Price Negotiation ................................................................. 483
6.7 The “Two Invoice System” in Public Hospital Drug Procurement .................. 485
6.8 Other Cost-containment Measures ............................................................... 486
6.9 Tiered Medical Service System ................................................................... 489
6.10 Service Model Transformation of Pharmacy Affairs Management ............. 490
6.11 China’s Medical Inflation Rate Is the Third-Lowest in Asia ......................... 491

PART III DISEASE AND DRUG CONSUMPTION PATTERNS

Chapter III-1 Growth of Drug Consumption and Demand

1.1 Sharp Growth in Drug Consumption and Healthcare Expenditures ............. 495
1.2 The State of Health of the Chinese Population ............................................. 499
1.3 Health Awareness and Literacy ................................................................... 500
1.4 China’s Struggle With Demographic Change ............................................. 501
1.5 Medical and Public Health Services ............................................................ 502
Chapter III-2  Popular Diseases and Morbidity .................................................. 504
  2.1 Leading Diseases .................................................................................. 504
  2.2 Leading Causes of Death ...................................................................... 510
  2.3 An Extensive Overview of Chronic and Epidemic Diseases in China ........ 513
  2.4 Recent Trends with Cancer Challenges in China .................................... 533
  2.5 China's Cancer Research Advances, Closing in with the U.S. .................. 543
  2.6 Prevalent Health Problems of Senior Citizens in China ......................... 543
  2.7 Chinese in Good Health Longer Than People in Other G20 Countries ....... 545
  2.8 Medium and Long Term Plan for Prevention and Treatment of Chronic Diseases ..... 546
  2.9 China to Complete Establishment of National Rare Disease Registry by 2020 .... 547

Chapter III-3  Medical Institution Attendance and Expenses .......................... 548
  3.1 Composition of Medical Care System in China ........................................ 548
  3.2 Hospital Attendance ............................................................................. 549
  3.3 Healthcare Expenditures and Medical Expenses ................................... 555

Chapter III-4  Drug Consumption Patterns in Medical Institutions ................. 557
  4.1 Patterns of the Chinese Hospital Drug Market ....................................... 557
  4.2 Drug Consumption in Chinese County Level Hospitals ......................... 566
  4.3 Drug Consumption of Public Primary Healthcare Facilities .................. 576
  4.4 Drug Consumption of Urban Community Healthcare Centers ............... 577
  4.5 Drug Consumption in Rural Township Health Centers .......................... 584
  4.6 Vaccine Consumption of Major Urban Chinese Hospitals ...................... 588

Chapter III-5  Retail Drug Consumption Patterns ........................................... 591
  5.1 Overview of the Chinese Pharmaceutical Retail Sales ............................ 591
  5.2 Consumption Patterns of Retail Pharmacy Sales of Medicine and Health Products .... 594
  5.3 Structure of Chinese B2C Online Pharmacy Market .............................. 604

Chapter III-6  Consumption Patterns of OTC Drugs ....................................... 606
  6.1 Structure of Chinese OTC Drug Market ................................................ 606
  6.2 Leading Chinese OTC Companies and Brands ..................................... 615
  6.3 China OTC Market Has Growth Potential despite Regulatory Uncertainty .... 618

Chapter III-7  Regional Drug Consumption Patterns ..................................... 622
  7.1 Gap Between Cities and Rural Areas .................................................... 622
  7.2 Regional Hospital Markets for Drug Products ....................................... 623
  7.3 Hospital Drug Sales Champions in 22 Chinese Cities/Regions in 2016 .......... 631
  7.4 Regional Markets by Pharmaceutical Distributor Sales .......................... 631
  7.5 Regional Retail Pharmacy Markets for Drug Products .......................... 635
  7.6 Regional OTC Drug Markets ............................................................... 639
  7.7 Regional Primary Healthcare Drug Markets .......................................... 641
Chapter III-8 Market Shares of Local, JV and Imported Drugs .......................... 645

8.1 Hospital Market – Domestic vs. MNC Drugs................................................. 645
8.2 Retail Pharmacy/OTC Market – Domestic Companies vs. JV/Foreign Players ....... 652
8.3 Future Trends and Outlook ............................................................................. 653

Chapter III-9 High Growth Market Segments.......................................................... 655

9.1 Overview of Chinese Oncology Drug Market ....................................................... 656
9.2 The Chinese Diabetes Drug Market................................................................. 664
9.3 The Chinese Cardiovascular Drug Market....................................................... 669
9.4 The Chinese Hepatitis Drug Market ............................................................... 672
9.5 Chinese Asthma and COPD Drugs Markets Poised for Steady Growth ............. 675
9.6 The Chinese Drug Market for Mental Disorders Has Huge Potential ............... 677
9.7 Prospects of Chinese Pediatric Drug Market .................................................... 680
9.8 Emerging Orphan Drug Market Is Hope for Millions of Chinese with Rare Diseases ..... 681
9.9 Chinese Geriatric Drug Market Offers Great Potential .................................... 683
9.10 Alzheimer’s Is China’s Biggest Future Health Problem - And Biggest Healthcare Industry Opportunity ................................................................. 684
9.11 Chinese Hospital Drug Market for Parkinson’s Disease Growing at Double Digit Rates..... 688

Chapter III-10 Snapshot of Generic Chemical Drug Consumption........................... 691

VOLUME 2 CHINESE PHARMACEUTICAL IP AND REGULATORY GUIDE .......................................................... 697

TABLE OF CONTENTS ......................................................................................... 699
LIST OF TABLES ................................................................................................. 703
LIST OF CHARTS ................................................................................................. 706
TABLE OF ABBREVIATIONS ................................................................................ 707

PART IV CHINESE PHARMACEUTICAL REGULATORY AND IP GUIDE .709

Chapter IV-1 Overview ....................................................................................... 711

1.1 Drug Regulation Statistics .............................................................................. 711
1.2 Overview of Drug Evaluation and Registration in Recent Years .................... 718
1.3 Review of Drug Applications under Special Approval, National S&T Major Project and Priority Review Paths with CDE 2004-H1/2018 ..................................................... 735
1.4 Adverse Drug Reaction Reporting ................................................................ 737
1.5 National Drug Abuse Monitoring Annual Report ........................................... 739
1.6 Review of New Chinese Pharmaceutical/Healthcare Regulations in 2017 and H1/2018 ...... 739
1.7 Major Drug-related Policies, Regulations and Laws under Drafting Process ........ 744
1.8 CFDA to Complete Legal Framework for Food and Drug Regulation by 2020 ........ 748
1.9 Drug Regulatory Reform Direction in 2018 .................................................... 749
1.10 Reform of China’s Drug Evaluation and Approval System .............................. 751
Chapter IV-2 Important Laws and Regulations .................................................................770

2.1 The Drug Administration Law of the People's Republic of China .......................... 770
2.2 Regulations for Implementation of the Drug Administration Law of the PRC .......... 779
2.3 Major Regulations under the Drug Administration Law of PRC .............................. 784
2.4 Other Drug Related Laws and Regulations ............................................................. 786

Chapter IV-3 Major Government Agencies and Industry Associations in The Pharma Field .................................................................................................................... 790

3.1 The National Medical Products Administration (NMPA) under the State Administration for Market Regulation (SAMR) / The China Food and Drug Administration (CFDA) .......... 792
3.2 The Center for Drug Evaluation under the NMPA ..................................................... 800
3.3 The National Health and Family Planning Commission (NHFPC)/The National Health Commission (NHC) ..................................................................................... 802
3.4 State Medical Insurance Administration (SMIA) ....................................................... 803
3.5 Ministry of Human Resources and Social Security (MOHRSS) ............................... 806
3.6 Ministry of Industry and Information Technology (MIIT) ......................................... 806
3.7 Ministry of Commerce (MOFCOM or MOC) .............................................................. 807
3.8 National Development and Reform Commission (NDRC) .......................................... 808
3.9 State-owned Assets Supervision and Administration Commission of the State Council ...... 811
3.10 State Administration of Traditional Chinese Medicine (SATCM) ............................ 811
3.11 State Intellectual Property Office (SIPO) ............................................................... 812
3.12 Pharmaceutical Industry Associations in China ....................................................... 815

Chapter IV-4 Drug Regulatory Framework in China (1) - Drug Registration Regime .................................................................................................................... 820

4.1 Overview .................................................................................................................... 820
4.2 General Principles of the Provisions for Registration of Drug Products (2007) ......... 826
4.3 Clinical Research for Drug Registration ................................................................... 838
4.4 Rules, Standards & Technical Guidelines / Drug Evaluation Management ............... 843
4.5 Special Approval of Drug Registration / Priority Review ......................................... 850
4.6 Registration of Copy/Generic Drugs and Their Quality/Efficacy Equivalence Studies ..... 854
4.7 Registration of Import Drugs ................................................................................... 867
4.8 Re-Registration of Imported Drugs ........................................................................... 870
4.9 Registration of Biosimilars ...................................................................................... 871
4.10 Registration of OTC Drugs ..................................................................................... 872
4.11 Registration of Certain Drug Related Products, Foods for Special Medical Purposes and Health Foods ......................................................................................... 873
4.12 Applications and Approvals for Supplemental Registrations .................................. 876
4.13 Drug Registration Reconsideration ......................................................................... 877
4.14 Post Approval Changes to Pharmaceuticals .............................................................. 879
## 4.15 Onsite Verification for Drug Registration .................................................. 879
## 4.16 Linked Review and Approval of APIs, Pharma Excipients and Packaging Materials 880
## 4.17 Chinese Pharmacopoeia (ChP) and Drug Standards .......................... 883
## 4.18 GLP/Preclinical Research and GCP/Clinical Research ........................... 886
## 4.19 China Pilots Drug Marketing Authorization Holder (MAH) System .................... 893
## 4.20 Conditional Approvals For New Drugs & Compassionate Use Of Investigational Drugs 902
## 4.21 Rare Diseases and Orphan Drugs .......................................................... 904
## 4.22 Interpretations for Application of Criminal Laws for Faking Drug and Medical Device 904

### Chapter IV-5  Drug Regulatory Framework in China (2) – Others ................. 906

5.1 Pharmaceutical Manufacturer Licensing ...................................................... 906
5.2 Contract Manufacture/OEM .................................................................. 908
5.3 Pharmaceutical Manufacturing and GMP Certification ............................ 914
5.4 Regulation of Pharmaceutical Excipients ................................................. 920
5.5 Drug Labeling and Packaging ................................................................. 922
5.6 Pharmaceutical Distribution Licensing ....................................................... 928
5.7 Pharmaceutical and Vaccine Distribution/GSP .......................................... 931
5.8 Drug and Excipient Import Process .......................................................... 941
5.9 Pharmaceutical Regulatory Inspections and Enforcements ..................... 946
5.10 Classified Control of Drug Products ......................................................... 948
5.11 Drug Advertising .................................................................................. 951
5.12 Drug Pricing and Price Control ............................................................... 959
5.13 Post-marketing Surveillance/ADR Reporting/Tracing ............................. 967
5.14 Counterfeit, Fake and Sub-standard Drugs ............................................... 974
5.15 Control of Narcotic, Psychotropic and Radioactive Drugs ....................... 981
5.16 Internet Information Service and Online Sales of Drug Products ............. 987
5.17 Drug Prescription/Rational Drug Use/Clinical Practices/Chinese Orange Book 993
5.18 Pharmaceutical Technology Transfer/ Administrative Protection/IP .......... 1005
5.19 Anti-corruption/Compliance/Black Listing/Confidentiality ...................... 1014
5.20 Drug Donations ..................................................................................... 1026
5.21 International Regulatory Cooperation ..................................................... 1035
5.22 Medical Representative Registration ....................................................... 1043
5.23 Others ................................................................................................... 1046

### Chapter IV-6  Intellectual Property Rights and Legal Issues ......................... 1049

6.1 Pharmaceutical Patent Protection ......................................................... 1059
6.2 Administrative Protection of Pharmaceuticals (APP) ............................... 1094
6.3 Data Exclusivity ..................................................................................... 1096
6.4 Patent and Trademark Registration ......................................................... 1100
6.5 Patent and IP Strategies for China ......................................................... 1109
6.6 Protecting and Policing IPRs in China .................................................... 1110
6.7 China Restructures IP Authorities ......................................................... 1112
6.8 Pharmaceutical Patent Litigation in China ................................................................. 1113
6.9 Importance of Patents in Chinese Pharmaceutical Tendering .................................... 1118
6.10 Trade Secret Protection ............................................................................................. 1120
6.11 Counterfeit Drugs ..................................................................................................... 1123
6.12 Judicial Interpretations of Law Applications over Drug Safety ................................ 1125
6.13 The Tort Liability Law: Impacts on Pharma ............................................................. 1133
6.14 Considerations for Compliance and Corruption Risks .............................................. 1136
6.15 Antitrust/Antimonopoly ............................................................................................ 1153
6.16 Merger & Acquisitions ............................................................................................. 1180
6.18 New Challenges Ahead: How to Comply With Cross-Border Data Transfer Regulation in China ................................................................. 1195
6.19 A Guide to the Two Invoices System in Chinese Pharmaceuticals Distribution ........ 1199
6.20 Biotech Deals Targeted for More Scrutiny in New Trump Administration Trade Report .. 1201

VOLUME 3  ANNUAL REVIEW, TRENDS, OPPORTUNITIES & STRATEGIC CONSIDERATIONS ................................................................. 1205

TABLE OF CONTENTS ................................................................................................. 1207

LIST OF TABLES ........................................................................................................... 1211

LIST OF CHARTS .......................................................................................................... 1216

TABLE OF ABBREVIATIONS ....................................................................................... 1217

PART V  ANNUAL REVIEW AND OUTLOOK OF THE CHINESE PHARMACEUTICAL INDUSTRY AND MARKET ........................................... 1219

Chapter V-1  The Broad Chinese Economy: Review and Outlook ............................... 1221

Chapter V-2  Annual Review of the Chinese Pharmaceutical Industry and Market ................................. 1225

2.1 Data Overview: Chinese Pharmaceutical Market Landscape .................................... 1225
2.2 Data Overview: Pharmaceutical Industry Performance .......................................... 1242
2.3 China Performance of Foreign Pharma Companies in 2017 .................................... 1249
2.4 Pharma Industry in the Process of Revamping Its Business Model to Fit with New Environment 1251
2.5 The Chinese Pharmaceutical Industry: Winners and Losers 2017 .......................... 1269
2.6 Review of Regulatory Developments in 2018 and H1/2018 .................................... 1272
2.7 Healthcare Reform Deepens amid Intensified Cost Containment .......................... 1288
2.8 Old IP Flaws Remained as New Issues Spring Up amid Regulatory Reform and Antimonopoly Enforcements ................................................................. 1302
2.9 China Pushes New Generic Drug Policy to Undermine MNCs amid Threat of Trade War .. 1309

Chapter V-3  Review of Chinese Pharma M&A, Licensing and Collaborative R&D Deals ................................................................................................. 1312

3.1 M&A, Licensing and Collaborative R&D Deals in 2017 and 1H/2018 .................... 1312
Chapter V-4  What Does the Future Hold for China’s Healthcare Economy?......... 1335

4.1  Light at the End of Tunnel in the Supposedly Hopeful Year of the “Earth Dog” .............. 1335
4.2  The Outlook of Chinese Pharma as Defined by the 2017 NRDL And Proposed Uniform BMI
Payment Standards........................................................................................................ 1337
4.3  More Challenges in the New Year, Despite Unchanged Long Term Prospects............... 1339
4.4  13th FYP Paints a Gloomy Picture for Healthcare MNCs ......................................... 1347
4.5  Harvard Researchers Recommend New System to Improve China Healthcare ............... 1350
4.6  Has China Done Enough to Keep Itself Attractive to Pharma MNCs? ......................... 1351
4.7  Four Key Areas Shaping the Chinese Pharma Industry .............................................. 1354
4.8  Top 10 Predictions on Implications of Healthcare IT in China................................... 1359
4.9  China’s Massive Government Restructure Explained .............................................. 1361
4.10 What Is The Ongoing Reorganization of Healthcare Agencies Really About? ............ 1365
4.11 China Pushes Generics over Brands with Another Round of New Pharma Policies ....... 1366
4.12 Biopharma Caught in the Crosshairs of U.S.–China Trade Tussle .............................. 1368
4.13 State Council Removes Import Duties on Anticancers as It Proposes New Market Access and
IPR Measures .............................................................................................................. 1370

PART VI  CONTEMPORARY TRENDS, OPPORTUNITIES AND STRATEGIC
CONSIDERATIONS ........................................................................................................ 1373

Chapter VI-1  Introduction ............................................................................................ 1375

Chapter VI-2  Market Dynamics and Strategic Considerations ............................... 1377

2.1  Impacts of Slowing Chinese Economy on the Country’s Healthcare Plans ................. 1377
2.2  China’s Healthcare Reforms, Who Will Survive? ...................................................... 1379
2.3  What Should We Know about the Merger of China’s Urban and Rural Resident Basic Medical
Insurance Schemes? .................................................................................................... 1380
2.4  Embracing China’s Brave New Pharmaceutical World .............................................. 1382
2.5  How To Think About China’s Special Economic Zones As A Foreign Pharmaceutical, Medical
Device, or Hospital Company ...................................................................................... 1386
2.6  China Fast Tracks Merck’s Cancer Drug For Approval, But There's A Catch ............. 1388
2.7  New Guidelines to Make China A More Drug-Friendly Market ................................. 1389
2.8  Cross-Sector Collaboration to Enhance Market Access for Pharmaceutical Companies in Asia:
Six Steps to Make It Work ............................................................................................. 1392
2.9  The View of China from Headquarters ..................................................................... 1396
2.10 Big Pharma Facing Roadblock in China .................................................................. 1398
2.11 Are You Ready for the Lower Tier Market? ............................................................... 1400
2.12 Leading Chinese Pharma Companies Buy Into The Medical Service Sector .......... 1401
2.13 Why Chinese Drugmakers Are Looking Overseas .................................................. 1403
2.14 Review of Off-label Drug Usage in Chinese Hospitals .............................................. 1405
2.15 Physician-Patient Relations and Health Literacy in China ........................................ 1406
2.16 China Healthcare Advertising: Failure to Learn ....................................................... 1408

Copyright © 2018 by WiCON International Group LLC
Chapter VI-3  Promising Opportunities of the Present and Future ...............1438

3.1  Chinese Healthcare Expenditures to Triple by 2020 Despite Challenges .......................1438
3.2  Commercial Models in China's Pharma Sector Must Change .................................1441
3.3  Two Way Traffic for Chinese Drug Licensing .................................................1442
3.4  Chinese Market Offers New Life to Many Drugs ...........................................1444
3.5  Pharmaceuticals: China Wishes to Transform Into A Hub for Innovation – Is It Possible?..1446
3.6  MNCs Boost Drug Research and Clinical Trials for Diseases Prevalent in China and Other Asian Markets .................................................................1449
3.7  Changing R&D and Manufacturing Strategies For MNCs in China..............................1451
3.8  Why Big Pharma Is Targeting China's Deadliest Diseases .......................................1453
3.9  Impact of GSK Crisis and China’s Law Enforcement Bias on Foreign Business Enthusiasm1455
3.10  Fast-Tracking the Introduction of New Drugs ....................................................1460
3.11  Review of Class 1 New Drug Applications and Approvals 2003-2017 .........................1462
3.12  Review of New Drugs on Special Approval Path 2004-2015 ....................................1466
3.13  Review of Drug Registration Applications on Three Fast Tracks 2011-2014 ..................1468
3.15  The Transformation and Future of China's Biomedical Innovation ...........................1474
3.16  China to Become Life Science Powerhouse by 2020 .............................................1477
3.18  Understanding China’s Marketing Authorization Holder Pilot Plan in Selected Regions ..1482
3.19  China Embraces Precision Medicine on a Massive Scale .....................................1484
3.20  Building a Translational Medicine Powerhouse in China .....................................1486
3.21  China Biotech Promise Struggles to Keep Foreign Innovators .............................1490
3.22  Winning in China's HCV Travails .......................................................................1492
3.23  Local Partnerships Key to Pharma’s Success in China ...........................................1497
3.24  Chinese Pharma Regulatory Reforms to Help Attract Foreign Investment ....................1499
Chapter VI-4 Trends and Prospects in Pharma Outsourcing

4.1 CMO/Manufacturing Outsourcing in China and Asia ............................................. 1520
4.2 Will China Lose Its Cost-Competitiveness in Pharma Manufacturing? ....................... 1529
4.3 Biopharmaceutical Manufacturing Growing Rapidly in China .................................. 1532
4.4 Chinese CRO Market Estimated to Grow 20% Annually Before 2018 .......................... 1535
4.5 Trends and Prospects of Clinical Research in China .................................................. 1537
4.6 SCPPR Survey Expects Growing Clinical Trials in China .......................................... 1542
4.7 Potential Compliance Risks in Clinical Research Outsourcing to China ......................... 1544
4.8 The Next Hotspots for CMO/CRO Growth in China ............................................... 1547
4.9 Regulatory Changes Position China as a Global Clinical Trial Destination ..................... 1549
4.10 Asia: Preferred Destination For Clinical Trials ......................................................... 1550
4.11 APAC Is the Fastest Growing Market for CRO Industry ........................................... 1555
4.12 Why Asian CROs are Turning to the European Biotech Market .................................. 1558
4.13 Chinese Government Launch Support Program for Biopharma CRO and CMO Service Platforms .................................................................................................................. 1561
2.1 National and Local Drug Reimbursement Lists ....................................................... 1589
2.2 Pricing of Drug Products .......................................................................................... 1594
2.3 Centralized Hospital Drug Purchase Tenders ......................................................... 1596
2.4 Product Launches ................................................................................................... 1599
2.5 Clinical Research ................................................................................................. 1600
2.6 Public Relations ................................................................................................... 1600
2.7 Lobbying for Industrial Policies and Regulations ................................................... 1601
2.8 Building a Better Government Affairs Function in China ....................................... 1602
2.9 Only 12.1% of the Doctors Are Satisfied with the Domestic Academic Meetings .......... 1608
2.10 Measuring Pharma's Success by Customer Reputation and Loyalty ....................... 1615
2.11 Snapshot of Chinese Pharmaceutical Marketing and Digital Communication Channels 1619

Chapter VII-3  Marketing and Sales of Ethical Drugs in Urban Hospitals ............... 1621
3.1 Mainstream Hospital Marketing and Sales Models ................................................ 1621
3.2 The Hospital Drug Purchase Approval Process .................................................... 1623
3.3 Hospital Drug Purchase Channels ....................................................................... 1624
3.4 Hospital Marketing/Sales Organization and Execution ......................................... 1625
3.5 Key Factors in Hospital Marketing and Sales ....................................................... 1626
3.6 Developing Effective Market Coverage and Sales Force Strategies in China ............ 1627
3.7 Shifting from Network Marketing to Evidence Based Medicine in China ............... 1630
3.8 More Chinese Pharma Cos Cuts Sales Force and Switch to Agency Sales ............... 1632

Chapter VII-4  Marketing and Sales of Ethical Drugs through Urban Retail Pharmacies .......................................................................................................................... 1634
4.1 Channels of Retail Pharmacy Sales and Distribution ............................................. 1634
4.2 Process and Key Components of Retail Pharmacy Sales ....................................... 1635
4.3 Key Factors in Sales of Ethical Drugs through Retail Pharmacies ........................... 1635
4.4 Case in Point: Pfizer's Retail Pharmacy Sales Efforts in China ............................... 1636

Chapter VII-5  Sales & Marketing of OTC Drug Products in Cities ...................... 1638
5.1 Channels of OTC Drug Sales ............................................................................... 1638
5.2 Process and Key Components of OTC Drug Sales .............................................. 1639
5.3 Key Factors in OTC Drug Sales ......................................................................... 1640

Chapter VII-6  Sales, Marketing and Distribution of Drugs in the "Third Terminal
Market" ..................................................................................................................... 1642
6.1 Pharmaceutical Sales & Distribution Channels to the "Third Terminal Market" ........... 1642
6.2 Sales and Marketing Strategies for the "Third Terminal Market" ............................ 1644
6.3 Special Characteristics of the "Third Terminal Market" ........................................ 1645

Chapter VII-7  Pharmaceutical Distribution ............................................................... 1646
7.1 Overview ............................................................................................................. 1646
7.2 Important Regulatory Requirements on Pharmaceutical Distribution ................... 1649
PART VIII  MARKET ENTRY STRATEGIES AND EXECUTION

Chapter VIII-1  Preparations for a Market Entry Strategy

1.1 The Need for a Market Entry Strategy

1.2 Long Term Perspective

1.3 Information Sources

Copyright © 2018 by WiCON International Group LLC
Chapter VIII-2  Strategic Approaches for Market Entry.................................1728
  2.1 Direct Export of Finished Products..........................................................1728
  2.2 Sino-foreign Joint Ventures......................................................................1730
  2.3 Solely Foreign-owned Companies in China.............................................1732
  2.4 Licensing and Technology Transfer.........................................................1732
  2.5 Merger & Acquisition (M&A) ....................................................................1734

Chapter VIII-3  Execution of The Market Entry Strategy..............................1736
  3.1 Product Registration....................................................................................1736
  3.2 New Drug Clinical Trials and Patient Recruitment in China....................1738
  3.3 Latest Regulatory Developments on Ethical Review in Chinese Clinical Trials........1740
  3.4 Selection of a Local Distributor for Imported Drugs...............................1742
  3.5 Selection of a Chinese Partner for Joint Venture......................................1743
  3.6 Product Launch ..........................................................................................1744
  3.7 Promotional Activities and Advertising ......................................................1745

Chapter VIII-4  Challenges and Realities for Operating in China....................1746
  4.1 The Importance of Patience ......................................................................1746
  4.2 The Value of Relationship .......................................................................1746
  4.3 Dealing with Chinese Style Laws ...............................................................1747
  4.4 The Ethical Challenges of Doing Business in China’s Healthcare Economy ........1747
  4.5 Commercial Briberies Seen as a Leading Risk as Chinese and Foreign Governments Step Up Enforcements .........................................................1749
  4.6 Behind China’s Corruption Crackdown: Whistleblowers.........................1751
  4.7 Compliance in China: Ongoing Regulatory and Operational Challenges ........1754
  4.8 Staff Turnover and Talent Retention A Growing Problem .......................1757
  4.9 Drawing Pharmaceutical Talents from the West .......................................1759
  4.10 Choosing Your General Manager for China.............................................1760
  4.11 Managing Sino-Foreign Joint Ventures in China .....................................1763
  4.12 Recruiting R&D Leaders in China and India .........................................1769
  4.13 Recruiting Medical Executives in China ..................................................1773
  4.14 Managing Clinical Trials in China ...........................................................1775
  4.15 Resourcing Clinical Research Programs in China ....................................1776
  4.16 Protecting the Accuracy of Clinical Trial Data in China .........................1779
  4.17 Survey: Clinical Research Experience, Practice and Attitudes of Chinese Physicians ....1781
  4.18 Why Your NDA Does Not Work For China .............................................1783
4.19 How To Protect Trade Secrets In China When Employees Leave ........................................... 1784

PART IX  MINI CASE STUDIES ............................................................................................................ 1789

Chapter IX-1  China Experiences of Foreign Drug Companies ............................... 1791

1.1 Quest PharmaTech’s Ill-fated China Venture ................................................................. 1791
1.2 Ranbaxy’s Successful Entry and Surprising Exit of the Chinese Market ....................... 1792
1.3 Zuellig Pharma China/Cardinal Health China – A One-Time Successful Case and Business Model for China’s Pharmaceutical Distribution Sector with A Disappearing End ......... 1795
1.4 West Pharmaceutical Services - Tapping into China's Growing Healthcare Industry ............ 1798
1.5 Novo Nordisk China - Focusing on Diabetes and Ample Room for Growth ..................... 1801
1.6 Abbott succeeds in China by Focusing on Nutrition Business ........................................ 1805
1.7 Bayer's Big Bet on China .................................................................................................. 1806
1.8 Bayer Troubled by Integration of Acquired OTC Business in China ............................. 1807
1.9 Roche's Unique, Global Strategy for China ...................................................................... 1808
1.10 Helping Establish Private Health Insurance for Cancer in China – A Roche Story ............ 1811
1.11 A Decade Old Drug Launch in China with Important Insights Today - BMS’s Experience with Baraclude in China ........................................................................................................ 1812
1.12 Ipsen Outlines Strategies for Continued Growth in China - The Success Story of a Mid-size Company ........................................................................................................................................ 1817
1.13 SciClone Pharmaceuticals: Building a Product Portfolio Optimized for China’s Evolving Pharmaceutical Market ................................................................. 1819
1.14 Leveraging U.S. Resources and Chinese Partnership for Drug Development and Commercialization .................................................................................................................. 1825
1.15 With a Band of Biotech Collaborators, RuiYi Sets Sail Developing New Biologics for China 1827
1.16 Why Did One of the World’s Largest Generic Drug Makers Exit China? ........................ 1829
1.17 CleveXel’s Collaboration with Guilin Pharma for Development of Artesunate Injection .. 1832
1.18 Lessons from Glaxosmithkline’s Record $492 Million Bribery Fine in China............... 1836
1.19 One Multinational’s Lessons Learned in China ............................................................... 1838
1.20 MSD and Nanjing Sincere Set to Go Their Own Ways .................................................. 1840
1.21 Merck Finds Shortcut for Anticancer Keytruda into China via Medical Tourism .......... 1842
1.22 Merck’s Gardasil Preps for Head-to-head with GlaxoSmithKline’s Cervarix in China, with Big Sales Targets Ahead ........................................................................................................ 1843
1.23 Pfizer Builds Viagra Success in China Despite Fierce Competition and Generics ............ 1844
1.24 Pfizer Eyes Huge Potential in Online Sales of Its Health Products in China ................... 1846
1.25 Eli Lilly Launches LEAP to Expand Lower Tier Market Access in China ....................... 1847
1.26 Roche Looks to Grow and Change with China’s Ever-evolving Healthcare Industry ....... 1848
1.27 Sanofi to Center Its China Biz Strategy on Primary Healthcare in the Next Five Years ...... 1851
1.28 Ten Years and $100M+ Later, GSK Shuts A China R&D Site amid Reorganization ......... 1852
1.29 Despite Strong Albumin Sales, CSL Complains of Barriers in China Business ............... 1853
1.30 Kobayashi Pharma: China Business Growth without China Presence ......................... 1854
1.31 American Drug Maker Finds His Dream in Beijing ...................................................... 1856

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Chapter IX-2  R&D and Outsourcing Case Studies

2.1  Birth of A New Novel Anticancer, Made in China

2.2  China Becomes Center of Startup CROs for Basic Research

2.3  Huya Bioscience - Tapping into China for Novel Drug Candidates

2.4  LEAD Therapeutics: A Unique US-China Drug Discovery Model

2.5  BeiGene Strives to Become China’s Genentech

2.6  Two Emerging Companies Leverage the Strength of Both China and the U.S. for Growth

2.7  Chinese Innovation: BGI’s Code for Success

2.8  Human Genomics in China: 10-Year Endeavor

2.9  China Learns the Lesson of Vaccine R&D Bubble - The Story of Chongqing Brewery's in Development of Its Novel HepB Vaccine

2.10  Research Partnership between BMS and Simcere: The Right Chemistry amid a Global Paradigm Shift of Drug R&D?

2.11  China’s Academic “Black Market” Fooled Canadian Medical Journal

2.12  A Setback For Chinese Drug R&D

2.13  USFDA Found China Data Irregularities for Key Study of Pfizer and BMS’s Eliquis

2.14  How Chinese Suppliers to Global Drug Firms Hide Bad Test Results

2.15  TCM Gets a Modern Look

2.16  Chinese Companies Make Progress on New Drugs from TCM Herbs

2.17  A Better Pill from China - Chinese Pharma Firms Target the Global Market

2.18  Novartis CEO on Why the Firm Opened a Major R&D Facility in China

2.19  Pfizer to Use GE’s Mobile Biotech Factory to Make Next-Generation Drugs in China

Chapter IX-3  Human Resource Management Case Studies

3.1  AstraZeneca China: Continued Mission on People

3.2  Novartis China: The Learning Strategy

3.3  Trends in Managing Pharmaceutical R&D and Medical Affairs Professionals

Chapter IX-4  Legal Case Studies: IPR/Counterfeits/AML/Others

4.1  Sankyo vs. Beijing Wansheng: First Lawsuit over Process Patent for Preparing Pharmaceutical Composites

4.2  Pfizer vs. 12 Local Drug Companies: Landmark Lawsuit over Viagra Patent

4.3  Eli Lilly vs. Beijing Ganli - Battle over Insulin

4.4  Boehringer Ingelheim vs. Chaitai Tianqing over Tiotropium Bromide

4.5  Legal Battle between Sanofi and Jiangsu Hengrui over Docetaxel

4.6  Merck vs. Henan Topfond over Chinese Patent for Finasteride

4.7  Aurisco Challenges Gilead’s Chinese Patent for Viread

4.8  Fake Drug Sting Operation – GSK Experience

4.9  Legal and Ethical Implications of ELAD Clinical Trial Death
4.10 Ruling over Liabilities of Distributors & Hospital in Fake Armillarisni-A Injection Case. 1933
4.11 Novartis Sued and Challenged for Deaths Linked to Its Hepatitis B Drug Sebivo .......... 1934
4.12 Illegal and Off-Label Use of Roche’s Avastin Led to Serious ADRs in Shanghai .......... 1936
4.13 Off-label Use of Bayer Healthcare’s XARELTO under Challenge in China............... 1937
4.14 Review of the 11-Year Trademark Fight between Roche and Southwest Pharma ......... 1939
4.15 Merck & Co. Loses Trademark Fight against Tianjin Zhongxin Pharma .................. 1942
4.16 Pfizer Loses Final Battle for Chinese Trademark of Viagra .................................. 1942
4.17 J&J Loses Trademark Suit against SAIC’s Trademark Review Board ....................... 1943
4.18 Bayer Settles Six-Year Trademark Infringement Lawsuit with Henan Baier Pharma ...... 1943
4.19 The Rio Tinto Case Lays New Ground for PR of Foreign Companies in China .......... 1944
4.20 Siemens Sued in the U.S. by Former Employee over Briberies in China .................. 1947
4.21 China’s Anti-Japanese Boycott Extended to Pharmaceuticals .................................. 1948
4.22 The Impact of Restricted Data-flows on China’s Digital Healthcare Solutions .......... 1950
4.23 Insight Into PRB Decisions on Pharma/Biotech Inventions Around 2015.................. 1952
4.24 SIPO Invalidates Gilead Sciences’ Viread Patent in China ................................... 1955
4.25 China Rejects Patent for Gilead’s Expensive Hepatitis C Drug .............................. 1956
4.26 I-MAK Challenges Gilead’s Remaining Chinese Patents of HCV Drug Sofosbuvir ..... 1958
4.27 Bayer Loses Avelox (Moxifloxacin) Patent Battle in China .................................... 1959
4.28 Eli Lilly vs. Changzhou Watson: China’s Supreme Court Sides with Local Firm After Court Designated Technical Investigations .................................................. 1960
4.29 Three Supreme Court Cases On Pharmaceutical Patents ....................................... 1960
4.30 MSF Challenges Gilead’s HCV Patent Application in China .................................... 1963
4.31 Novartis Lost Gleevec Infringement Lawsuit in China against Jiangsu Hansoh Pharma ... 1965
4.32 Review of China’s High Profile Investigation of GSK for Corruption ...................... 1966
4.33 GSK Sued by Couple It Hired to Investigate Whistleblower in 2013 ......................... 1981
4.34 The “Dignified” Drug-Dealer – A Case for Thought over Patient Access to Medicines, Parallel Import, Compulsory Licensing and Drug Pricing ..................................................... 1983
4.35 Pfizer Fined by Shanghai Government for Irregular Pharmacy Display Fees .......... 1986
4.36 Shanghai Fines Novo Nordisk CNY 2.6 Mln for Distributor License Violation ............ 1987
4.37 Shanghai AIC Hits Foreign Firms with Fines for Compliance Violations .................. 1987
4.38 Other Anti-Monopoly Enforcement Cases .............................................................. 1989
4.39 FCPA Compliance Cases and Other Related Foreign Lawsuits .............................. 1997

Chapter IX-5  Success and Failure Stories of Domestic Companies .............................. 2002

5.1 BGI: The Kung Fu Panda of the Genomic World ....................................................... 2002
5.2 China’s Bid To Be A DNA Superpower .................................................................... 2005
5.3 3SBio – The Success Story of a Chinese Biogeneric Company ............................... 2008
5.4 Shanghai Sunway Biotech – The Success Story of a Chinese Gene Therapy Drug Co. ... 2012
5.5 SinoVac Biotech – The Story of a Chinese Vaccine Developer ............................... 2014
5.6 Zhejiang Hisun Pharmaceutical Ltd. – A Showcase for International Business Transformation of Chinese Pharma Companies .............................................................. 2016
5.7 Jiangsu Hengrui – What Does the Future Hold for China’s Largest Oncology Drug Firm? 2020

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5.8 Tongjitang Chinese Medicines Company – The Tale of a Fallen Wall Street Darling and One of the Earliest "China Concept" Drug Stocks
5.9 Shenogen Pharma Blends East and West
5.10 GenePharma - The Story of a Small Niche Chinese Biotech Company
5.11 Luqa Pharmaceuticals – Expatriate-founded Chinese Pharma Startup with a Strategy of Tailoring Products for China through Partnerships
5.12 The Rise and Fall of Sincere Pharmaceutical as a US-listed Company
5.13 Fosun Pharma Expands Global Business Via M&As and Innovative R&D
5.14 Backed by China, Ambrx No Longer Dependent on Partnerships with MNCs
5.15 BeyondSpring Pharma: Communicating Across US-China Lines
5.16 EOC Pharma Strives to Bring Potential Oncology Blockbusters to China
5.17 Hua Medicine Mulls Hong Kong IPO as Diabetes Drug Enters Crucial Clinical Phase
5.18 China’s Tech Tycoons’ Healthcare Dreams Aren't Coming True
5.19 Ali Health’s Reversal of Fortune on the Back of Soaring Online Pharmacy Sales
5.20 Dendreon Chairwoman Figures Provenge Growth Can Pave Its Way into CAR-T

APPENDICES

Appendix I  Drug Administration Law of the PRC
Appendix II  Regulations for Implementation of the Drug Administration Law of the PRC
Appendix III  Regulations on Administrative Protection for Pharmaceuticals
Appendix IV (1)  Provisions for Registration of Drug Products
Appendix V  Special Review and Approval Procedure for Drug Registration of the CFDA
Appendix VI  Administrative Reconsideration Measures of CFDA
Appendix VII  Provisions for Drug Insert Sheets and Labels
Appendix VIII  Provisions for Supervision of Drug Distribution
Appendix IX  Provisions for Drug Advertisement Examination
LIST OF TABLES

Table 1.1 Number of Pharmaceutical Businesses in China Since 1997 .......................125
Table 1.2 Core Revenues of Chinese Pharma Industry in H1/2017 ............................127
Table 1.3 Net Profits of Chinese Pharma Industry in H1/2017 .................................128
Table 1.4 Growth of the Chinese API/Bulk Drug Sector 2002-2017 ..........................134
Table 1.5 Chinese Foreign Trade of Biochemical Drugs 2007-2017 (US$ mln) ............149
Table 1.6 # of Accepted Biological Drugs Applications by CDE 2008-2017 ...............150
Table 1.7 Biologic Applications Accepted by CDE 2013-2017: Domestic vs. Import .....150
Table 1.8 Type of Biologic Applications Accepted by CDE in 2017 ............................150
Table 1.9 Accepted New Biologic Applications by Dosage Form 2017 .......................151
Table 1.10 Accepted New Biologic Applications by Class 2017 .................................151
Table 1.11 Top 15 Companies by CDE Accepted Biologic Applications 2017 ............152
Table 1.12 Top 9 Cos by # of CDE Accepted New Biologic Applications 2017 ...........152
Table 1.13 Status of CDE Accepted Biologic Applications in 2017 .............................153
Table 1.14 Classification of Approved Biological Applications in 2017 .......................153
Table 1.15 CDE Acceptance Time of New Biologic Approvals 2017 .........................153
Table 1.16 Number of Pharma Distribution License Holders 2013-2017 ....................168
Table 1.17 Structure of Chinese Retail Pharmacy Sector 2006-2017 .........................168
Table 1.18 Chinese Drug Distribution Industry Performance 2011-2017 ....................169
Table 1.19 Chinese Pharma Distributor Sales by Terminal Markets 2016-2017 ...........170
Table 1.20 Composition of Chinese Pharmaceutical Distributor Sales in 2016 .............170
Table 1.21 Chinese Retail Pharmacy Market Segmentation in 2017 .........................171
Table 1.22 Chinese Pharma Distributor Segmentation by Ownership 2017 .................171
Table 1.23 Regional Chinese Pharma Distribution Sales in 2017 ..............................171
Table 1.24 Regional Pharmaceutical Distributor Sales Structure 2016-2017 ...............172
Table 1.25 E-Commerce Composition of Chinese Drug Distributor Sales 2017 ..........174
Table 1.26 Composition of B2B Sales by Chinese Drug Distributors 2016-2017 ........175
Table 1.27 Composition of B2C Sales by Chinese Drug Distributors 2016-2017 .......175
Table 1.28 Top 10 Domestically-listed Pharma Cos by R&D Investment 2016 .......... 180
Table 1.29 Top 20 Chinese Pharma Companies by R&D Capability 2016 ............... 181
Table 1.30 China Pharma Companies Ranking by R&D Investment 2015/2016 .......... 182
Table 1.31 R&D Centers of RDPAC Members in China ........................................ 186
Table 1.32 Eight MNCs with Over 40 Chinese Drug Registration Submissions 2016 . 193
Table 1.33 Selected Outbound Sino-Foreign Licensing Deals 2015 - 2016 ............. 199
Table 1.34 Out-licensing Deals of Novel Drugs Originated in China 2011-2017 .......... 199
Table 1.35 A-Share IPOs of Pharma Companies in 2017 ........................................ 206
Table 1.36 Review of Chinese Pharma IPOs 2012-7Ms/2017 ................................ 208
Table 1.37 25 Chinese Pharma IPOs in 7Ms/2017 ...................................................... 208
Table 1.38 Top 20 China Pharma Companies by Sales in 2017 ................................ 213
Table 1.39 Top 20 Domestically-listed Pharma Companies by Capitalization (06/2017) .......................................................... 214
Table 1.40 Top 20 Domestically-listed Pharma Companies by Capitalization (06/2017) .......................................................... 216
Table 1.41 Top 10 Chinese Listed Pharma Companies by R&D Innovation Capacity 2017 .......................................................... 217
Table 1.42 Top 18 A Share-listed Chinese Pharma Cos by R&D Spending 2017 ........ 217
Table 1.43 Top 30 A Share-Listed Biopharma Sector Cos by Sales Expense 2017 ..... 218
Table 1.44 Top 7 Chinese Listed Pharma Companies by R&D Investments H1/2017. 219
Table 1.45 Performance of 41 Chinese Pharma Cos Launching IPOs in 2017 (CNY mln) .......................................................... 221
Table 1.46 Top 20 Chinese Retail Pharmacy Chains by Sales Revenues in 2015 ........ 223
Table 1.47 Top 20 Chinese Retail Pharmacy Chains by 2015 Sales ....................... 224
Table 1.48 New Foreign Investments in Chinese Pharma Industry 2013 ............... 248
Table 1.49 First Ten Sino-Foreign Pharmaceutical Joint Ventures in China .......... 248
Table 1.50 Foreign Investment in the Chinese Pharmaceutical Industry in the 1990s .. 249
Table 1.51 Pharma Foreign Investments in China between 2000 and 2006 ............ 249
Table 1.52 Top 10 Pharma MNCs in China by Investment ...................................... 251
Table 1.53 Drug Sales by Three Major Terminal Markets 2014-2017 (CNY bln) ...... 271
Table 1.54 Shares of Three Major Drug Terminal Markets 2014-2017 (CNY bln)........271
Table 1.55 Growth of Three Major Drug Terminal Markets 2014-2017 (%) ............271
Table 1.56 Top 20 Drug Suppliers to Chinese Hospitals Q4/2017 .........................272
Table 1.57 China Pharma Market Size by Product Category 2011-2020E .................276
Table 1.58 Chinese Biopharma Market 2013-2016 .............................................294
Table 1.59 Top 10 TCs of the Chinese Biopharma Market 2016 ..........................294
Table 1.60 Top 10 Biopharma Drugs in China 2013-2016 .................................295
Table 1.61 Top Ten Chinese Biopharma Companies 2013-2016 .......................295
Table 1.62 Chinese Biologics Market Structure by TCs 2014 .........................296
Table 1.63 Chinese Biologics Market Structure by Chemical Identities 2014 ....297
Table 1.64 Urban Biologics Market Structure by Disease Areas 2014 ...............297
Table 1.65 Top 10 Biologics Companies in China 2014 ..................................297
Table 1.66 Top 10 Domestic Biologics Companies in China 2014 .....................298
Table 1.67 Chinese Sales of SIP Pediatric Vaccines 2006-2016 .........................304
Table 1.68 Chinese Vaccine Market 2006-2014 .............................................306
Table 1.69 Chinese Vaccine Consumption 2005-2020E ..................................310
Table 1.70 Compound Vaccines with No Local Production in China ..................311
Table 1.71 Polyvalent Vaccines with No Local Production in China .................311
Table 1.72 Therapeutic Vaccines Launched Outside China ..............................312
Table 1.73 Application Status of Therapeutic Vaccines in China 2017 .............313
Table 1.74 Chinese OTC Drug Market Segmentation 2013-3015 ...................317
Table 1.75 Chinese Foreign Trade of Medicines and Health Products in 2017 (1) ....328
Table 1.76 Chinese Foreign Trade of Medicines and Health Products in 2017 (2) ....329
Table 1.77 Chinese ANDAs Approved by the U.S. FDA ................................331
Table 1.78 Chinese ANDAs Tentatively Approved by the U.S. FDA 2017 ..........332
Table 2.1 Improvement of Medical Provision in China ..................................337
Table 2.2 Comparisons of Healthcare Provision by China vs. Other Countries (1) ....338
Table 2.3 Comparisons of Healthcare Provision by China vs. Other Countries (2) ....338
Table 2.4 Comparisons of Healthcare Provision by China vs. Other Countries (3) .... 339
Table 2.5 Birth, Death and Population Natural Growth Rate ........................................ 340
Table 2.6 Rising Life Expectancy of the Chinese Population ........................................... 340
Table 2.7 Composition of the Chinese Population by Urban/Rural Division and Sex .. 341
Table 2.8 Composition of the Chinese Population by Age ............................................. 342
Table 2.9 Composition of the Chinese Population by Education ..................................... 343
Table 2.10 Composition of China’s Healthcare Expenditures 1980-2016 ......................... 347
Table 2.11 Medical Institutions and its Inpatient Beds by Type and Ownership .......... 349
Table 2.12 Healthcare Personnel in China 2010-2016 ....................................................... 350
Table 2.13 Healthcare Personnel by Medical Institute Type and Ownership .............. 351
Table 2.14 Outpatient Visits and Inpatients by Medical Institution Type in 2013-2016 353
Table 2.15 Occupancy Rate and Average Days of Hospitalization by Hospital Type 2013-2016 .......................................................... 354
Table 2.16 Number of Village Clinics and Healthcare Professionals ....................... 354
Table 2.17 Statistical Summary of Community Healthcare Service Centers .......... 354
Table 2.18 Statistical Summary of Community Healthcare Service Stations .......... 355
Table 2.19 TCM Medical Institutions and its Inpatient Beds by Type and Ownership . 356
Table 2.20 Outpatient Visits and Inpatients in TCM Medical Institutions by Type in 2013-2016 .................................................................................................................. 357
Table 2.21 Share of Primary Healthcare Facilities with TCM Services (%) ............ 357
Table 2.22 TCM Healthcare Professionals in China ...................................................... 357
Table 2.23 Structure of Outpatient and Inpatient Medical Expenditures 2015-2016 ... 358
Table 2.24 Medical Institutions by Specialties and Affiliations ................................. 368
Table 2.25 Inpatient Beds of Medical Institutions by Specialties and Affiliations ...... 369
Table 2.26 Medical Institutions by Ownership Type ....................................................... 370
Table 2.27 Inpatient Beds of Medical Institutions by Ownership Type .................... 370
Table 2.28 Inpatient Beds of Medical Institutions by Hospital Grade ..................... 370
Table 2.29 Number of Medical Institutions by Grade in 2012 ................................... 371
Table 2.30 Number of Medical Institutions by Grade 2013-2017 ............................ 371
Table 2.31 Number Growth (%) of Medical Institutions by Grade 2013-2017 ............372
Table 2.32 Regional Population Distribution in China 1990-2016 .........................372
Table 2.33 Regional Distribution of Medical Institutions in Q1/2017 .......................373
Table 2.34 Regional Distribution of Medical Institutions and Inpatient Beds in 2016 ..374
Table 2.35 Regional Distribution of Healthcare Professionals in 2016 .....................375
Table 2.36 Distribution of Inpatient Beds by Medical Specialty 2005-2012 .............376
Table 2.37 Distribution of Physicians by Medical Specialty 2000-2012 ....................377
Table 2.38 Healthcare Personnel in China 1990-2016 .......................................378
Table 2.39 Distribution of Healthcare Professionals in Cities and Counties 1990-2016 .................................................................378
Table 2.40 Key Healthcare Reform Goals for 2017 .............................................398
Table 2.41 Key Healthcare Reform Goals by 2020 ..........................................399
Table 2.42 Makeup of Healthcare Expenditures in China between 1980 and 2016 .....410
Table 2.43 Income and Outlays of Urban BMI Program M1-9/2016 .......................413
Table 2.44 Income and Outlays of Urban BMI Program 2011-2016 .....................413
Table 2.45 Urban BMI Fund Surplus 2011-2016 ...............................................414
Table 2.46 Number of Enrollees of Urban/Rural BMI Programs 2011-2015 ..........414
Table 2.47 China’s Population Structure by Age 1982-2020 .............................414
Table 2.48 Current Structure of Patient Visits and Expense in Urban BMI 2014 ......414
Table 2.49 Structure of Inpatient Expenses 2010-2014 .......................................415
Table 2.50 Coverage/Finance of New Rural Cooperative Medical System (NRCMS) .418
Table 2.51 Overview of Medical Assistance Coverage in Urban & Rural Areas ....424
Table 2.52 Coverage of Chinese Population by Basic Medical Insurance (Mln) .....432
Table 2.53 Coverage and Finance of Urban BMI Programs ...............................433
Table 2.54 New Added Western Medicines by TC in 2017 NDRL .......................439
Table 2.55 Newly Added Cardiovascular Drugs by Sub-TCs in 2017 NDRL ..........440
Table 2.56 WM Product Composition by TC: 2017 NRDL vs. 2009 NRDL ..........440
Table 2.57 CAGR Growth of Chinese Hospital Drug Market by TCs 2010-2013: All Drugs vs. Newly Added Drugs of 2009 NRDL .............................................441
Table 3.22 Breakdown of Cancer Survival Patients: Male vs. Female (2011)...........536
Table 3.23 Breakdown of Cancer Survival Patients: Urban vs. Rural (2011)...........536
Table 3.24 Composition of Medical Care Providers in China 1950-2016..................548
Table 3.25 Composition of Medical Care Providers in China 2016-2017..................549
Table 3.26 Number of Outpatient Visits and Inpatients in Medical Institutions 1980-2016

Table 3.27 Outpatient Visits and Inpatients by Medical Institution Type in 2013-2015551
Table 3.28 Outpatient Visits and Inpatients by Medical Institution Type in Q1/2016 ...551
Table 3.29 Regional Distribution of Outpatient Visits and Inpatients in Q1/2016 ......552
Table 3.30 Number of Outpatient Visits and Inpatients by Medical Specialties in 2012

Table 3.31 No. of Outpatient & Emergencies Visits by Medical Specialties 2011-2012

Table 3.32 Average Days of Hospitalization 1985-2012.................................554
Table 3.33 Occupancy Rate and Average Days of Hospitalization by Hospital Type
2013-2015.................................................................554
Table 3.34 Regional Distribution of Medical Institutions and Inpatient Beds in 2016..555
Table 3.35 Overall Healthcare Expenditures in China 2013-2016..........................555
Table 3.36 Composition of Healthcare Expenditures in China 2013-2016..............556
Table 3.37 Structure of Outpatient and Inpatient Medical Expenditures 2015-2016.....556
Table 3.38 Drug Sales Value in Chinese Hospital 2013-2017 ............................557
Table 3.39 Top 10 Drug Suppliers to Chinese Hospitals by Sales Value 2017.........558
Table 3.40 Top 10 Drug Products by Sales in Chinese Hospitals 2017...................558
Table 3.41 Top 10 TCs by Chinese Hospital Drug Consumption Value 2017 ..........559
Table 3.42 TCM Consumption by Dosage Form 2015-2017...............................559
Table 3.43 TCM Consumption by Therapeutic Category 2015-2017....................559
Table 3.44 China’s Public Hospital Drug Markets 2010-2017 ............................560
Table 3.45 Top 20 Pharma Companies by Hospital Drug Purchase Value 2017 .......561
Table 3.46 Top 10 TCs by Drug Sales in Chinese Rep Hospitals 2017...................562
Table 3.47 Top 20 Pharma Cos by Drug Sales in Chinese Rep Hospitals 2017.........562
Table 3.48 Top 20 Products in Chinese Rep Hospitals 2017 ................................. 563
Table 3.49 Top 10 Pharma Suppliers to Rep Urban Hospitals by Sales 2015-2016 .... 564
Table 3.50 Top 20 Pharma Suppliers to Rep Urban Hospitals by Sales 2016 .......... 564
Table 3.51 Top Drug Suppliers to Representative Chinese Hospital in Leading 20 TCs 2016 .................................................................................................................. 565
Table 3.52 Medical Institution Drug Consumption by Facility Type 2007-2016 .... 566
Table 3.53 Number and Distribution of Medical Facilities in China 2014 ............. 567
Table 3.54 Chinese County Public Hospitals Market 2011- H1/2017 ................. 567
Table 3.55 TC Composition of County Level Public Hospital Chemical Drug Sales 2016 .................................................................................................................. 567
Table 3.56 TC Composition of County Level Public Hospitals FTCM Sales 2016 ..... 568
Table 3.57 Top 20 Chemical Drugs by Sale Value in County Level Public Hospitals 2016 .................................................................................................................. 568
Table 3.58 Top 20 FTCMs Drugs by Sale Value in County Level Public Hospitals 2016 .................................................................................................................. 569
Table 3.59 Growth of County Level Hospital Drug Market in Six Provinces 2015 .... 571
Table 3.60 Shares of County Level Hospital Drug Market in Six Provinces 2015 ...... 571
Table 3.61 MNC Market Share in Urban and County Level Hospitals 2009-2015 .... 572
Table 3.62 Top 10 TCs in Chinese County Level Hospitals M10/2015 ............... 574
Table 3.63 Top 10 Drug Suppliers to Chinese County Level Hospitals M10/2015 .... 574
Table 3.64 Shares of MNC/Local Cos in County Level Hospitals of Six Provinces M10/2015 ................................................................................................. 575
Table 3.65 Top 10 Drug Suppliers to County Level Hospitals in Six Chinese Provinces M10/2015 ................................................................................................. 575
Table 3.66 Top 10 Products in Chinese County Level Hospitals M10/2015 .......... 576
Table 3.67 China’s Public Primary Healthcare Drug Markets 2010-2017 ............ 577
Table 3.68 Drug Consumption by Urban Public CHCs 2010- H1/2017 .............. 577
Table 3.69 TC Composition of Urban Public CHC Chemical Drug Sales 2016 ....... 578
Table 3.70 TC Composition of Urban Public CHC FTCM Sales 2016 ................. 578
Table 3.71 Top 20 Chemical Drugs by Sale Value in Urban Public CHCs 2016 .... 579
Table 3.72 Top 20 FTCMs Drugs by Sale Value in Urban Public CHCs 2016..............580
Table 3.73 Market Shares by Major TCs: Hospitals vs. CHCs MAT Q4/2017 .............581
Table 3.74 Market Shares by City Tiers: Hospitals vs. CHCs MAT Q4/2017 .............582
Table 3.75 Drug Sales and Market Shares of CHCs in Six Cities 2016 .......................582
Table 3.76 Top Five TCs in CHCs and Hospitals of Six Tier 1 & 2 Cities 2016.............582
Table 3.77 Top 5 TCs by Sales Value 2015: Hospitals vs. CHCs ..........................583
Table 3.78 Top 10 Suppliers to Tier 1 City CHCs by Sales Value 2015 .....................583
Table 3.79 Top 10 Products in Tier 1 City CHCs by Sales Value 2015 ........................584
Table 3.80 Drug Consumption by Rural Township Health Centers 2010-H1/2017 ..584
Table 3.81 TC Composition of Drug Consumption by Chinese Township Health Centers 2014-2015.................................................................................................585
Table 3.82 TC Composition of Drug Consumption by Chinese Township Health Centers 2014-2015: WMs vs. TCMs ........................................................................585
Table 3.83 Top 20 WMs of Chinese Township Health Centers 2014-2015 ...............586
Table 3.84 Top 20 WMs of Chinese Township Health Centers 2014-2015 ...............586
Table 3.85 Top 20 FTCMs of Chinese Township Health Centers 2014-2015E ..........587
Table 3.86 Top 20 FTCM Brands of Chinese Township Health Centers 2014-2015....588
Table 3.87 Vaccine Sales in Major Urban Hospitals 2008-2017E ..........................588
Table 3.88 Top 5 Human Rabies Vaccine Sales in Major Urban Hospitals 2008-2017E ..............................................................................................................589
Table 3.89 Top 5 Cowpox Vaccine Sales in Major Urban Hospitals 2012-2017E......589
Table 3.90 Top 5 Pseudomonas Aeruginosa Vaccine Sales in Major Urban Hospitals 2012-2017E ..................................................................................................589
Table 3.91 Top 5 BCG Vaccine Sales in Major Urban Public Hospitals 2012-2017E...590
Table 3.92 Top 5 Recombinant HepB Vaccine Sales in Major Urban Hospitals 2008-2017E ........................................................................................................590
Table 3.93 Number of Chinese Retail Pharmacy Outlets 2006-2017 ..........................591
Table 3.94 Chinese Retail Pharmacy Drug Sales 2010-2017 ..................................592
Table 3.95 Growth of Top 20 OTC Drug & Health Food Players in Urban Retail Pharmacy Market 2017 .................................................................................................594
**Table 3.96** Top 20 Products by OTC Drug & Health Food Sales in Urban Retail Pharmacy Market 2017 ................................................................. 595

**Table 3.97** Top 20 Products by Rx Drug Sales in Urban Retail Pharmacy Market 2017 ................................................................. 596

**Table 3.98** Retail Drug Consumption by Channel 2010-2017 ........................................ 597

**Table 3.99** Chinese Retail Pharmacy Drug Sales 2013-2016 ........................................ 597

**Table 3.100** Retail Pharmacy Drug Sales in 22 Cities 2016: Chemical Drugs vs. TCMs ................................................................. 598

**Table 3.101** TC Composition of Urban Retail Pharmacy Chemical Drug Sales 2015-2016 ................................................................. 598

**Table 3.102** TC Composition of Urban Retail Pharmacy FTCM Sales 2015-2016 .... 599

**Table 3.103** Top 20 Chemical Drugs by Sale Value in Urban Retail Pharmacies 2016. 599

**Table 3.104** Top 20 FTCM Drugs by Sale Value in Urban Retail Pharmacies 2016..... 600

**Table 3.105** Chinese Pharma Retail Sales Value and Growth 2015-2017E ............... 602

**Table 3.106** Sales of Chinese Pharma Retail Sales Q3/2016-Q3/2017 ..................... 602

**Table 3.107** Top 20 Western Medicines by Retail Sales 2016 ..................................... 603

**Table 3.108** Chinese Retail Pharmacy Market Segmentation in 2017 ...................... 603

**Table 3.109** Chinese Online Pharmacy Market and Forecast 2011-2017E .............. 604

**Table 3.110** Chinese Online Pharmacy Drug Sales Value 2011- 2017 .................. 605

**Table 3.111** Overview of Chinese OTC Drug Market 2016-2017 (US$ mln) ............ 607

**Table 3.112** Chinese OTC Drug Market Forecast 2017-2027 (US$ mln) ................. 609

**Table 3.113** Shares of OTC and Rx Products in Chinese Drug Terminal Sales 2015 ... 611

**Table 3.114** Structure of Chinese OTC Drug Terminal Market 2014-2015 .............. 611

**Table 3.115** Share of OTC Drugs in Terminal Markets of 3 Cities* 2014-2015 ........... 611

**Table 3.116** Structure of OTC Drug Sales in Different Tiers of Retail Pharmacy 2015 612

**Table 3.117** Number of Retail Pharmacies 2013-2015 ............................................. 612

**Table 3.118** Number of Retail Pharmacies by Level 2015 ........................................ 612

**Table 3.119** Top 10 TCs by Chinese Retail Pharmacy OTC Drug Sales 2015 .......... 613

**Table 3.120** Chinese OTC Market Growth and Market Segmentation 2013-2016 ..... 613

**Table 3.121** Top 10 TCs in China Chemical OTC Market 2016 ............................... 614
Table 3.122 Top 10 OTC Chemical Drug Suppliers in China 2015-2016 ...............614
Table 3.123 Top 10 Chemical OTC Products in China 2015-2016..........................614
Table 3.124 Top 10 OTC Drug Brands and Suppliers by Retail Pharmacy Sales 2015 ...615
Table 3.125 Top 10 OTC Suppliers to Chinese Retail Pharmacies 2015 ..................616
Table 3.126 Top 20 OTC & Health Food Players in China Retail Pharmacy Market 2015 .........................................................616
Table 3.127 Top 20 OTC & Health Products in China Retail Market 2015 ..........617
Table 3.128 Chinese Drug Market Size by Major Segments 2014-2017 .................623
Table 3.129 Provincial Level Hospital Drug Markets MATQ4/2017 ......................624
Table 3.130 Chinese Hospitals Market Growth by City Tiers Q4/2017 ......................624
Table 3.131 Chinese Hospitals Market Share by City Tiers Q4/2017 ......................625
Table 3.132 Growth of Chinese Hospital Drug Sales by City Tiers 2016 ..................625
Table 3.133 MNC Share of Hospital Drug Markets in 24 Provinces/Regions 2016 ....625
Table 3.134 Growth of Chinese Hospital Drug Sales by City Level in 2014-2016 ......626
Table 3.135 2015 Hospital Drug Sales Growth in 24 Provinces ..................................627
Table 3.136 Growth of Rx Drug Sales Value in Rep Shanghai Hospitals 2016........628
Table 3.137 Rx Drug Sales Value by TCs in Rep Shanghai Hospitals 2016 ............628
Table 3.138 Top 10 Pharma Suppliers to Rep Shanghai Hospitals 2016 .................628
Table 3.139 Drugs Rx Value of 62 Rep Hospitals in Shanghai 2016 .....................629
Table 3.140 Top Outpatient/Emergency Depts by Biologic Rx Value of 62 Rep Hospitals in Shanghai 2016 .................................................................629
Table 3.141 Top Inpatient Depts by Biologic Rx Value of 62 Rep Hospitals in Shanghai 2016 .................................................................629
Table 3.142 Top 10 Biologics by Rx Value of 62 Rep Hospitals in Shanghai 2016 ......630
Table 3.143 Top 3 Dosage Forms by Biologic Rx Value of 62 Rep Hospitals in Shanghai 2016 .................................................................630
Table 3.144 Top 3 TCs by Biologic Rx Value of 62 Rep Hospitals in Shanghai 2016 ..630
Table 3.145 Top 3 Indications by Biologic Rx Value of 62 Rep Hospitals in Shanghai 2016 ......................................................................................630
Table 3.146 Drug Sales Champions in Rep Public Hospitals of 22 Cities/Regions 2016
Table 3.170 Chinese Hospital Drug Sales Growth by City Tier 2016 vs. 2017 ............647
Table 3.171 MNC Market Share Changes by City Tiers 2013-2017 ........................................647
Table 3.172 China Drug Consumption in Hospitals 2008-2017 ..................................................648
Table 3.173 Hospital Market Value Growth (%): Domestics vs. MNCs 2015-2017 ............648
Table 3.174 Hospital Market Volume Growth (%): Domestics vs. MNCs 2015-2017 ..........648
Table 3.175 MNC Hospital Drug Sales Value by TC 2015-2017 ........................................648
Table 3.176 Domestic Hospital Drug Sales Value by TC 2015-2017 ........................................648
Table 3.177 Foreign New Product Launches in China 2008-2017 ..................................................649
Table 3.178 Top 10 Foreign New Product Launches in China 2015-2017 ..........................649
Table 3.179 Chinese Drug Market Segmentation 2013-2015: MNCs vs. Domestics (1) .............................................................................................................................................650
Table 3.180 Chinese Drug Market Segmentation 2013-2015: MNCs vs. Domestics (2) .............................................................................................................................................650
Table 3.181 Drug Sales Champions in Rep Public Hospitals of 22 Cities/Regions 2016 .............................................................................................................................................651
Table 3.182 Drug Sales Champions by TCs in Rep Urban Public Hospitals 2016..............652
Table 3.183 Top 7 Diseases by Mortality Rate among Chinese Urban Residents 2014 655
Table 3.184 Chinese Oncology Drug Market Project 2008-2018E ........................................656
Table 3.185 20 Approved Target-oriented Anticancers Approved by the CFDA..............657
Table 3.186 Cancer Immunotherapy Drug Consumption by Urban Rep Hospitals 2016E .............................................................................................................................................658
Table 3.187 Cancer Immunotherapy Drug Consumption by Urban Rep Hospitals 2006-2016E .............................................................................................................................................659
Table 3.188 Target-oriented Micromolecule Anticancers (Tinibs) on the Chinese Market .............................................................................................................................................659
Table 3.189 Top Four Tinibs by Urban Rep Public Hospital Consumption 2007-2016E .............................................................................................................................................659
Table 3.190 Top Four Imatinib Brands by Rep Urban Public Hospitals 2016....................660
Table 3.191 Chinese Market of Digestive System and Metabolism Drugs 2014-2016 666
Table 3.192 Chinese Market of Digestive System and Metabolism Drugs by Major Category .............................................................................................................................................666
Table 3.193 Top 10 Suppliers of Digestive System and Metabolism Drugs .......... 667
Table 3.194 Top 10 Digestive System and Metabolism Chemical Drugs by Share 2015 ................................................................................................................................. 667
Table 3.195 Top 10 Digestive System and Metabolism Biologics by Share 2015 ...... 668
Table 3.196 China Insulin Market 2015 .................................................................. 668
Table 3.197 Leading Players of Insulin & Analogues in China 2015.................... 669
Table 3.198 Cardio-/Cerebro-vascular Drug Consumption in Public Hospitals of 16 Major Cities 2007-2016........................................................................................................ 669
Table 3.199 Top 10 Cardio- and Cerebro-vascular Drugs in Public Hospitals of 16 Major Cities 2016 .................................................................................................................. 670
Table 3.200 Hypertensive Sales in Hospitals of Major Chinese cities 2012-2016 ..... 670
Table 3.201 Hypertensive Sales Value by TCs in Hospitals of Major Chinese cities 2012-2016 .......................................................................................................................... 671
Table 3.202 Hypertensive Submarket Shares in Hospitals of Major Chinese cities 2012-2016 ....................................................................................................................... 671
Table 3.203 Top 10 Hypertensive Drugs in Hospitals of Major Chinese Cities 2016 ... 671
Table 3.204 Rep Hospital Consumption of Hepatic Drugs in Major Cities 3Qs/2015 .. 672
Table 3.205 Rep Hospital Consumption of Hepatic Drugs in Major Cities 2011-2015 672
Table 3.206 Top 10 Hepatic Drugs by Rep Hospital Consumption in 3Qs/2015 ........ 672
Table 3.207 Top 10 Rep Hospital Suppliers of Hepatic Drugs in 3Qs/2015 .......... 673
Table 3.208 Cause of Respiratory Diseases in Shanghai H1/2016 ....................... 676
Table 3.209 COPD Incidence Rate by Gender in Shanghai ................................. 676
Table 3.210 COPD Incidence Rate by Age in Shanghai ....................................... 677
Table 3.211 Top 10 COPD Drugs in Shanghai Rep Hospitals................................ 677
Table 3.212 Antidepressant Consumption in Rep Urban Hospitals of Major Cities 2009-2016 .......................................................... 678
Table 3.213 Top 10 Antidepressant by Value in Rep Hospitals of Major Cities 3Qs/2016 .............................................................. 679
Table 3.214 Antidepressant Market Landscape in Rep Hospitals of Major Cities 3Qs/2016 .......................................................................................................................... 679
Table 3.215 Top Antidepressant Suppliers in Rep Hospitals of Major Cities 3Qs/2016679
Table 3.216 Statistical Summary of Chinese Senior Population..........................683
Table 3.217 Consumption of Geriatric Drugs in Major Cities Public Hospitals 2011-2014 .................................................................683
Table 3.218 PD Drug Consumption by Rep Chinese Hospitals 2013-2017........688
Table 3.219 Top 10 PD Drugs in Chinese Rep Hospitals by Share in 2017..........688
Table 3.220 Chinese Generic Drug Market Size 2016-2021E..........................691
Table 3.221 Generic Drug Shares in Three Major Terminal Drug Markets 2016...691
Table 3.222 Top 10 Generic Drug TCs in Chinese Rep Hospitals 2016..............691
Table 3.223 Top 13 Generic Drug Cos with CNY 10B+ Revenue 2016..............692
Table 3.224 Major Product Market Shares: Originator Drugs vs. Generics 2017 ....692
Table 3.225 Oral WM Market Shares: Originators vs. Generics/MNCs vs. Domestics 2017 .................................................................693
Table 4.1 Number of Pharma Manufacturers 2013-2017.................................712
Table 4.2 Number of Pharma Distribution License Holders 2013-2017...............712
Table 4.3 Number of Retail Pharmacy Chain Companies 2011-2017.................712
Table 4.4 Number of Retail Pharmacy Stores 2011-2017...............................713
Table 4.5 Number of Protected TCM Products 2013-2017.............................713
Table 4.6 Review of Vaccine Batch Releases and Rejections 2010-2016.............714
Table 4.7 Structure of Vaccine Batch Release: Domestic vs. Import (2012-2016)......715
Table 4.8 Review of Batch Released Import Vaccines 2016.............................715
Table 4.9 Review of Batch Released Blood Products 2016..............................716
Table 4.10 Overview of All Registration Applications in 2011-2017...................718
Table 4.11 Number of Drug Registration Applications with Concluded CDE Review 2013-2017.................................................................719
Table 4.12 Breakdown of Drug Applications Concluding CDE Review 2013-2017....719
Table 4.13 Breakdown of Registration Applications with Concluded CDE Review in 2017 .................................................................719
Table 4.14 Breakdown of CDE Recommendations for Chemical Drug Applications in 2017........................................................................720
Table 4.15 # of Concluded Chemical Drug Registration Applications by the CDE in
Table 4.16 Breakdown of CDE Recommendations for TCM Registration Applications in 2017

Table 4.17 # of Concluded TCM Registration Applications by the CDE in 2012-2017

Table 4.18 Breakdown of CDE Recommendations for Biologic Applications in 2017

Table 4.19 # of Concluded Biologic Registration Applications by CDE in 2012-2017

Table 4.20 No. of Newly Accepted Applications Subject to CDE Review 2013-2017

Table 4.21 Breakdown of Newly Accepted Applications Subject to CDE Review 2017

Table 4.22 Chemical Drug Registration Applications Accepted by CDE in 2011-17

Table 4.23 Breakdown of CDE Accepted Chemical New Drug Applications 2014-2017

Table 4.24 TC Distribution of Newly Accepted Chemical Drug INDs by CDE 2017

Table 4.25 TCM Registration Applications Accepted by the CDE in 2012-2017

Table 4.26 Newly Accepted Biologic Applications subject to CDE Review 2017

Table 4.27 Biologic Registration Applications Accepted by the CDE in 2012-2017

Table 4.28 Breakdown of Applications Designated for Priority Review 2017

Table 4.29 Breakdown of Communication Meeting Requests and Fulfillment with CDE

Table 4.30 # of Approved Products by CFDA 2017

Table 4.31 Drug Approvals in 2017: Domestic vs. Foreign

Table 4.32 Drug Approvals by TCs 2017

Table 4.33 Drug Approvals by Dosage Forms 2017

Table 4.34 Drug Approvals to Leading MNCs 2017

Table 4.35 Drug Approvals to Leading Domestic Companies 2017

Table 4.36 Drug Approvals by Product Names 2017

Table 4.37 # of Chemical Drugs Applications Accepted by CDE 2010-2017

Table 4.38 # of Accepted New Chemical Drugs Applications 2010-2017

Table 4.39 Leading Applicants of Class 1 New Drugs 2016-2017

Table 4.40 First-Time Chemical Drug Approvals by TCs 2017
Growth ........................................................................................................... 1226

Table 5.4 China’s Three Major Terminal Drug Markets 2010- H1/2018 – Retail Value and Market Share ........................................................................................................... 1227

Table 5.5 Public Medical Institution Drug Consumption by Facility Type 2010-2017 ........................................................................................................... 1227

Table 5.6 Retail Drug Consumption by Channel 2010-2017 ........................................... 1228

Table 5.7 Composition of Chinese Retail Pharmacy Sales 2013-2016 .................... 1228

Table 5.8 Retail Pharmacy Drug Sales by City Tiers 2015-2016 .............................. 1228

Table 5.9 Urban Retail Pharmacy Drug Sales: Chemicals VS TCMs 2015-2016 ...... 1229

Table 5.10 Urban Retail Pharmacy Drug Sales: OTC VS Rx 2015-2016 .................... 1229

Table 5.11 Composition of Urban Retail Pharmacy Chemical Drug Sales 2015-20161229

Table 5.12 Composition of Urban Retail Pharmacy FTCM Sales 2015-2016 ............ 1229

Table 5.13 Chinese Drug Terminal Market Structure 2015-2017 .............................. 1231

Table 5.14 Chinese Rx Drug Market Structure 2016-2017 ........................................ 1231

Table 5.15 Chinese OTC Drug Market Structure 2016-2017 .................................... 1231

Table 5.16 Chinese Rx Drug Shares by Terminal Markets 2017 .............................. 1232

Table 5.17 CAGR Growth of Chinese Drug Sales Channels 2015-2017 .................... 1232

Table 5.18 ETCD Share in Chinese Rx Drug Market 2016 ........................................ 1232

Table 5.19 Top 3 ETCD Suppliers by Sales by Terminal Markets 2016 .................... 1233

Table 5.20 Chinese Hospital Drug Market 2011-2017 ............................................ 1233

Table 5.21 Chinese Drug Market Segmentation 2013-2016: Terminal Markets* ...... 1237

Table 5.22 Overview of Chinese OTC Drug Market 2016-2017 (CNY mln) ............ 1239

Table 5.23 Sales Revenues Value of Chinese Pharma Industry in 2017 ....................... 1243

Table 5.24 Net Profits of Chinese Pharma Industry in 2017 ........................................ 1243

Table 5.25 Revenues and Profits of Chinese Pharma Industry 2010-2017E ........... 1244

Table 5.26 Growth of Chinese Pharma Industrial Value Added vs. GDP .................... 1245

Table 5.27 Chinese Performance of MNC Pharma Companies in 2017 .................... 1249

Table 5.28 Summary of Chinese Pharma Events Q2/2018 and H1/2018 .................. 1312

Table 5.29 Summary of Sino-foreign Licensing Deals in H1/2018 (1) ..................... 1313
Table 5.30 Summary of Sino-foreign Licensing Deals in H1/2018 (2) ......................1314
Table 5.31 Summary of Sino-foreign Licensing Deals in H1/2018 (3) ....................1315
Table 5.32 Summary of Sino-foreign Licensing Deals in H1/2018 (4) ....................1316
Table 5.23 Summary of Sino-foreign CDMO/Collaborative R&D Agreements in H1/2018 (1) .................................................................................................................1317
Table 5.34 Summary of Sino-foreign CDMO/Collaborative R&D Agreements in H1/2018 (2) .................................................................................................................1318
Table 5.35 Summary of Selected JV/Strategic Alliance Deals in H1/2018 ............1319
Table 5.36 Summary of Sino-foreign M&A Deals in H1/2018 ..........................1320
Table 5.37 Summary of Chinese Pharma Events in 2013 - 2017 .......................1320
Table 5.38 Summary of Sino-foreign Licensing Deals in 2017 (1) ....................1322
Table 5.39 Summary of Sino-foreign Licensing Deals in 2017 (2) ....................1323
Table 5.40 Summary of Sino-foreign Licensing Deals in 2017 (3) ....................1324
Table 5.41 Summary of Sino-foreign Licensing Deals in 2017 (4) ....................1325
Table 5.42 Summary of Sino-foreign M&A Deals in 2017 (1) .........................1326
Table 5.43 Summary of Sino-foreign M&A Deals in 2017 (2) .........................1327
Table 5.44 Summary of Selected Sino-foreign JV/Strategic Alliance Deals in 2017 (1) .................................................................................................................1328
Table 5.45 Summary of Selected Sino-foreign JV/Strategic Alliance Deals in 2017 (2) .................................................................................................................1329
Table 5.46 Summary of Sino-foreign CR/Collaborative R&D Agreements in 2017 (1) .................................................................................................................1330
Table 5.47 Summary of Sino-foreign CR/Collaborative R&D Agreements in 2017 (2) .................................................................................................................1331
Table 5.48 # of Chinese In-licensing Deals of Foreign INDs 2007-2017 ............1332
Table 5.49 Origins of Chinese In-licensing of Foreign INDs 2007-2017 ............1332
Table 5.50 Ranking of Chinese In-licensors of Foreign INDs 2007-2017 ..........1333
Table 5.51 Share of Chinese In-licensed Foreign INDs by TCs 2007-2017 ..........1333
Table 5.52 Share of Chinese In-licensed Foreign INDs by R&D Stage 2007-2017 ....1334
Table 5.53 Chinese Drug Terminal Market Forecast 2018E .............................1341
Table 6.22 Number of Recorded Novel New Drug Projects in China in 2012 - 2017
Table 6.23 Chinese New Drug Projects by R&D Phase in 2010 - 2017
Table 6.24 Summary of Chinese New Drug Projects Recorded in 2017 (1)
Table 6.25 Summary of Chinese New Drug Projects Recorded in 2017 (2)
Table 6.26 Chinese Pharmaceutical CRO Market Size 2011-2021E
Table 6.27 Four CRO Companies in Shanghai Stock Market 2016-2017
Table 6.28 Financial Highlights of Select Chinese CROs 2015 – Q1/2017
Table 6.29 No. of Drug Clinical Trials Registered on the CDE Platform 2013-2017
Table 6.30 Top 10 Products by # of Registered Drug Clinical Trials 2017
Table 7.1 Major Pharma Marketing Spending by Channels in China 2016
Table 7.2 Chinese Pharma B2C Market Size and Forecast 2011-2017
Table 7.3 E-Commerce Composition of Chinese Drug Distributor Sales 2016
Table 7.4 Composition of B2B Sales by Chinese Drug Distributors 2016
Table 7.5 Composition of B2C Sales by Chinese Drug Distributors 2016
Table 7.6 Anticipation of Mobile Health Development in China
Table 7.7 Mobile Health Will Change the Way People Acquire Medical Info
Table 7.8 Purposes of Mobile Health Purchases
Table 7.9 Anticipated Leading Application Centers of Mobile Health Products
Table 7.10 Leading Issues of Mobile Health Products
Table 7.11 Perceived Reasonable Pricing of Mobile Health Hardware
Table 7.12 Feedbacks on Existing Prices of Mobile Health Products
Table 7.13 Mobile Health APP Downloads by Respondents in 2014
Table 7.14 Reasonable Fee Structure of Mobile Health APPs
Table 7.15 Chinese Mobile Healthcare User Population 2011-2015E
Table 7.16 Penetration of Healthcare APPs in Chinese Mobile Netizens 2011-2015
Table 7.17 Users Demand Preference for Mobile Healthcare APPs
Table 8.1 Types of Clinical Research Participated by Respondents
Table 8.2 # of Clinical Trials Participated by Respondents
Table 8.3 Understanding of WMA's Helsinki Declaration ........................................ 1782
Table 8.4 Relevant Clinical Research Experience of Respondents .......................... 1782
Table 8.5 Origins of Clinical Research Knowledge of Respondents ....................... 1782
Table 8.6 Benefits of Clinical Research Perceived by Respondents ....................... 1782
Table 8.7 Barriers of Clinical Research Faced by Respondents ............................ 1783
LIST OF CHARTS

Chart 1.1 Core Business Revenues of Broad Chinese Pharma Industry 2006 – 2017...126
Chart 1.2 Pretax Net Profitability Trend of the Chinese Pharma Industry 1997-2017 ..127
Chart 1.3 China in Global API Market 2011-2020 .................................................. 135
Chart 1.5 Net Profit of Chinese Biologic Products Subsector 2006-2017............... 149
Chart 1.6 Profit Margins of the Chinese Pharma Distribution Sector Since 2002....173
Chart 1.7 R&D Centers of RDPAC Members by Research Stage in China ..........187
Chart 1.8 R&D Centers of RDPAC Members by Function in China.................... 188
Chart 1.9 Locations of R&D Centers of RDPAC Members in China.................... 188
Chart 1.10 Chinese Market Access by New Drugs – 1 Year After Launch.........189
Chart 1.11 Chinese Market Access by New Drugs – 2 Years after Launch ........190
Chart 1.12 Number of Chinese Retail Pharmacy Stores 2006-2017.................... 282
Chart 1.13 Number of Chinese Retail Pharmacy Chains 2006-2017................... 282
Chart 1.14 No. of Outlets Owned by Chinese Retail Pharmacy Chains Since 2006 ....283
Chart 1.15 Number of Independent Chinese Retail Pharmacy Stores Since 2006 ......283
Chart 1.16 Structure of Retail Pharmacy Outlets Since 2006 .............................. 283
Chart 1.17 Growth of Chinese Retail Pharmacy Sales Since 2000...................... 285
Chart 1.18 Shares of Retail Drug Sales Channels Since 2001 ......................... 286
Chart 1.19 Chinese Sales of SIP Pediatric Vaccines 2006-2016 .......................... 304
Chart 1.20 Chinese Sales of Adult Vaccines 2006-2016 .................................... 305
Chart 1.21 Chinese Vaccine Market Size 2010-2019E ................................... 306
Chart 1.22 Chinese Foreign Trade of MHPs 2008-2016 ................................... 328
Chart 1.23 Medical Institutions Inpatient Beds in China 2009-2016.................. 348
Chart 1.24 Number of Medical Institutions in China 2009-2016 ...................... 349
Chart 1.25 Healthcare Professionals in China 2009-2016 ................................ 350
Chart 1.26 Outpatient Visits in China 2009-2016 ............................................ 352
Chart 1.27 Inpatients of Medical Institutions in China 2009-2016 .................... 353
Chart 2.1 Healthcare Spending by Funding Source 1980-2016 (%) ................................. 412
Chart 3.1 Growth of Healthcare Expenditures in China Since 2000 .............................. 497
Chart 3.2 Growth of Per Capita Healthcare Expenditures in China Since 1990 .............. 497
Chart 3.3 Market Share Trend of County Level Hospitals in China 2014-2020 ............... 572
Chart 3.4 Distribution of County Hospitals by Drug Sales (Per Hospital) 2014 ............. 573
Chart 3.5 Chinese OTC Drug Consumption Value by City Tier and Sales Channel ......... 640
Chart 3.6 Chinese Retail OTC Drug Consumption Value by Cities ............................. 641
Chart 3.7 Rx Drug Growth in Various Levels of Shanghai Rep Medical Facilities 2013 ................................................................. 642
Chart 4.1 Administrative Structure of Drug Regulation in China .................................. 794
Chart 4.2 CFDA/NMPA Organizational Chart* ............................................................ 795
Chart 4.3 Application and Approval Procedures for Clinical Trials .............................. 839
Chart 4.4 Application and Approval Procedure for Imported Drugs (1) ......................... 868
Chart 4.5 Application and Approval Procedure for Imported Drugs (2) ......................... 868
Chart 4.6 Supplemental Application & Approval Procedure for Imported Drugs (1) ... 869
Chart 4.7 Supplemental Application & Approval Procedure for Imported Drugs (2) ... 869
Chart 4.8 Compulsory License Application Process ...................................................... 1089
Chart 4.9 The Model for Realizing Minimum Drug Resale Profit Margin in China ......... 1174
Chart 6.1 Pharmaceutical Industry’s Expenditure on R&D ......................................... 1447
Chart 6.2 Supply Structure of Chinese Drug Manufacturers 2008/2014 ....................... 1448
Chart 6.3 Government Spending on R&D ................................................................. 1448
Chart 7.1 Structure of the Chinese Pharma Distribution System in the Old Days ......... 1581
Chart 7.2 Hospital Distribution of the Respondents .................................................. 1609
Chart 7.3 Professional Title Distribution of the Respondents .................................. 1609
Chart 7.4 No. of Conferences in Average Attended Annually (last two years) .......... 1610
Chart 7.5 Lengthen of Optimal Duration for an Academic Conference ...................... 1610
Chart 7.6 Which Sponsors of Academic Conferences Are Most Trusted by You? ...... 1611
Chart 7.7 What Types of Meetings Do You Prefer to Attend? .................................. 1611
Chart 7.8 The Major Purpose of Attending an Academic Event ................................. 1612
Chart 7.9 Registration Fee Paid to Attend an Academic Conference? .................... 1613
Chart 7.10 Evaluation on Overall Situation of Domestic Academic Conferences ...... 1614
Chart 7.11 Any Areas for Improvement? (Check all that apply)......................... 1614
Chart 7.12 Top 10 Companies in Academic Marketing (All Physicians) ............... 1616
Chart 7.13 Top 10 Companies in Academic Marketing (Endocrinologists) ........... 1616
Chart 7.14 Top 10 Companies in Academic Marketing (Oncologists) ................. 1617
Chart 7.15 Online/Digital Platforms Attractive to Chinese Physicians ................. 1617
Chart 7.16 Top Five High Customer Loyalty Scores (All Physicians) ................. 1618
Chart 7.17 Top Five High Customer Loyalty Scores (Oncologists) ..................... 1619
Chart 7.18 Approval Process of Hospital Drug Purchase .................................. 1624
Chart 7.19 Hospital Market Potential Assessment Process .................................. 1628
Chart 7.20 Pharmaceutical Distribution Channels in the Urban Areas .................. 1652
Chart 7.21 Pharmaceutical Distribution through Retail Pharmacies ..................... 1653
Chart 7.22 Pharma Distribution in Sub-urban & Rural Areas (3rd Terminal Market) 1654
Chart 7.23 Dominant Distribution Models Used by MNCs in China ................. 1660
### TABLE OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td>API</td>
<td>Active Pharmaceutical Ingredients</td>
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<td>APP</td>
<td>Administrative Protection of Pharmaceuticals</td>
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<td>AmCham</td>
<td>American Chamber of Commerce</td>
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<td>CAGR</td>
<td>Compound Annual Growth Rate</td>
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<tr>
<td>CCCIEMHP</td>
<td>China Chamber of Commerce for Import &amp; Export of Medicines and Health Products</td>
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<td>CAPC</td>
<td>China Association of Pharmaceutical Commerce</td>
</tr>
<tr>
<td>CFDA</td>
<td>China Food and Drug Administration (predecessor of NMPA)</td>
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<tr>
<td>NMPA</td>
<td>National Medical Products Administration, successor of CFDA</td>
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<tr>
<td>ChP</td>
<td>Chinese Pharmacopoeia</td>
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<td>CMH</td>
<td>China Monitor Health</td>
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<tr>
<td>CNCM</td>
<td>China National Corporation of Medicines</td>
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<tr>
<td>CNY</td>
<td>Chinese Yuan</td>
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<tr>
<td>CPIIC</td>
<td>China Pharmaceutical Industry Information Center</td>
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<tr>
<td>CRO</td>
<td>Contract Research Organization</td>
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<tr>
<td>DRGs</td>
<td>Diagnosis Related Groups</td>
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<td>ED</td>
<td>Erectile Dysfunction</td>
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<tr>
<td>FDA/USFDA</td>
<td>U.S. Food and Drug Administration</td>
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<tr>
<td>FDI</td>
<td>Foreign Direct Investment</td>
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<tr>
<td>FIEs</td>
<td>Foreign Invested Enterprises</td>
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<tr>
<td>GCP</td>
<td>Good Clinical Practices</td>
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<td>GDP</td>
<td>Gross Domestic Products</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practices</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>GSP</td>
<td>Good Supply Practices</td>
</tr>
<tr>
<td>IFPMA</td>
<td>International Federation of Pharmaceutical Manufacturer Associations</td>
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<tr>
<td>JV</td>
<td>Joint Venture</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>Merger and Acquisition</td>
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<tr>
<td>MIIT</td>
<td>Ministry of Industry and Information Technology</td>
</tr>
<tr>
<td>MOFCOM or MOC</td>
<td>Ministry of Commerce</td>
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<tr>
<td>MOF</td>
<td>Ministry of Finance</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>MoHRSS</td>
<td>Ministry of Human Resources and Social Security</td>
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<tr>
<td>MNCs</td>
<td>Multinational pharmaceutical companies (<em>in the context of this guide</em>)</td>
</tr>
<tr>
<td>MR</td>
<td>Medical Representative</td>
</tr>
<tr>
<td>NBS</td>
<td>National Bureau of Statistics</td>
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<tr>
<td>NCGHSR</td>
<td>National Coordination Group for Healthcare System Reform</td>
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<tr>
<td>NDRC</td>
<td>National Development and Reform Commission</td>
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<tr>
<td>NHC</td>
<td>National Health Commission, successor of NHFPC</td>
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<tr>
<td>NHFPC</td>
<td>National Health and Family Planning Commission, predecessor of NHC</td>
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<tr>
<td>NMPA</td>
<td>National Medical Products Administration (formerly CFDA)</td>
</tr>
<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
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<tr>
<td>OTC</td>
<td>Over the Counter</td>
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<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>QC</td>
<td>Quality Control</td>
</tr>
<tr>
<td>PRC</td>
<td>People’s Republic of China</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>RDPAC</td>
<td>R&amp;D-based Pharmaceutical Association Committee in China</td>
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</table>
SATCM – State Administration of Traditional Chinese Medicine
SDA – State Drug Administration, predecessor of SFDA
SFDA – State Food and Drug Administration of China (predecessor of CFDA)
SAMR – State Administration for Market Regulation, governing body of NMPA
SIPO – State Intellectual Property Office
SMEI – Southern Medicine Economic Institute under the CFDA
SOE – State Owed Enterprise
SPAC – State Pharmaceutical Administration of China, predecessor of SDA
STD – Sexually Transmitted Disease
TC – Therapeutic Class
TCM – Traditional Chinese Medicine
USTR – US Trade Representative
VAT – Value Added Tax
VC – Venture Capital
WM – Western medicine
WHO – World Health Organization
WTO – World Trade Organization

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EXECUTIVE SUMMARY

The Chinese Horoscope 2018 predicts that the Year of the Brown Earth Dog is going to be a good year in all respects, but it will also be an exhausting year. From this perspective, President Donald Trump, being born in the year of the fire dog, is set to remain very influential of this year, which will bring both opportunities and tension.

Turning to the Chinese healthcare sector, the structural reform and anti-corruption campaign have now been expanded to all corners of the country. The “top level” design or reform blueprint is now near completion but it will take years before the medical system can digest the tasks and goals.

Meanwhile, the structural flaw of Chinese healthcare financing remains untackled. The central government continues to draw up grand plans with ambitious goals, while most of bills, however, need to be footed by local governments, which are already suffering from a chronic decline of fiscal revenues as housing market plummeted and debt escalated to an unsustainable level. Government healthcare budget increases have been limited at all levels and are not expected to be raised substantially in a stumbling economy. Achieving reform objectives set by top officials therefore rest mostly on savings from cost containments, which are doomed to hurt healthcare quality.

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

It’s encouraging, however, to see the pharmaceutical industry in China, especially leading MNCs, are making considerable progress reshaping its business model to adapt with the fast changing marketplace and fast emerging opportunities in the area of innovative new medicines. What will be the name of the new game? The answer is no longer blowing in the wind anymore for MNCs.

China needs to make good on its own repeated calls to open up its markets, or face consequences, warned the European Union Chamber of Commerce in China. In recent years, China has publicly avowed to do so, with President XI Jinping making speeches on openness and globalization. But critics say China's many words have few actions behind them. It appears that in many areas, China is no longer opening up, but selectively closing up.

Recent moves of pharma MNCs to scale back and refocus their China businesses coincide with the growing discontent of foreign companies in China. The Chamber said in its latest whitepaper that their members are suffering from "promise fatigue" in Chinese pledges to open up markets. Foreign firms have long complained of an uneven playing field and an opaque regulatory environment.

As money rushes into China’s fledgling biotechnology sector and reform of the country’s drug registration and regulatory system to accelerate harmonization with international norms, some foreign drugmakers are scaling back, a Bloomberg feature article noted.
Eli Lilly and GlaxoSmithKline announced plans in 2017 to cut research teams in China, after Novartis AG shuttered a biotech research unit there a year before. The high-profile cutbacks, part of a broader restructuring that pharmaceutical companies are undertaking, contrast with the Chinese government’s push to speed the uptake of innovative drugs that’s spurred a rush of money into the industry.

While drug discovery may have disappointed, pharma giants are doubling down on the development part of R&D in China. In Shanghai’s Pudong Zhangjiang Hi-Tech Park, Glaxo is preparing for growth, the company said in August, when it announced it would narrow the range of global neuroscience research and development activities, including terminating some projects.

The Bloomberg article concluded with a quote from Zhang Fangning, a partner at McKinsey & Co. in Shanghai, who said “closing research sites in China doesn’t diminish the importance of the market. Instead, it means multinational companies have alternative ways to gain access to innovation here.”

Meanwhile, China has been introducing various policies since late 2017 to speed up review and approvals of foreign innovative medicines, as well as timely negotiations for and inclusion of such products for BMI reimbursement. Many MNC patent drugs, which had previously been held up in the registration matrix, have been unleashed in recent months, with MSD’s newest HPV vaccine approved within nine days of submitting its NDA.

It all seems to be primed for a fast takeoff. In China is too big to be neglected both in terms of its current market size and future potential, but MNCs should stay sober despite positive developments recently and remain realistic with goals.

**Chinese pharmaceutical market growth fell to single digit in 2017**

The Chinese pharma growth continued to slide in all terminal markets in 2017 as a result of intensified cost containment and deepening healthcare reform. The chronic falling trend is anticipated by most industry observers to continue in 2018.

The three major Chinese terminal drug markets, which include the public hospital market, the retail pharmacy market and the public primary healthcare market, rose 7.6% in 2017, reaching CNY 1,611.8 billion at retail level, according to a recent information release by SMEI. Adding the drug market of private hospitals and clinics as well as village clinics, the entire Chinese pharmaceutical market is estimated to be around CNY 1.9 trillion at retail level. The public hospital market, the retail pharmacy market and the public primary healthcare market rose 6.98%, 8.06% and 11.63% respectively in 2017, reaching CNY 1,095.5 billion, CNY 364.7 billion and CNY 151.7 billion, representing 68.0%, 22.6% and 9.4% of total value.

The Chinese Pharmaceutical Association (CPA) also released topline data of its latest hospital drug purchase audit, which are based on drug purchases of representative hospitals nationwide, including level 3 hospitals (69.0%) and level 2 & below hospitals (31%). National hospital drug consumption growth slowed further to only 3.3% in 2017, down from 9.0% in 2016. The growth of level 3 hospitals was in line with the broad
market at 3.6%.

Nicholas Hall & Co. reported that OTC drug market size in China reached CNY 160,980 million in 2017, up 5.7%, a fraction below the 5.8% rise recorded in 2016. Growth failed to strengthen during the year owing to increased competition from the cross-border e-commerce channel (not tracked in the DB6 topline), the reverse switches of Ketoconazole (which affected the general antifungals and scalp treatments categories) and Xianling Gubao (joint health) as well as the initial impacts of the new two-invoice system on pricing and company operations. The company also forecasts that the annual Chinese OTC drug market size to grow 6% CAGR between 2017 and 2022 to reach US$33,406 million and surge at another 6% CAGR again between 2022 and 2027 to reach US$44,299 million at the end of their respective periods.

**CFDA powers forward drug regulatory system reform as it boosts support of drug innovation**

Two years into the drug regulatory reform, the CFDA made significant advancements in 2017 to overhaul the regime with numerous new regulations and draft documents released monthly. A number of progresses are made in the year.

At the beginning of 2017, CFDA Minister BI Jingquan outlined the direction of the agency’s drug evaluation and approval system reform in 2017 before the end of last month. Bi said the agency will deepen reform in 2017 to resolve the backlog completely and further energize the pharmaceutical industry through the following seven measures: 1) accelerating the generic drug quality and efficacy evaluation; 2) encouraging drug innovation; 3) establishing the review-oriented drug and medical device evaluation and approval technical system; 4) facilitating the responsibilities of onsite inspections; 5) building drug product master files; 6) establishing and implementing the drug eCTD system this year for electronic application and review; and 7) expediting manufacturing process verification.

In late March 2017, the CFDA hosted the National Drug Registration Regulatory Conference. CFDA Vice Minister WU Zhen delivered a keynote speech at the conference. He admitted the current CFDA approval time for clinical trials is too long, therefore needing reform. He then outlined the following considerations for future reform in the clinical trial approval area: 1) Reform of drug clinical trial management model to accelerate approval; 2) Accelerating registration approvals of urgently needed; 3) Enhancing technical support capacity and level of drug evaluation; and 4) Strengthening IP protection and researching on the formulation of drug clinical trial data protection system to secure rights of drug patent holders.

The State Council’s major reform policy covering full process of the pharmaceutical industry, *Certain Opinions for Further Reform and Improvement of Pharmaceutical Manufacturing, Distribution and Application (Guo Ban Fa 2017 #13)*, has been dissected into 58 specific reform tasks which have been assigned to different government departments with deadlines for implementation. Among all tasks, two are in the center, according to an official with the State Council’s healthcare reform office at an industry hearing event. The two critical tasks are: 1) encouraging development of first-to-copy...
generic drugs; and 2) import drug price negotiation.

CFDA Minister BI Jingquan delivered a report to the National People’s Congress in August 2017 over the progress of the Chinese drug evaluation and approval system reform. Besides progresses made on the fronts of prioritized review and approval of innovative drugs, generic drug quality and efficacy equivalence evaluation, MAH trial and clinical research quality, he said the CFDA has essentially eliminated the backlog of drug registration review and reduced the number of applications pending review to around 6,000 at present from 22,000 at a peak in 2015. All types of drug registration applications, including those for chemical drugs, vaccines and TCMs, are now up to speed with official timeline requirements.

Throughout the year, China persisted to toughen up its drug regulation and enforcement. In April 2017, the National People’s Congress has set up a drug administration law enforcement inspection group which would focus its inspection on 13 areas including formulation of complementary rules and regulations of the DAL, infrastructural building of the drug regulatory regime, supply security of commonly-used and emergency aid medicines as well as orphan drugs, development and execution of policies relevant to encouragement of new drug R&D, top issues of drug R&D, and reform of drug evaluation and approval system.

The CFDA was also given more teeth to police pharmaceutical R&D with issuance of the Interpretations of the Supreme People's Court and the Supreme People's Procuratorate for Application of Criminal Laws over Cases Relating to Faking Drug and Medical Device Registration Data in August 2017.

Besides, the PRC Law on Traditional Chinese Medicine became effective in July 2017. It is well-known that the law aims to give traditional Chinese medicine (TCM) a bigger role in the healthcare system.

The CFDA published its 2018 legislation plan in February 2018. According to the plan, the agency plans to work on 36 legislation projects including three laws, three regulations and 31 rules in the year of 2018. The three laws to be worked on include: 1) continued amendment of the Drug Administration Law of PRC; 2) completion of the amendment draft of the Drug Administration Law of PRC for review by the State Council; and 3) continued proposal of the National People’s Congress Decision on Authorizing the Trial of Patent Link Compensation of Selected Drugs and Exploration of Drug Patent Link System. Among the 31 rules to be worked on, 15 are related to reform of the drug and medical device evaluation and registration system.

In March 2018, after about five years as a standalone agency, the China Food and Drug Administration (CFDA) will merge into the gigantic State Market Supervision General Administration (SMSGA) and survive on as the National Medical Products Administration (NMPA) as a subordinate agency. Other than spinning off its food related responsibilities, the NMPA is almost identical to its predecessor CFDA in terms of drug registration and regulation.

The newly established National Medical Products Administration (NMPA) held its first
meeting of officials in April 2018 following inauguration earlier in the month. The meeting outlined five focal areas of the agency’s work in 2018, including continuing to deepen reform of drug and medical device evaluation and approval system, expanding regulation and enforcement of drugs, medical devices and cosmetics with boosted sample testing, and cracking down on violations with emphasis on production and online sales of fake medicines.

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

Another major development in the same month was the State Council’s decision to remove tariffs on certain imported drugs. According to the *Announcement of the Customs Tariff Commission of the State Council on Reducing the Import Tariff of Drugs*, import tariffs on all general medicines including anticancers, alkaloid drugs with anticancer efficacy, and formulated TCMs with actual imports will be reduced to zero starting from May 1, 2018.

Thereafter the Ministry of Finance (MOF), the General Administration of Customs (SGAC), the State Administration of Taxation (SAT) and the NMPA issued a new policy, *Notice on Value-Added Tax Policy of Anticancers* (*Cai Shui 2018#47*), to offer ordinary VAT tax payers engaging in production, sales, wholesale and retailing of anticancer drugs the simplified 3% VAT option and at the same time cuts the VAT rate of imported anticancers will be reduced to 3% (import portion only).

Besides the import tariff slash for anticancers, the State Council decision mentioned above also calls for research into substantially reducing prices of urgently needed anticancers, expedited launch of imported innovative new medicines, strengthened intellectual property protection with a maximum data protection period of six years to be set up for innovative chemical drugs and a maximum of five year patent term compensation for innovative medicines applying for marketing in China and overseas synchronically.

Most recently, the NMPA and NHC issued a joint document, *Announcement on Matters Concerning Optimization of Drug Registration Evaluation and Approval (2018#23)*, in May 2018. It became effective upon issuance. The move aims to prioritize review and approval of drugs which prevent and treat life threatening diseases currently without effective and orphan drugs for rare diseases. It is provided that domestic clinical trials can
be waived for such drugs already marketed overseas.

Furthermore, NMPA Commissioner Jiao Hong pledged in June 2018 the following measures to speed up new drug approvals: 1) adjusting import chemical drug registration testing process, changing current pre-approval testing requirement to the new post marketing sampling provision; 2) implementing data protection and provide corresponding data protection periods during which no other same products will be approved; and 3) introducing patent link and patent term restoration mechanisms to allow reasonable profits to innovators and encourage drug innovation.

**Healthcare reform deepens amid intensified cost containment**

Chinese Premier LI Keqiang delivered his government working report at the National People's Congress in March 2017, spending considerable time healthcare reform. Later on March 28, the National Healthcare Reform Teleconference was held and Premier Li repeated the ten major healthcare reform tasks in 2017. Tasks most relevant to the pharma industry include:

- Deepening coordinated healthcare reforms of medical service, BMI and pharmaceutical industry;
- Advancing the development of medical consortiums and developing demand-oriented family doctor contract services;
- Achieving full elimination of hospital drug sales margins;
- Introduction of two invoice system;
- Advancing BMI payment system reform in all urban hospital reform and overall healthcare reform trial sites;
- Completing integration of urban and rural resident BMI schemes in six primary aspects; and
- Pushing forward infrastructural building of healthcare IT and accelerating connectivity across platforms and regions.

A month later, the State Council recently issued a policy document, *Opinions for Major Tasks of Deepening Economic Reform in 2017*, which calls for accelerated reform in select areas including healthcare. The government remains committed to its planned spending and investments into healthcare reform. Besides, the reform of medical service pricing will be advanced with emphasis on “full implementation of medical service and drug price reform in urban public hospitals.” Finally, the government will dedicate its full force into coordinated reform of medical service, BMI and pharmaceutical sectors.

The General Office of the State Council followed up one more official document, *Major Tasks of Deepening Healthcare System Reform in 2017*, on May 2. The document includes a total of 70 major tasks to be implemented this year. The first part of the document includes 14 new policies to be formulated and issued in 2017 by various central government agencies. The rest 56 major healthcare reform tasks are mostly provided in various earlier documents. For details of this comprehensive document with deadlines and
responsible agencies for implementation of each reform task, please refer to our full coverage of this story in the latter part of this journal edition issue.

In July 2017, the Healthcare Reform Leaders Group under the State Council released a surveillance report of healthcare reform progress in 2016. According to the report, the healthcare reform expanded to 200 trial site cities in 2016 covering 2,335 public hospitals. 92.6% municipalities and prefectures revised their medical service fees. It claims that healthcare quality has risen and relevant resource allocation has improved with continuously falling medical expenditures following the reform. The share of drug expenditures in outpatient and inpatient expenditures of public hospitals in reform trial areas fell to 49.0% and 34.2% respectively in 2016, compared with 51.0% and 36.7% in 2015.

Into the New Year, the NHFPC celebrated the following major advances of Chinese healthcare reform in 2017 at the 2018 National Health and Family Planning Conference in January 2018:

♫ Important phased reform victories have been won with all public hospitals abandoning drug sales margins and all provinces introducing plans for the “two invoice” system in pharmaceutical sales.

♫ The capacity of primary healthcare facilities has significantly improved.

♫ Fallen share of personal out-of-pocket expenses in China's overall healthcare expenditures to 28.8%.

♫ Continued growth of healthcare facilities and professionals to new highs of 990,000 and over 1.2 million respectively.

♫ Increased life span of Chinese population to 76.5 years and dropped death rates of maternity women and new born babies.

Earlier in late 2017, Harvard researchers designed for and proposed to China a system that aligns financial incentives for physicians and hospitals with key measures of performance, hoping to improve health care for millions of patients in some of China's poorest regions. The initiative – called APPROACH, for Analysis of Provider Payment Reforms on Advancing China's Health – is being conducted in collaboration with provincial governments and with teams from Chinese universities. It seeks to alter a system whose incentives are "mal-aligned".

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

More recently, after a State Council executive meeting chaired by Premier LI Keqiang decided in April 2018 to launch a major initiative to enhance China's public health services through development of Internet + Healthcare, the State Council issued its
official document, *Opinions for Enhancing Development of Internet Plus Healthcare*, at the beginning of May 2018. This policy is expected to liberalize telemedicine and online pharmacy restrictions. Specifically, online filling of physician drug prescriptions for common and chronic diseases may be delivered by qualified third parties following pharmacist verifications. Additionally, real time mutual sharing of physician drug Rx information of medical facilities and sales information of drug retailers will be explored.

Last but not the least, LAI Shiqing, Inspector at the System Reform Department under the National Health Commission (NHC), revealed at a industry meeting in June 2018 that the national BMI payment standards may be released by the State Medical Insurance Administration (SMIA) before the end of 2018. Lai said that the primary task of the SMIA, at its infancy at least, is not cost containment as rumored on the Chinese press. Instead, the chief tasks of the new agency will be: 1) integrating BMI funds; 2) elevating the level of premium funding; 3) introducing the BMI payment standards; and 4) strategic purchasing of medical services and clinical drugs.

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

The NDRC release issued its official statistics on performance of the Chinese pharmaceutical industry performance in 2017. The core business revenues of Chinese pharmaceutical manufacturers grew 12.2% in 2017, reaching CNY 2,982,600 million. The growth speeded up by 2.3 percentage points last year compared with that in 2016. Among all subsectors, TCM crude drug sub-industry and API sub-industry saw the highest growth, followed by pharmaceutical formulations sub-industry. The industry’s net profit rose 16.6% in 2017, totaling CNY 351,970 million. The growth accelerated by 1.0 percentage point compared with that in 2016. Sub-industries with the highest profit growth last year were biologics and pharmaceutical formulations.

Things began to accelerate for Chinese pharma in 2018. According to latest official data from the MIIT, core revenues of the Chinese pharmaceutical industry rose 17.6%, while its net profits grew much faster at 35.5% in Q1/2018. The sharp growth in the quarter is stimulated by implementation of the new national reimbursement drug list (NRDL) and two invoice system, steady growth of leading chemical drug formulation players, and accelerating industry consolidation and M&As, according to industry experts.

21 MNC pharmaceutical companies had Chinese revenues totaling CNY 149.2 billion in 2017, up about 10%, according to “incomplete statistics” of E-Healthcare Executive journal. The pack was led by Pfizer with CNY 23.3 billion in Chinese sales last year, followed by AstraZeneca and Bayer with CNY 20.0 billion and CNY 17.0 billion respectively. Allergan led all MNC pharmaceutical companies by Chinese revenue growth in the same year at 22%, followed by Abbvie and Bayer. It is also notable that GSK China’s growth rebounded to 18%. Besides, UCB and Lundbeck also witnessed impressive growth despite smaller revenue size at the moment. 11 of the pack saw revenue growth above 10% in 2017. Two companies, namely BMS and Takeda, experienced 40% and 19% Chinese revenue fall last year. The 40% revenue drop of BMS is 8% after deducting financial impacts of its OTC business spinoff.
However, structural issues with the Chinese healthcare system continued to haunt the pharmaceutical industry in 2017. Notwithstanding the touted pharma industry ambitions of the Chinese government, slogans are nothing but pies in the sky when it comes to paying for better medicines. The healthcare reform has long been hijacked by cost containment and gone astray from the pledged path of improving efficiency and fixing structural flaws. The crashing course of reform is deeply rooted in the growing contradictions between wishful goals and budget reality, as well as among different government policies and their pursuits.

With tax and other revenues drying up and under increasing threat of BMI system deficit amid a 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. Shortage of low cost but clinically essential medicines has become widespread, forcing the central government to step in and often intervene administratively.

Pushed to the corner, the Chinese pharmaceutical industry is now at the brink of business 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 change so as to meet the new challenges of the Chinese healthcare business today.

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

The U.S. Trade Representative (USTR) recently issued its 2017 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 and market access, including such issues related to the pharmaceutical sector.

On the basis of the USTR report primarily and drawing references from other foreign government/trade association reports, I have built the case for contemporary IP concerns in relation to the Chinese pharmaceutical sector.

**IP and market access related issues**

[*Patent application and related issues*] – It 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. Besides, amended patent examination guidelines that entered into force in April 2017 now require patent examiners to take into account supplemental test data submitted during the patent examination process. However, there are reports that China’s patent examiners continue to deny applicants’ requests to supplement their test data.

[*Patent infringement*] - In its Economics and Trade Bulletin on January 8, 2018, the
USDOC highlighted that, under Chinese law, companies are unable to bring patent infringement cases against a patent violator until the product has been launched to the market by the alleged violator.

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. China’s law, and a commitment that it made in its WTO accession agreement, require China to ensure that no subsequent applicant may rely on the undisclosed test or other data submitted in support of an application for marketing approval of new pharmaceutical products for a period of at least six years from the date of marketing approval in China. 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. An 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. These concerns, along with analogous concerns relating to medical devices, have been the focus of various bilateral meetings with China.

Protectionist measures - Another serious concern stems from China’s proposals in the pharmaceuticals sector that seek to promote government-directed indigenous innovation and technology transfer through the provision of regulatory preferences.

Drug distribution - China committed to allow foreign suppliers to distribute pharmaceuticals by December 11, 2004, and it began accepting applications from and issuing wholesale licenses to foreign pharmaceutical companies about six months after that deadline. At the same time, 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 distribution commitments.

Price control - In its WTO accession agreement, China agreed that it would not use price controls to restrict the level of imports of goods or services. China agreed that it would try to reduce the number of products and services on this list. In 2016, China continued to maintain price controls on several products and services including Pharmaceuticals.

Antimonopoly and other legal issues

Counterfeit drugs and API/bulk drug regulation - Despite years of sustained engagement, China still needs to improve its regulation of the manufacture of active pharmaceutical ingredients to prevent their use in counterfeit and substandard medications. In October 2017, China published limited draft revisions to the Drug Administration Law and stated that future proposed revisions to the remainder of this law would be forthcoming.
Anti-monopoly Law enforcement – Chinese regulatory authorities’ implementation of China’s Anti-monopoly Law poses multiple challenges. One key concern relates to how the Anti-monopoly Law will be applied to state-owned enterprises. While Chinese regulatory authorities have clarified that the Anti-monopoly Law does apply to state-owned enterprises, to date they have only brought enforcement actions against provincial government-level state-owned enterprises, not any central government-level state-owned enterprises under the supervision of SASAC. In addition, provisions in the Anti-monopoly Law protect the lawful operations of state-owned enterprises and government monopolies in industries deemed nationally important. Overall, many U.S. companies cite selective enforcement of the Anti-monopoly Law as a major concern to doing business in China, and they have highlighted the limited enforcement of this law against 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 NDRC pressure to “cooperate” in the face of unspecified allegations or face steep fines and actions by NDRC to discourage or prevent foreign companies from bringing counsel to meetings.

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

In 2017, Chinese pharma continued to be overshadowed by many old flaws of the Chinese healthcare sector with no fixes as new challenges develop. The industry is expected to face mounting challenges in 2018 amid intensified cost containment flood the country.

With growing emphasis on reform of the BMI payment system, 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. The biggest hope for MNCs lies with the reform of drug evaluation and approval system, which appears to be opening a new door for innovative medicines in China.

Chinese pharmaceutical industry experts have predicted ten upcoming Chinese pharma industry and market trends in 2017 as follows:

- The Chinese biosimilar drug market is going to take off, led by monoclonal antibody drugs.

- As MAH system experiment deepens, the domestic contract manufacturing business will surge. The demand for integrated pilot and scaled production will increase sharply from 2018.

- The new provincial BMI reimbursement drug lists (developed on the basis of 2017 NRDL) will begin to have full impacts on the market this year with half of the
provinces already initiating implementation in late 2017 and the rest expected to do so in the first quarter of 2018. In addition, the dynamic BMI reimbursement drug negotiation may provide opportunities to many recently approved innovative new drugs. These are expected to boost the overall Chinese pharmaceutical market.

Drug evaluation and approval will be more efficient and accelerated after introduction of various reform measures and participation of the CFDA in ICH in 2017.

Direct-To-Patient (DTP) Pharmacies will flourish and more hospital drug prescriptions will be filled by such pharmacies, especially innovative medicines and premium-priced chronic disease drugs. Many of the DTP pharmacies will be owned and operated by retail pharmacy chains.

Support policies for generic drugs passing quality and efficacy equivalence studies are expected to be implemented this year. It is expected the first batch of such drugs will rip the benefits of higher market shares and profit margins.

Import substitution of major off-patent originator drugs are expected to accelerate in 2018 as more generic drugs pass equivalence studies.

The two-child family planning policy and regulatory liberalizations will give rise to a CNY 100 billion in-vitro fertilization (IVF) market. The market for reproductive assistance drugs will grow with accelerated import substitution.

The in-vitro diagnostics (IVD) market will be reshuffled under intensified cost containment with only selected optimal channel distributors prevailing.

Coronary DNA testing market is taking shape and will see explosive growth. Meanwhile, new opportunities are also emerging for pharmaceutical companies, especially in the area of drug innovation, as China boosts support for new drug R&D, uplifts review and speed up approval process with increased harmonization with international standards and enhanced IP protection. In early 2018, the CFDA issued a new policy, *Opinions for Priority Review and Approval to Encourage Drug Innovation*, to accelerate the R&D and marketing of new drugs with clinical value and urgently needed generic drugs. The agency and the Ministry of Science and Technology (MOST) also issued a joint policy document, *Guidance Opinions for Promoting and Enhancement of Food and Drug Science and Technology Innovation*.

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

The short and intermediate term outlook of Chinese pharmaceutical market remains to be tough and blurred, but long term prospects are hopeful and warrant patience of those with sustaining power. Conversely, let’s also remember that most Chinese pharma industry observers still agree that the Chinese healthcare market will keep on growing in the foreseeable future, albeit at a slower rate and with lower profitability.
Has China done enough to keep itself attractive to pharma MNCs?

Regardless the challenges, we should still be thankful that the Chinese pharmaceutical market continued to grow at an impressive speed of around 8% by some estimates, albeit at further reduced speed than the previous year.

Looking ahead, the Chinese pharmaceutical market remains clouded by structural flaws, contradictions in government healthcare and industry policies, irrational cost containment, and irregular enforcements. Before these clouds and imbalances are contemplated and resolved, market growth is likely to be bottlenecked for an extended period of time despite the positive long term growth trend for healthcare demand in China.

In early 2017, CFDA Minister BI Jingquan told journalists at a press interview on the sidelines of the “Two Conferences” that there is a huge market potential for drug products and more foreign pharmaceutical companies should tap the sector. When asked about the delayed access to new drugs, Bi said his agency will streamline approval procedures for drugs, intensify protection of intellectual property rights, and increase the staff for drug approval.

The State Council and CFDA launched in the last quarter of 2017 new policies including the *Opinions on Deepening Reform of Evaluation and Approval System to Encourage Drug and Medical Device Innovation*, as well as proposals to amend the *Drug Administration Law of PRC* and the *Provisions for Registration of Drug Products* in order to help the country remain attractive to MNC innovators. Major policy incentives for research-based MNCs include a more streamlined drug evaluation and approval system which seeks to encourage innovation, renewed government promise to enhance reimbursement of new drugs, support of global clinical trials in China, removal of restrictions for phase I clinical trials of foreign new drugs, and conditional acceptance of overseas clinical data in support. Besides, the Chinese government has also made specific promises, though still somewhat vague, in these policies to introduce patent linkage & patent term restoration systems as well as enhanced data protection. As a concrete step to show its sincerity, the CFDA has hastened its approval of foreign innovative drugs recently.

These are all worth some serious applauses and it is indeed encouraging to see the Chinese government committed to harmonize its drug regulatory system with the world and to foster drug innovation. Nevertheless, readers are reminded to concentrate on the overall pie of Chinese healthcare/drug expenditures, which is what truly matters in the big picture and need to be watched at all times.

What will happen if that pie doesn’t change much as new drug approvals speed up? How should research-based MNCs position themselves to maximize their slices in the Chinese healthcare matrix? What shall be the realistic healthcare policy goals for China?

These are the questions without straightforward answers. I encourage our readers to dig into this comprehensive publication for references, clues and advice on which I hope effective solutions will be developed.

Most recently in April 2018, despite recent pledges of the Chinese government to open up
the domestic market further and faster approvals of innovative medicines, MNCs should be alarmed by China’s latest generic drug policy, *Opinions on Reform and Improvement of Generic Drug Supply Security and Application*, which is everything about raising the market share of domestic companies at the expense of foreign companies.

Under the new policy, China will openly offer preferential tax rates to domestic generic drugmakers, setting corporate income tax for qualified high-tech firms at 15%. The State Council also said it would draw up additional incentives aimed at encouraging the development and production of generic drugs. Besides, while the country said it would boost IP protection, as it also makes compulsory licensing easier than ever.

While recent positive policy moves undertaken by Beijing may improve market access of innovative drugs somewhat, but they are constrained by a host of other government policies for healthcare cost containment and import substitution. Without fundamental changes of Chinese mentality for self-reliance, industrial policies supporting domestic and state-owned enterprises, and relentless healthcare cost containment over-emphasizing on price competition, the bulk of demands for innovative and premium quality import drugs is likely to remain bottlenecked.

The root of the problem lies with the contradiction between reluctance of the Chinese government to pay for better healthcare of its people by sharply increase its healthcare spending budget and the public’s expectation to receive mostly government funded healthcare as the last welfare of socialism, with or without Chinese characteristics. So far, central and local governments have done little to find consensus with the public to reconcile this growing contradiction, other than resorting to cost containment as almost the only way to expand and upgrade BMI coverage.

The government’s preoccupation with price competition of drug products and relentless healthcare cost containment has led to fallen healthcare quality broadly and will continue to bottleneck consumption of more expensive but premium quality and innovative import drugs.