



PHARMACEUTICAL INDUSTRY CHINA

CUTTING-EDGE ANALYSIS OF MULTINATIONAL
& CHINESE BIOPHARMA COMPANIES,
INDUSTRY TRENDS, ENVIRONMENT,
REGULATION, MARKET DRIVERS, RESTRAINTS,
OPPORTUNITIES & CHALLENGES

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CUTTING-EDGE MARKET INTELLIGENCE

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1.0 Summary

“Pharmaceutical Industry in China 2014- Cutting-Edge Analysis of Multinational and Chinese Biopharma Companies, Industry Trends, Environment, Regulation, Market Drivers, Restraints, Opportunities & Challenges” by Kelly Scientific Publications is a comprehensive report on the pharmaceutical and biotechnology industry in China and its impact on international markets. This report tackles not only global pharmaceutical company interest in China but also home grown companies and their battle for position. The business environment in which they compete is analysed as are key drivers, constraints, challenges and opportunities.

The Chinese Pharmaceutical market is currently the third greatest pharma market globally, after the US and Japan, and in 2011 was worth \$████████. It is forecast to increase dramatically to \$████████ by 2020 and increase its dominance as a leading player in Asia. As the current third market leader it is predicted that the Chinese pharma market will be the main competitor of the US by 2020.

This report describes current therapeutics that are propelling the pharmaceutical market in China. It examines the current economic climate and how China compares to other emerging markets and also evolved markets such as the US and Europe. Current developments relating to patent expirations, government funding, and regulations are discussed. The emerging trends that appear in key sub-markets such as generics, oncology, diabetes and vaccines are elucidated and analysed. This report is supported by 199 tables and figures over 153 pages.

This study reveals market figures of the overall Chinese pharmaceutical market and sub-markets. Forecast projections and future growth rates are provided to give the reader a forthcoming perspective of this growing industry.

The study also provides a comprehensive financial and product review of key players in the pharmaceutical industry in China. Strategic drivers and restraints of this market are revealed and market opportunities and challenges are identified.

In summary, the Chinese biopharmaceutical market has huge opportunities for growth. This industry will significantly affect the international healthcare market and has enormous potential for investment.

1.1 Objectives of Report

The main objectives of this report are:

- To comprehensively summarize current developments in the Chinese pharmaceutical industry.
- To identify emerging trends in key markets and sub-markets such as biogenerics, oncology therapeutics, diabetic care, vaccines and anti-infective agents.
- To comprehensive review and analyse financial and product details of key international and domestic players in the industry
- To present market figures of the current Chinese pharmaceutical market value and give forecast projections and growth rates
- To identify key drivers and restraints of the Chinese pharmaceutical market
- To report and analyse market opportunities and challenges

This report tackles key concerns to the Chinese pharmaceutical market such as:

- Lack of regulatory policy and legislation
- Reimbursement schemes and payers concerns
- Funding and government sponsorship issues
- International scepticism of Chinese safety and efficacy therapeutic profiles

The reader of this report will gain:

- An in-depth understanding of the Chinese pharmaceutical market and its environment
- Current market facts, figures and product lines of key players in the industry
- An insight into how generic therapeutics will propagate the Chinese pharmaceutical market
- Knowledge of how the Chinese biopharma market will integrate into the global healthcare market
- Information on key regulatory and government policies
- Data on levels of private and publically funded biopharma studies in China
- Strategies on how to adapt and restructure current business models to this industry

1.2 Scope of Study

The Chinese pharmaceutical market is the main driver of the country's healthcare industry. Three subsectors of the pharmaceutical market have arisen in China:

- Western Medicine Companies
- Biotech Companies
- Chinese Medicine Companies

Within the pharmaceutical industry the following areas are the main revenue generators:

- Drugs and active pharmaceuticals (API)
- Over the Counter (OTC) medication
- Prescription medicines
- Traditional Chinese medicine (TCM)

This report focuses on Chinese and multinational pharmaceutical and biotechnology companies and reveals the top players in sub-markets such as:

- Anti-depressant Drug market
- Dermatitis Drug Market
- Diabetic Drug Market
- Hypertension Drug Market
- Dyslipidaemia Drug Market
- Senile Dementia Drug Market
- Cancer Drug Market
- Rheumatoid Arthritis Drug Market
- Ophthalmological Drug Market
- Liver Disease Drug Market
- Antibiotic Drug Market

The study provides a comprehensive description of current companies with an interest in the Chinese market and their financial and product portfolios. This paper also identifies key therapeutics that are driving the biopharma market in China and current restraints and challenges that may weaken this emerging industry.

1.3 Data Sources and Methodology

The project leader and author of this research obtained a Ph.D. in Medicine from the Royal College of Surgeons in Ireland, following completion of a M.Sc. in Biotechnology (NUIG) and an honours degree in Biochemistry from Trinity College Dublin. She has extensive experience in drug target discovery and vaccine research and development and conducted post-doctoral studies and lecturing in Trinity College Dublin. With many years of medical writing and publishing the author also has

extensive experience and knowledge of genetics, molecular biology, immunology, bioinformatics and diagnostic testing. As a pharma/biotech industry analyst she has significant expertise in laboratory diagnostic testing and instrument and reagent development technology.

Sources of information for this report were collected and compiled from company specific corporate websites, annual reports, press-releases, international scientific and medical journals and news and research reports. Graphical and numerical data have been referenced and sourced accordingly. Specific websites were consulted and referenced throughout the completion of this report including that of the World Health Organization (www.who.int), European Medicines Agency (www.ema.europa.eu), the State Intellectual Property Office of the People's Republic of China (www.sipo.gov.cn), the State Drug and Food Administration (www.sfda.gov.cn), Chinese Ministry of Commerce, China's Pharmaceutical Commercialisation Association, Chinese International Electronic Commerce Network and the EC Trade Link. Financial and business environment sources such as the World Trade Organization (www.WTO.org) and the International Monetary Fund (www.IMF.org) and other government agencies worldwide were also accessed. Kelly Scientific Publications has used the most recent statistical and numerical data available. The most reliable of data sources were used in the production of this report, however we cannot guarantee complete accuracy or completeness from secondary information sources.

1.4 Key Findings and Observations

In 2011 the Chinese pharmaceutical market was worth \$ [REDACTED] and is now the third largest pharma market globally. It is also top player in emerging markets. These positions are fuelled by the significant level of chronic disease in the country which is estimated at 260 million. Within the next ten years over 80 million people will die from chronic disease such as cancer, cardiovascular disease and diabetes in China. Vaccine production and generic drug manufacturing are key products for the Chinese market and Kelly Scientific Publications predict that international markets will also be significantly penetrated with these products in the near future.

The government in China has identified biotechnology as a key area of growth and to that end has provided significant funding for opportunities within this area. The 12th Five Year Plan (2011-2015) has detailed that innovation is also a key area and aims to produce 3.3 patents per 10,000 individuals over the coming years. Another significant objective of this economic plan is to promote a GDP growth rate of 7%.

Generic therapeutics play a significant role in the Chinese marketplace, however novel product development has increased with increased funding and the introduction of R&D facilities by multinational pharma companies. All of the top global biopharma companies have a presence in China and recognise it not only as the main hub for Asian markets, but as an essential market in its own right. International presence is supplemented with a wide variety of domestic biopharma companies that are attracting Chinese scientists and clinicians back to China. The immediate and long term aim is to increase the high-tech and R&D power of Chinese biopharma products and in doing so create safe and effective therapeutics for an international market.

1.5 Executive Summary

Chronic Disease in China

One fifth of the total Chinese population – 260 million people suffer from chronic disease and according to the World Health Organization 79% of all deaths are due to chronic disease. The main chronic disease states in China are as follows:

- Diabetes
- Respiratory illness
- Cancer
- Cardiovascular disease
- Cerebrovascular disease

Given that almost half of the total Chinese population are at risk of developing a chronic disease, a three year 'Chronic diseases prevention and control work plan' was implemented in 2012 to help combat this health issue. Economically, chronic disease costs China billions. The World Health Organization estimated that between 2005-2015 diabetes, cardiovascular disease and stroke will cost the country \$ [REDACTED].

Within the next decade, the WHO predicts that 80 million people will die from chronic disease in China. Disease states that are thought to increase include infectious disease, maternal and perinatal conditions and diabetes. Chronic disease deaths will increase by almost 20%, and diabetic deaths will increase by a predicted 50%. One of the key factors in chronic disease death is obesity and this is predicted to increase to 57% of men and 46% of women by 2015.

Chinese Pharmaceutical Market

The Chinese Pharmaceutical market is currently the third greatest pharma market globally, after the US and Japan, and in 2011 was worth \$ [REDACTED]. It is forecast to increase dramatically to \$ [REDACTED] by 2020 and increase its dominance as a leading player in Asia. As the current third market leader it is predicted that the Chinese pharma market will be the main competitor of the US by 2020. The Chinese pharmaceutical market is the main driver of the countries healthcare industry and in 2011 dominated with almost 90% share. Three subsectors of the pharmaceutical market have arisen in China:

- Western Medicine Companies
- Biotech Companies
- Chinese Medicine Companies

Within the pharmaceutical industry drugs and active pharmaceuticals (API) are the main revenue generators. Over the Counter (OTC) medicines had a Chinese market figure of \$ [REDACTED] in 2008 ([REDACTED]% of total market share) and by 2013 will become the world's second largest OTC market. In the same year prescription medicines dominated the market place with [REDACTED]% share, and traditional Chinese medicine (TCM) made up almost [REDACTED]%.

Diabetes is one of the most successful therapeutic areas in the Chinese market and will reach over \$ [REDACTED] in annual sales in 2019, compared to \$ [REDACTED] in 2009. Currently Novo Nordisk and Bayer are the primary market leaders however Eli Lilly, Merck and Sanofi will certainly compete strongly for the diabetes market. In order to gain a foothold pharma companies are increasing their marketing campaigns, providing educational training and increasing R&D and manufacturing budgets.

Vaccine production is a leading strength in China with the ability to produce almost [REDACTED] doses each year according to the State Food and Drug Administration (SFDA). The country has almost [REDACTED] ([REDACTED]) companies with vaccine manufacturing capabilities and the vaccine market was worth an estimated [REDACTED]. Over 40 different vaccines covering more than 26 indications are currently being made in China. The main vaccines that are currently exported are against hepatitis A, influenza and Japanese encephalitis.

The oncology market in China is forecast to grow steadily and reach \$ [REDACTED] by 2017 from \$ [REDACTED] with a CAGR of [REDACTED]%. In comparison the global oncology market in 2011 grew by [REDACTED]%. The high growth rate in China is driven by increased prevalence of a number of cancer sub-

types such as breast cancer, colorectal cancer, prostate cancer, lung cancer and Non-Hodgkin's Lymphoma (NH). The Chinese Ministry for Health indicated that 2,127 million newly diagnosed tumors are reported annually, and of these 1,06 million are newly diagnosed oncology patients.

Government and Regulation Environment

12th Five Year Plan

The Communist Party of China (CPC) approved the 12th Five Year Plan (12th FYP) for National Economic and Social Development in 2010 for the 2011-2015 period. One of the primary objectives of this economic plan is to promote a GDP growth rate of 7%. Within urban areas the 12th FYP wants to create 45 million jobs with an unemployment level of less than 5%. R&D expenditure will account for 2.2% of total GDP. Innovation is a key player in the 12th FYP with an objective of 3.3 patents per 10,000 people.

This report details the current intellectual property regulations for Pharmaceuticals in China as specified by the State Food and Drug Administration (SFDA). It also examines the pharmaceutical distribution process in China and yields opinions as to how it may improve.

China – At the Forefront of Emerging Markets

As the top player among emerging markets, China is forecast to generate \$ [REDACTED] in 2020 from the pharmaceutical market. Emerging markets contributed [REDACTED]% to industry growth in 2009, and [REDACTED]% of global sales or \$ [REDACTED]. It is expected that these growing economies will further penetrate the market in 2013 and generate an estimated \$ [REDACTED] or [REDACTED]% of sales.

Generic Medication Market and China

China plays a significant role in the biogenerics or biosimilar market. An estimated [REDACTED]% of all therapeutics produced in China are generic compounds. Today [REDACTED]% of the world's top genetically engineered therapeutics are made in China, following the production of Schenzhen Kexing Biotech's IFN γ launch in 1989. Today the Chinese pharmaceutical industry produce EPO, hGH, G-CSF, IFN, human insulin, interleukins, monoclonal antibodies and vaccines to fuel the biogeneric market.

Given that biological therapeutics are expensive medications to produce, a thriving biogenerics industry is forecast to rival parent drugs. As all pharmaceuticals lose patent protection, biogeneric medications will undoubtedly increase in market share as long as intellectual property stipulations and government healthcare policies are favourable. The Chinese biogenerics market is driven by a domestic population that requires healthcare and therapeutics at a cost significantly below Western nations.

Novel Product Drug development

In 2011 the Chinese pharmaceutical market was worth a reported \$ [REDACTED]. The majority of the market share was due to biosimilars and generic medication, however over the last few years there has been a significant increase in the level of R&D projects to develop novel therapeutics. This has been aided with government backing and investment of \$ [REDACTED] between 2008-2010 and another \$6 [REDACTED] between 2011-2016. Since 2003 the number of investigational new drug applications in China has increased, and between 2003-2010 192 applications were received. A lower number of new drug applications were documented with 29 applications received over the same time period. The SFDA adhered to more rigorous regulatory stipulations from 2007, and therefore since then there has been less new drugs being approved.

Global Pharmaceutical Companies Interest in China

The top multinational pharmaceutical companies with a presence in China are discussed in this report. Specific information relating to their operations in China are detailed as are current products on the market, future patent expirations and novel pipeline therapeutics. Financial analysis on the following companies is also presented.

- Abbott
- AstraZeneca
- Boehringer Ingelheim
- Eli Lilly
- GlaxoSmithKline
- Johnson & Johnson Medical
- Merck
- Novartis
- Pfizer
- Roche

This report also highlights a number of domestic biopharma companies and gives details of their operations, products, financials and business strategy. The following companies were chosen for analysis as they have specific advantages that we believe will drive the pharmaceutical industry in China.

- Amoytop Biotech
- Active Pharmaceutical Products
- Beijing Continent Pharmaceuticals
- FusoGen Pharmaceuticals
- Shanghai Huaguan Biochip
- SiBiono GeneTech

Figure 2.1: Proportional (%) Mortality Rate of Total Deaths in China, All Ages

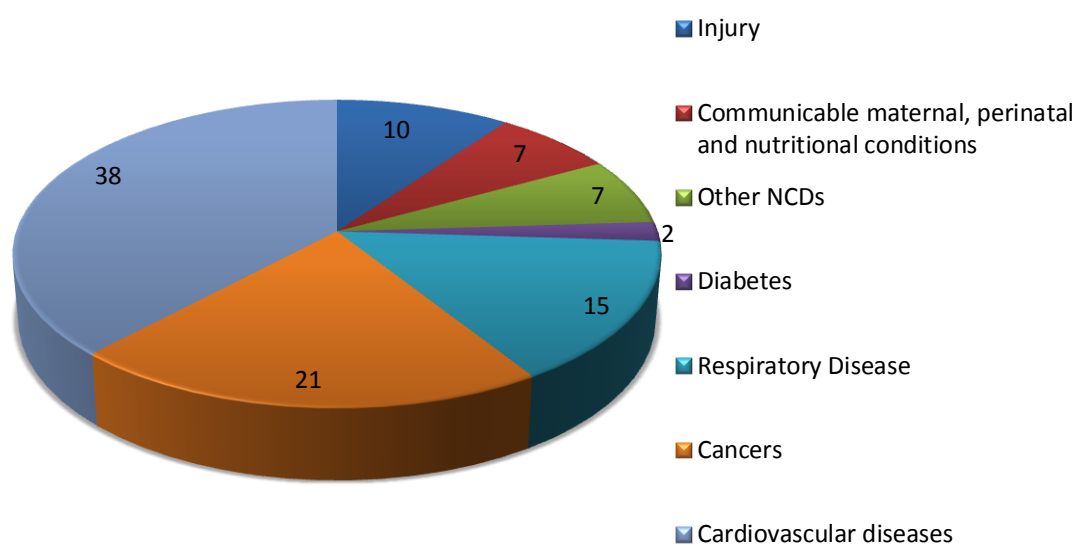


Figure 5.1: Projected Figures of Strategic Emerging Industry GDP Percentage Contribution 2011-2020

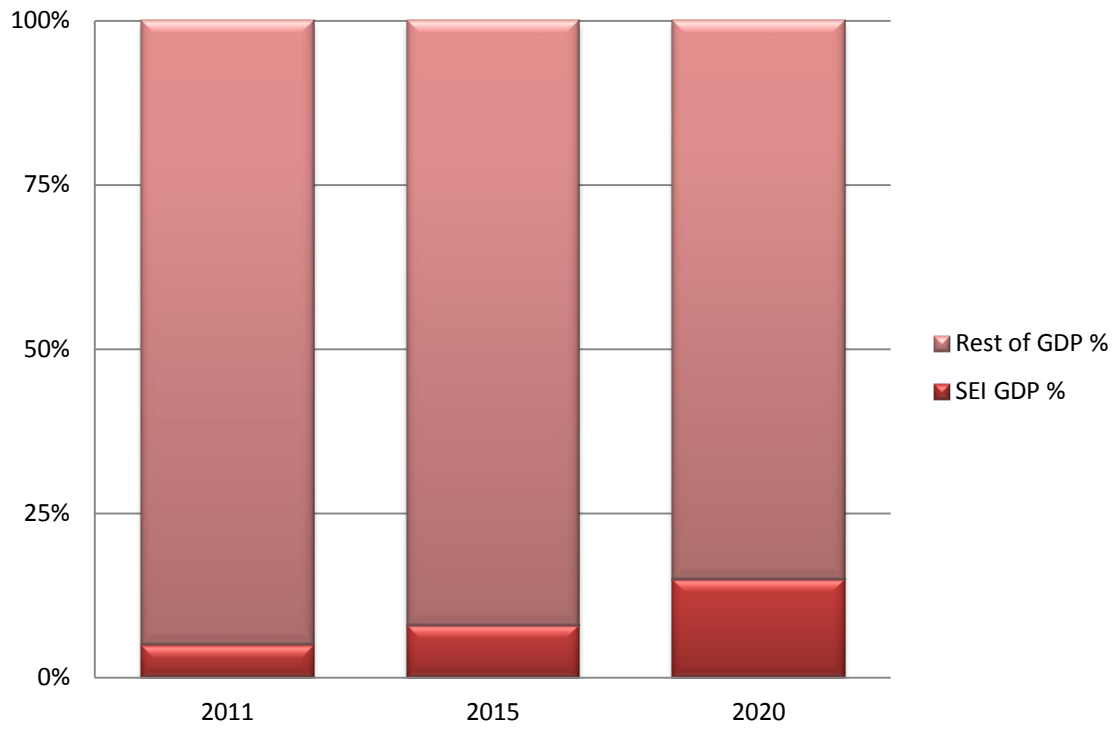


Figure 5.4: Revenue Share (Percentage) of Major Players in Chinese Pharmaceutical Distribution Market

