



COUNTRY REPORT

China

Overview of the Health
& Life Sciences Sectors



TABLE OF CONTENTS

1. Introduction
 - 1.1 The country
 - 1.2 Chinese market overview
 - 1.3 Doing business in China
2. Health and population
 - 2.1 Introduction
 - 2.2 Health main issues
 - 2.3 The Chinese health system
3. Life science sector in China
 - 3.1 Main life science sectors
 - 3.2 Main life science clusters
 - 3.3 Life science parks
4. Public organizations & policies within the life science sector
 - 4.1 Organizations
 - 4.2 Policies
5. Opportunities for medical devices
6. Entering the Chinese market
 - 6.1 Importing through distributors
 - 6.2 Partnering with a local company
 - 6.3 Licensing
 - 6.4 Co-development
 - 6.5 Intellectual property
 - 6.6 Registration and regulation
 - 6.7 Chinese culture regarding business
 - 6.8 European programs
7. Resources

This report is made of a compilation of sources that we have tried to put together in order to offer a quick overview of the Chinese life science market. The majority of sources are available in our website; www.bioxclusters.eu.



1. INTRODUCTION

1.1 The country

China is the most highly populated country in the world, with an estimated population above 1.3 billion people, 47% of which live in urban areas. In the last 30 years, China, without leaving its status of a centrally planned economy, has been putting in place some market-oriented economic mechanisms. The direct result has been that life standards of a great part of the population have dramatically increased.

The biggest cities of China are: Shanghai, Beijing (capital), Chongqing, Shenzhen and Guangzhou.

In parallel to the evolution of the country, the health sector has experienced an annual growth above 20% in the last 10 years. Even though it's expected that this growth will slow down, figures will still be above those of most of the so-called developed countries.

China is a very appealing market for life sciences sector but not easy at all. The sector has grown at a rate of two digits during the last years. Biotechnology is a strategic sector within the government's 12th Five-Year Plan 2011-2015. In addition, recently the Ministry of Health has announced an additional funding of \$11.800 million devoted to innovation in biopharma for the 2016-2020 period. Such funding should allow the biotech industry to double the number of jobs in the sector as well as to increase the scientific talent.

China Life Science Industry Drivers in 2011 and Beyond

- Government Investment: over \$250B in five years
- Commercial Investment: \$10B in VC, M&A, IPO and corporate investment in 2011
- China pharma market growth: 22%/year for the last five years
- Financial Growth: 9.2%GDP in 2011
- Urbanization: adding 300M to cities in 15 years
- Returnees: 430,000 in last five years; 150,000 in life science alone
- Aging population: growing from 13% to 31% by 2050
- Chronic Disease: increasing 20-30%/year

Source: ChinaBio

Despite these perspectives, cultural issues and issues regarding IP regulation, amongst others, are aspects to be seriously taken into account when evaluating doing business in China.

1.2 Chinese market overview

- The Chinese market is not only 1.4 billion people, but rather around 300 million people that have an average purchasing power equivalent to or higher than in Europe.
- Managing China and the Chinese market from Europe is hopeless.
- China is a large territory with complex and fragmented distribution channels. No Chinese life sciences company is currently able to distribute products in all of China. They focus on certain provinces or areas.
- Entering the Chinese market is a time-consuming and lengthy process; do not expect to be able to do everything at once without traveling regularly to China.
- Be aware of and open to the local needs and constraints, you may need to adapt your offer or your products in order to fit the Chinese demands.

1.3 Doing Business in China

“Anything is possible, but nothing is easy” (Mr. Weiyan Zhu, Boehringer Ingelheim Shanghai)

1. Business in China is about relationships and networks. Developing a good relationship with your partner is mandatory if you want to succeed.
2. Chinese employees or acquaintances with good networks and relationships in China help.
3. Contracts are important in China. But it is more a departure point for negotiation than the end.
4. Nothing is obvious and everything needs to be clearly defined and discussed in order to avoid further misunderstandings.
5. Don't be careless, keep control over your most important technology or know-how.



2. HEALTH AND POPULATION

2.1 Introduction

China's health care system today still shows strong regional and economic differences, with highly developed areas and underdeveloped ones. Diseases affecting the Chinese population reflect this economic situation. Like in underdeveloped countries, infectious diseases are still a major threat for some of the population. Some characteristics like high density of population, extremely poor countryside and overcrowded health institutions are major threats to the country.

On the other hand, recent economic success has also faced China with well-known developed country health issues, like obesity, cardiovascular diseases and cancer (especially lung cancer).

The one-child policy and the healthcare development have been great successes to some point, but today the Chinese population is ageing at very high rate. While in 2010, less than 9% of the population was over 60 years old, in 2050 more than 30% of the population will be over 60 years old.

2.2 Health main issues

Cancer

Cancer has become China's leading cause of death among urban and rural residents. The incidence is increasing rapidly, with about 2.6 million people suffering annually from cancer, of which 70% die. The main cancers are:

- Lung cancer due to the high rate of smokers in China
- Breast cancer among the female population
- Digestive tract cancer
- Liver cancer due to the hepatitis virus

Chronic diseases

Economic development and the ageing of the population are two major driving forces for the increase of chronic diseases in China.

Cardiovascular diseases

Cardiovascular diseases are now the leading cause of death in China (3 million deaths in 2011)¹.

The number of people suffering from cardiovascular diseases has reached more than 230 million, meaning that about one in five adults suffer from it. Of this group, about 200 million are diagnosed with hypertension or high blood pressure, a common disease especially among workers.

Diabetes

Nowadays the number of people with diabetes in China is estimated to be 1 out of 10 among Chinese adults, and it is a major threat to the Chinese health.

Diabetes is underdiagnosed in China and, with 5 to 10% of obesity incidence in the Chinese population and 10 to 15% of overweight people, its prevalence is expected to keep rising over the next decade.

Infectious diseases

Infectious diseases are not a major cause of death in China but they are still a major concern for the population and the government for several reasons:

- Underestimation of the number of cases, especially in rural areas
- Recent major crises (H1N1, SARS...)
- Antibiotics overconsumption and resistance problems
- Concentration of population in cities

For infectious diseases, China relies mainly on vaccines and generics.

2.3 The Chinese health system

One characteristic is the strong regulation and the price control in the healthcare sector in China. Until recently, in the absence of a public social insurance, the government was paying little attention to healthcare prices. But the recent reforms of the healthcare system, which aim to improve access to health treatments for more people, have lead the government to increase the pressure on pharmaceutical and medical device companies to cut their prices. These policies may lead to deeper changes in the healthcare landscape in the coming years.

The Chinese health market has had a growth rate of over 20% during the last 10 years. The situation is expected to

¹ - 2011 Report on Cardiovascular Diseases in China



remain similar but at a lower pace. Today the Chinese market is the 2nd largest market in the world with more than \$355 billion in 2011 but the healthcare expenditure per capita is very low compared to the figures of Japan or France. So, Chinese figures are expected to grow in the next years.

Two major factors will keep the healthcare expenditure growing in China:

- More and more Chinese people are moving up into the “middle class”. Studies estimate that 200 to 300 million of Chinese people have attained living conditions which can be compared to western standards.
- Current reform of the healthcare system done by the government, which aims to provide a universal medical insurance to its population and optimise access to healthcare for all.

The Chinese health system is strongly influenced by the communist doctrine and organizes itself around a network of community health centres which provide basic health-care coverage to the population. Those centres are supposed to dispatch the population to the different hospitals depending on the needs of the patient. But the healthcare system was left out during the opening of the economy in the 80s, and it is only recently that the government has started to pay more attention to the centres. Today the population often distrusts community health centres and mostly relies on high level hospitals.

Hospitals are classified according to their size, their equipment and the kind of operations they can handle. In this system, level 3 hospitals are the best, the biggest and the best equipped and are currently overcrowded, as the population is massively invading them instead of going to the community health centres or level 1ones. Population in general distrusts low level hospitals.

3. LIFE SCIENCE SECTOR IN CHINA

- 500 universities and institutes
- 150 000 yearly graduated students
- 7 500 companies
- 250 000 employees (expected to double in the next five years)
- 2 500 top researchers
- 200 incubators
- 100 parks across the country

3.1 Main life science sectors

Pharmaceutical market

- Currently dominated by generics but the patented drugs market is expected to see a significant growth, because of the government encouragement of innovation and the distrust in current Chinese brands (and therefore the preference for foreign ones)
- Infectious diseases are still an important market in China, even if the mortality is decreasing.
- Cancer is a major threat with more than 25% of the deaths, especially in lung, digestive and liver cancer.
- Chronic diseases are a growing problem with the development of western habits in the population (diabetes, cardiovascular diseases...)

Diagnostics and medical devices market

- The government is building and upgrading hospitals and community health centres all over China.
- Recent studies estimate that still around 50% of the equipment in hospitals in China is more than 20 years old and needs to be renewed.
- For the medical devices, more than 50% of products are being imported. USA, Germany and Japan account for two thirds of the market.

Biotech market

- Size of the market: \$15 billion in 2010 and is growing with a rate of 30% every year.
- This growth is supported by two pillars:
 1. Development of biosimilars related to the current or future expiration of major biopharmaceutical patents.
 2. Support of the government for the development of “me-better” (instead of “me-too”) and innovative drugs by Chinese companies and their use in hospitals.



- More than 30 therapeutic proteins are available on the market today and more than 150 new biotech products are currently in clinical development in China.

Chinese authorities are fostering biotech zones all over the country. The objective is to overcome some of the current Chinese weaknesses, like the lack in drug innovation and the low number of promising products and technologies in the pipeline².

3.2 Main life sciences clusters

According to the ChinaBio report³, there are four major life sciences “clusters” in China:

- Capital Cluster: Beijing and Hebei, Shandong and Liaoning provinces
- Yangtze River Delta Cluster: Shanghai and Jiangsu and Zhejiang provinces
- Central Cluster: Chongqing and Sichuan, Hubei and Shaanxi provinces
- Pearl River Delta Cluster: Shenzhen, Guangzhou and Hong Kong



3.3 Life Science Parks

Main Characteristics of science parks in China are:

- Most of the life science parks have developed dedicated incubators for start-ups. Some of them are also setting up pilot plants for industrialization of the production for the first step of development.
- Free or reduced rental fees are granted to the companies for the first years in the incubator.
- Agreements are signed between public research centres or university laboratories and incubators for projects requiring specific skills or equipment, or public service platforms offering R&D-specific services at a competitive price.
- Fiscal incentives: reduced VAT, income tax, tax refunds for specific investments or milestones
- Human resources: talent grants, housing programs, tax refunds on salaries
- Subsidies: for R&D, patents, technological awards etc.
- Market access offer: consulting services, green channel for innovative products, access facilitated to public market.

² <http://asia.legalbusinessonline.com/contents/features/109755/1/details.aspx>

³ China Life Science 2012: from Local to Global at <http://www.chinabiotoday.com/articles/20120320>



Some relevant life science parks in China are:

- Zhongguancun Science Park (Beijing): <http://www.lifesciencepark.com.cn/en/index.asp>
- Shanghai Zhangjiang High-Tech Park - Pharma Valley: <http://www.zjbpb.com/>
- Wuhan Biolake: <http://www.biolake.gov.cn>
- Taizhou National Medicine Hi-Tech Industry Development Zone (China Medical City)

4. PUBLIC ORGANIZATIONS & POLICIES WITHIN LIFE SCIENCE SECTOR

4.1 Organizations

Ministry of Science and Technology

The Ministry of Science and Technology (MOST) is the backbone of the Chinese Science and Technology sector in China. The MOST is in charge of defining the national orientation of science and technology in China, from the fundamental science to industrialization. The MOST's mission is to encourage innovation in S&T to boost the economic development in China.

State Food and Drug Administration (SFDA)

The SFDA is in charge of comprehensive supervision on the safety management of food, health food and cosmetics and is the competent authority for drug regulations in China. A concise presentation of the drug registration process in China is described in Deloitte's report "The Next Phase. Opportunities in China's Pharmaceutical Market" published in 2011⁴.

Chinese Academy of Science

The Chinese Academy of Science (CAS) is the most important academic institution in China, but is quite different from the European ones. The CAS is not only an honorific organization. It has the mission to develop fundamental, applied and industrial research and development. It owns around 100 research institutes and many companies. Lenovo for example was originally created by the CAS.

Local Governments

Local/regional governments in China are in charge of implementing the national programs. They usually support national policies by putting in place complementary actions. For example, science parks and incubators are set up and run by local governments, which are implementing the national regulations while reinforcing certain issues through local policies.

Industrial Associations

Given the importance of the government in China, most industry associations are related to the government. Companies have to be a member of such an association and have to be involved in its activities.

4.2 Public Policies

China has issued the "National Program on Bioscience Technology Development 2010-2020". The program, issued by the Ministry Of Science and Technology, includes a series of ambitious, very specific goals for developing a world-class biotech and pharma industry in China.

The 12th Five-Year Plan 2011-2015 is currently in place, as said before, and some highlights regarding the next plan have been recently unveiled.

Chinese policies are driven by the central government, which decides the main guidelines and allocates the funds. Regional and local governments are competing to attract companies, research centres, etc. by stressing concrete areas in order to be more attractive than other regions/cities.

⁴ Deloitte: Next Phase. Opportunities in China's Pharmaceuticals Market (2011), pg 20



5. OPPORTUNITIES FOR MEDICAL DEVICES

More than 50% of the medical devices in China are imported from the US, Europe and Japan, especially high technology products.

As said in the 2011 US Commercial Service Report, the best-selling products and technologies in the healthcare sector in China include:

- *In vitro* diagnostics equipment and reagents: clinical and diagnostic analysis equipment, diagnostic reagents, medical tests and basic instruments.
- Implantable and intervention materials and artificial organs: interventional materials, implantable artificial organs, contact artificial organs, stents, implantable materials and artificial organ- assisting equipment.
- Therapeutic products: tri-dimensional ultrasonic focused therapeutic systems, body rotary gamma knives, simulators, linear accelerators, laser diagnostic and surgery equipment, nuclide treatment equipment, physical therapy and rehabilitation equipment.
- Medical diagnostics and imaging equipment: black & white and coloured supersonic diagnostic units, sleeping monitors, digital X-ray systems, MRI, CT, DR, and ultrasound equipment.
- Surgery and emergency appliances: anaesthesia ventilation systems and components: high frequency surgery equipment, high frequency and voltage generators.
- Healthcare Information Technology-related equipment and products: medical software, computer- aided diagnostic equipment and hospital information systems (HIS, CIS, and HLT).
- Medical equipment parts and accessories.

6. ENTERING THE CHINESE MARKET

6.1 Importing goods through distributors

Import of healthcare products in China is allowed through distributors after registration. This solution can be a costly and complex process for SMEs:

- Cost issue: healthcare products, especially drugs and IVDs need to be validated through clinical trials in China. Such registration can cost from \$49K to \$98K for a medical devices and from \$245K to \$490K for a new drug that is already marketed in another country.
- Finding and managing distributors can result in a long process, given the size, complexity and fragmentation of the market.

6.2 Partnering with a local company

Partnering with a local Chinese company in the same field could prevent problems with registration and high costs, as the partner can take care of the process and the cost of the registration for the product in China as well as the distribution of the product. In the long term, co-development of local products based on European technology or know-how and adapted to the Chinese market can be a field to explore.

IP can be an issue that should be taken into account from the beginning ⁵.

Companies willing to expand on their own in China should be cautious when choosing this option.

6.3 Licensing

Licensing can be a good option, especially for drug development and biologics SMEs:

- 18-24 months is the time required to register an already marketed drug on the Chinese market
- Clinical trials in phase IIb or III including China will save time in the development process
- Drug manufacturing in China for the internal market could allow offering a competitive price.
- For biologics, Chinese production cannot be exported for clinical use in Europe or the US
- Partners in some cases can manage the distribution issues

6.4 Co-development

With the economic growth of China, the investment of the Chinese government in R&D and the priority given to innovation and biotech, European companies can benefit from the situation for their own development or to develop products adapted to the Chinese market. Such co-development with a Chinese partner can be done at any stage,

⁵ Read the report from Asian Legal Business. [click](#)



from the discovery phase to the clinical trials.

Chinese companies are usually looking for products that are already on the market elsewhere or that are in later clinical phases, in order to take advantage of final stage co-development opportunities. After a successful project, the partner can then be interested in further co-development projects.

6.5 Intellectual property

The Chinese IPR situation is improving at the same time as the economic and technological evolution of the country. It is advisable to:

- Register patents in China.
- Register names and trademarks.
- Sign CDA and NDA with your Chinese partner. If a document is confidential, this should be clearly stated on it.
- Define ownership of IPR before starting any project, especially in co-development projects.

An IP lawyer with good knowledge of China is mandatory when starting business in the country.

The China Intellectual Property Help Desk project founded by the EU commission is a good information resource (<http://www.china-iprhelpdesk.eu/>).

6.6 Registration and Regulation

- The healthcare sector is highly regulated and controlled.
- Clinical trials are faster in China but the registration phase takes longer.
- A good relationship with and contacts in the SFDA helps in the registration process.

6.7 Chinese culture regarding business

Business in China is about building relationships. Establishing links between people and personal relationships are more important than in Europe. Extensive cultural guides are available online and this report is too short to give more than a few key concepts that are important in China:

- “Face”: roughly translated as “good reputation”, “respect” or “honour”. One must learn the subtleties of the concept and understand the possible impact it could have on your doing business in China.
- Title, rank and respect for the eldest
- Patience and moderation
- Politeness
- Modesty

However, biotech is a specific business area. For many years China has been exporting its talent overseas. Today 10-20% of the people in the biotech sector in the US are of Chinese origin. With the economic growth of China the trend is reverting. Overseas returnees are massively coming back to China after 10 to 30 years in the US, especially since 2007. Thanks to their western experiences, they are appointed to the top management of Chinese companies and will often be your interlocutor during negotiations. Although western culture is familiar to them, they would have Chinese partners and in most of the cases Chinese culture will still prevail.

6.8 European programs

Large and well-known programs are available on the European website www.access4.eu/China/

7. RESOURCES

Take a look at a compilation of interesting documents related to the Chinese life sciences market at:

www.bioXclusters.eu



Catalunya

Mamen Martí

Head of Internationalisation
cmarti@biocat.cat



Biotech Cluster
Development

Bavaria

Dr. Daniela Tonn

International Affairs & Training
tonn@bio-m.org



Piemonte

Alberto Baldi

Business Development &
Technology Transfer
baldi@bioindustryark.it



Rhône-Alpes

Isabelle Scarabin

Economical and International Affairs
isabelle.scarabin@lyonbiopole.com

Project coordinated by:



Céline Mainier

European Funding Project
Manager
celine.mainier@erai.org