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FX rates (as of 05.05.2015)

1 USD = 6.2062 RMB
1 CHF = 6.6321 RMB
1 EUR = 6.8721 RMB

Source: Bloomberg
Introduction and management summary

Investing in China is a complex task with multifaceted drivers and regulatory uncertainties. This is especially true for the healthcare sector. While in the western world healthcare has been one of the hottest investment topics for several years, the Chinese healthcare stock market lagged somewhat behind despite rapid progression of reform within the healthcare system. For us reason enough to take a closer look at the healthcare sector, its underlying drivers and prospects.

During China’s swift economic growth over the last 30 years, tremendous progress and reforms have been made, which have fundamentally improved people’s living standards in all areas of life. This has led to a growing willingness of the Chinese emerging middle class to spend on healthcare products and services. Therefore, China's importance to the global healthcare market is growing and also the domestic healthcare industry is gradually catching up. The enormous economic and social developments have also brought challenges and problems to China's healthcare system. In many cases consumers are stuck between expensive healthcare suppliers and an underdeveloped medical insurance system with an inefficient allocation of resources.

The first part of this report is devoted to the fundamental drivers of the Chinese healthcare sector. The rising healthcare awareness and affordability, demographic shifts, continuing urbanization and relevant lifestyle changes, an improving business environment and capability for innovation, as well as the ongoing industry consolidation which will create a healthier and more competitive environment for well positioned domestic healthcare companies. Based on the large unmet medical needs and the above-mentioned drivers, we expect China’s healthcare market to consistently grow over the coming decades.

The second part provides a general introduction into the Chinese healthcare system. We first focus on hospitals, the main healthcare service providers in China. Hospital’s reliance on drug sales, the difficulties of getting healthcare services in higher level hospitals and uneven allocation of healthcare resources between urban and rural healthcare institutions are challenges which are being addressed by the government. Next we describe the healthcare insurance framework, especially the basic medical insurance schemes covering the majority of the population. We also have a look at the pharmaceutical regulatory system in China with its time consuming application processes and the implementation of the essential drug list and the reimbursement drug list. Along with reforms of the country's healthcare
infrastructure, the Chinese government has also carried out new standards and regulations throughout the healthcare system which will foster the consolidation led by domestic leaders.

In the third part of this report, our preferred healthcare subsectors are outlined: pharmaceutical, medical devices and private hospitals. We analyze their history, current developments and evaluate their upside potential. The perspective of these subsectors is also largely driven by the government’s intention to support domestic innovation and industry upgrade, which could generate a favourable phase of development and expansion inside and outside of China for the surviving companies.

We see opportunities for global investors in China’s healthcare market especially during the phases of reform and industry consolidation over the next years. We finish our report with an outlook into 2015.
1 Drivers for the Chinese healthcare market

1.1 Rising healthcare awareness and spending

Today, Chinese people have better access to and increasing financial means for healthcare products and services. With the deterioration of the living environment, air pollution and food security issues, Chinese customers have become more interested in topics such as healthy living, strengthening the immune system or taking care of the nutritive element balance. In addition, confronted with increasing cases of chronic diseases, Chinese people are nowadays more willing to spend a greater percentage of their income on innovative treatments and high quality products and services with a good reputation, an established brand or better efficacy. Meanwhile, the Chinese government has also committed itself to increase its healthcare spending to improve the public healthcare infrastructures and healthcare insurance coverage. As a result, the total national healthcare spending in China has increased by over 100% to RMB 3000 bn from 2008 to 2013, which includes expenditures on drugs, medical devices, healthcare services and facilities, distribution and healthcare insurances.\(^1\) While personal out-of-pocket spending on healthcare only increased at a CAGR of 11%, government spending, which has grown at a CAGR of 22.8% from 2000 to 2012, counts for the key driver of total national spending on healthcare.\(^2\) (Figure 1-1)

Nevertheless, China’s total healthcare spending as a percentage of GDP still lags behind compared to many developed countries. In 2013, only 5.6% of the GDP was spent on healthcare in China, compared to 10-18% of the GDP expenditure on healthcare of the western world.\(^3\) (Figure 1-2) This gap illustrates the enormous potential for higher expenditures. In August 2012, the Ministry of Health has released a “Healthy China 2020 Strategy Research Report”\(^4\) with the target to increase the total national health expenditure to 6.5% - 7% of GDP by 2020, referring to over RMB 6000 bn.\(^5\) (Figure 1-3)

Urban households of the middle to affluent class are the biggest contributors to the total personal healthcare spending. A Boston Consulting Group survey shows that healthcare and nutrition products climbed from No 11 in 2011 to No 2 in 2013 in the products categorized by consumers’ spending

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\(^1\) National Bureau of Statistics of China (2014)
\(^2\) National Bureau of Statistics of China (2014)
\(^3\) World Health Organization Global Health Expenditure database (2013)
\(^4\) 健康中国2020战略研究报告
readiness, mainly fuelled by the middle and affluent classes. According to estimates, urban consumers' private expenditure on healthcare will at least grow at 11% p.a. in the coming decades.

The personal healthcare spending in rural areas has also increased, yet at a lower rate compared to the urban areas. Rural residents' spending still concentrates on basic medical needs. In addition, the increasingly expensive healthcare products and services are hardly affordable in rural areas, resulting in an imbalance of healthcare development across regions in China.

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**Figure 1-1 – National healthcare spending growth year over year in China**

![Graph showing national healthcare spending growth year over year in China](image)

Source: NHFPC (2015)

**Figure 1-2 – Total health spending in % of GDP in 2012**

![Bar chart showing total health spending in % of GDP in 2012](image)


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Figure 1-3 – China’s national healthcare spending (in RMB bn)

![Graph showing China’s national healthcare spending](image)


Figure 1-4 – Healthcare spending per person in urban and rural regions (in RMB)

![Graph showing healthcare spending per person in urban and rural regions](image)


1.2 Demographic trends

1.2.1 The aging population

As life expectancy rises and birth rates fall as a result of the one-child policy, China has become a country with a sizeable aging population that brings along burdensome consequences to the younger generation. The average life expectancy in 2013 was 75 based on estimations of the World Bank\(^8\). There were 132 mn people aged over 65, making up 9% of the total population in 2013, which is larger than the

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\(^8\) The World Bank Data (2015)
sum of this age group in the US, Japan, Germany, UK and South Korea together. Until 2020, the population over 65 will increase by 35 mn, representing 12.4% of China’s population. (Figure 1-5) This development is driven by a baby boom from 1950 to 1960, shortly after the establishment of the People’s Republic of China. These baby-boomers suffered from the three-year-famine from 1958 to 1961 in their childhood, in which 30 million Chinese died. Due to the lack of necessary nutrition and inadequate healthcare services, many of them have been suffering from various chronic diseases. Among the aging population, chronic and non-communicable diseases incidence rates are distinctly higher. The elderly population demands up to 40% of the prescription drug market and around 50% of the OTC drug market. Besides, they need advanced caring and well-being services the older they get. Most prevalent among chronic diseases are cardiovascular diseases, diabetes, cancer and respiratory system diseases. These diseases require permanent monitoring and care.

**Figure 1-5 – Development of population aged 65+ in China (in mn)**

![Graph showing population aged 65 and over from 2008 to 2020E]


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9 The World Bank Data (2015)
10 The Economist (1998): China’s baby-boomers: The unlucky generation
1.2.2 Continuing urbanization and the relevant changes in life style

By the end of 2013, the urban population made up 54% of the total population in China. As the economy rises, the consumption of China's middle and affluent classes is further expanding. In 2013, 186 mn urban households in middle and affluent classes accounted for 66% of all urban households in China. This is projected to reach 83% of all urban households, an increment of 94 mn by 2020.

Figure 1-7 – Urban population as a % of total population and in absolute numbers (in mn)


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14 BCG (2014): From Insight to Action: Capturing a share of China’s consumer health market
The continuing urbanization has profound influences on people’s living conditions and health status. Urban lifestyle can impact health conditions positively and negatively. Urbanization enables access to better infrastructure and healthcare facilities, which drives up the underlying demand. In addition, higher affordability helps to improve healthcare service quality, but it may also foster unhealthy dietary and life styles. In China, the changes in dietary tend to high calorie food, high alcohol consumption and smoking. Combined with less physical activities and overloaded work patterns, the risk for chronic diseases is increasing. Furthermore, urbanization also brings about a series of public health consequences and challenges such as environmental degradation, infectious diseases prevention in big cities, vaccines coverage etc.

As discussed in the previous part, urban residents contributed greatly to the increase in domestic healthcare expenditure. The Chinese government has announced comprehensive initiatives to continuously upgrade healthcare services in urban areas, with the commitment of providing urban residents with better access to affordable healthcare services.

**Figure 1-8 – Growth of urban household consumers (in mn)**

![Graph showing growth of urban household consumers](source: BCG (2014))
An increasing lifespan and urbanization have resulted in a higher disease burden. An ever rising number of chronic disease cases accounts already for more than 86% of all deaths and makes up 70% of the total diseases burden in China.\(^1\) In this chapter, two out of the most common disease areas in China are discussed.

**Diabetes**

Data from the International Diabetes Federation shows that there are worldwide more than 380 mn people living with diabetes and 316 mn with impaired glucose tolerance (IGT), among which one third are living in China.\(^1\) China is the country with the largest number of diabetes patients. In 2013, the estimated diabetes prevalence in China has reached 9.6% of the population aged between 20 to 79 years, which has led to over 1.2 mn patients dying from diabetes-related diseases during that year. As disclosed in recent data, there are 5% to 7% Type I diabetes and 93% to 95% Type II diabetes patients in China.\(^2\) According to estimates, diagnosed and undiagnosed, nearly 143 mn people in China will have diabetes by 2035.\(^3\)

The charts below illustrate the prevalence of diabetes among different age groups and among female and male. There is higher diabetes prevalence among males, urban residents, as well as people aged 40 and over. While Type I diabetes is classified as an autoimmune disease, Type II diabetes is caused by a

\(^{15}\) NHFPC (15.04.2015)  
\(^{16}\) International Diabetes Federation (2013): IDF Diabetes Atlas  
\(^{17}\) Biodiscover (19.09.2014): Diabetes, Sanofi’s growth engine  
\(^{18}\) International Diabetes Federation (2013): IDF Diabetes Atlas
combination of factors, such as the imbalance between caloric intake and physical activity and the resulting increase in overweight and obesity rates.\textsuperscript{19}

The diabetes burden in China has been rising at an unbearable pace. Zhu Chen, the former Chinese Health Minister said that chronic diseases such as diabetes and hypertension are becoming public health challenges.\textsuperscript{20} People with diabetes are often suffering from a series of disabling and life-threatening diseases affecting the kidney, the central nervous and the cardiovascular system.\textsuperscript{21}

The Chinese insulin market is dominated by big multinational corporations (MNCs), namely Novo Nordisk, Sanofi and Eli Lilly with their established products. The Chinese local players were less innovation-oriented and their market shares are very limited at the moment. However, there are many insulin products in the pipelines of Chinese companies, which are expected to come to the market over the next 3 to 5 years. The goal is to offer 2nd generation and even 3rd generation insulin products, which would be as effective as foreign products but at lower costs. Together with oral drugs, western drugs make up over 80\% of the whole diabetes market. In China, TCM (Traditional Chinese Medicine) oral drugs for diabetes are often used as first line treatment and account for the other 20\% of the market.\textsuperscript{22}

The diagnosis rates of people with diabetes or pre-diabetes remain much lower compared to western countries. Outside of big cities, the knowledge of both doctors and patients about diabetes remains inadequate and limited. Despite the big absolute number of diabetes patients in China, its total expenditure on diabetes still lies far behind the US. In 2013, China spent USD 38 bn to treat diabetes, while the US had expenditures of USD 239 bn.\textsuperscript{23} In terms of the mean diabetes-related expenditures per person, patients in China spent USD 333 in 2013, which is much lower than that of developed countries (USD 9’800 in the USA and USD 4’700 in Germany) and even the world average of USD 1’436.\textsuperscript{24}

\textsuperscript{19} NDIC (27.08.2014): Causes of diabetes  
\textsuperscript{20} China Daily (20.02.2008): Diabetes becoming 'major problem'  
\textsuperscript{21} International Diabetes Federation (2013): IDF Diabetes Atlas  
\textsuperscript{22} Novo Nordisk (2013)  
\textsuperscript{23} Statista (2015): Healthcare expenditures to treat diabetes in the U.S. and China in 2013  
\textsuperscript{24} International Diabetes Federation (2013): IDF Diabetes Atlas
Cancer has become one of the main causes of death in China. The incidence rate of cancer in China is close to the world average, while its mortality rates are substantially higher. The five-year survival rate lies at around 30%, lagging behind the USA with 60% to 70%.25 The main causing factors of cancer are chronic infections of carcinogenic viruses such as Helicobacter pylori, HBV, HCV and HPV, which account for around 30% of all causes.26 (Figure 1-12) The other major cause for the increasing prevalence and

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25 China National Center for Biotechnology Development (05.02.2015): China’s mortality cancer patient account for one fourth of the world
26 Shanghai Municipal Commission of Health and Family Planning (11.09.2012): Chronic infection has become the leading cause of cancer in China
mortality rates of cancer is the severe deterioration of the environment. While toxic air contaminates mostly cities, water and soil contamination primarily affect rural areas in China.

As a consequence, the prevalence rate of both malignant and benign tumor has increased significantly from 2003 to 2013 compared to previous years. Annually identified new cases of cancer reached over 3.5 mn in 2013, representing 8’550 persons per day. Around 2.5 mn Chinese died from cancer in 2013. According to estimates of Wanqing Chen, the director of National Oncology Registration Center, cancer prevalence and mortality rates will continue to climb annually. By 2020, there will be 6.6 mn cancer patients each year and 3 mn patients will die from cancer. Cancer is predicted to give rise to an economic output loss of USD 5.6 tn from 2012 to 2030 in China. The most common types of cancer among males are lung (23%), stomach (16%) and liver cancer (15%), while breast (16%), lung (15%) and colorectal cancer (9%) are most frequently diagnosed among females.

Oncology attracts innovative drug R&D and has promoted the most number of drugs in pipelines or with approvals. However, cancer drugs and treatments mean big economic burden for patients and their families. According to data of Ping An Insurance Group, the average treatment costs for malignant tumors ranges between RMB 100’000 to 300’000, while the average annual income per person in a urban family in China amounts to around RMB 27’000 and in a rural family around RMB 8’900. The reimbursement for disaster diseases like cancer has been gradually covered by different medical insurances. Nonetheless, the coverage is still limited and varies strongly.

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27 Sina news (07.04.2013): High prevalence of cancer in China in recent years
28 Sina news (07.04.2013): High prevalence of cancer in China in recent years
29 Bloomberg business (12.01.2015): Let me die, Chinese mother says as cancer bills pile up
1.3 Increasing importance of R&D

1.3.1 From world factory to world R&D center

While it is commonly known that China has become the largest manufacturing country in the world, the willingness and efforts to enhance R&D and innovation capabilities have also surged over the last decades. China’s R&D expenditure of all sectors rose from USD 10.8 bn in 2000 to USD 168 bn in 2012, representing around 1% and 2% of its GDP respectively. China’s R&D expenditure has exceeded the
European Union for the first time in 2012, as the latter devoted 1.97% of the total GDP. In absolute terms, China’s R&D spending still lags behind the US, Germany and Japan. However, the increasing trend seems much stronger than in many other countries. Not only are the rising investments from local companies and governments contributing to the increase, a number of international companies also relocate their R&D activities to China and promote the development of R&D in the healthcare sector. With establishing own R&D centers in China, international healthcare companies get closer to customers and thus better understand the Chinese patients.

**Figure 1-14 – R&D expenditure as a percentage of GDP**

The Chinese government has outlined solid incentive policies to foster the flourishing R&D environment in China, with the goal of making China an international R&D center instead of the traditional impression of a world factory. In the 12th Five-Year Plan, the government planned RMB 10 bn investments in the biopharmacy sector to be spent over 2011 and 2015. The goal is to provide new drug R&D with an average of RMB 5 to 10 mn funding for each project. In order to fundamentally support the emerging trend of innovation within the healthcare industry, the government has established nationwide 22 biotech clusters and industrial parks, such as the Shanghai – Zhangjiang High Tech Park, where R&D centers of the largest international healthcare companies are located. Traditionally, Beijing and Shanghai are the most favourite cities for MNCs to set up their R&D centers. The recent trend is that MNCs have started to expand their R&D locations to second- and third-tier cities in China.

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33 OECD Estimates (2014)
35 Deloitte (2011): The next phase: Opportunities in China’s pharmaceuticals market
In addition, beneficial tax policies are applied to R&D activities of healthcare enterprises. Tax incentives such as 15% preferential corporate income tax (CIT) for recognised hi-tech companies and value added tax (VAT) exemptions for incomes derived from technology-related activities have greatly helped innovative companies.\textsuperscript{37} Favourable policies have boosted the rapid increase of the number of total patent applications in China, which have outpaced Japan and USA in 2010 and 2011 respectively.\textsuperscript{38}

![Figure 1-15 – Trend in total patent applications by country (direct and PCT national phase entries)](source: WIPO IP Statistics Data Center (2015))

1.3.2 R&D and innovation reality check for healthcare companies in China

Today, western healthcare companies are confronted with challenges of sustaining their growth whilst maintaining profitability. Especially MNCs are seeking possibilities of increasing R&D efficacy. According to estimates, the clinical trials costs in China only make up 30% to 50% of costs in western countries.\textsuperscript{39} International healthcare companies also aim to take advantage of the huge healthcare workforce base in China, trained either locally or overseas, with relatively low costs compared to similar professionals in western countries. The rate of returnees educated abroad has also accelerated over the past years. Since 2008 the Chinese government has been implementing “The Recruitment Program of Global Experts” (1'000 Talent Plan), which is designed to help China to become one of the leading innovative countries. Until the end of 2012, over 2'200 experts and scientists of Chinese origin were recruited back by universities, research institutions, or started their innovative and entrepreneurial ventures under this

\textsuperscript{37} KPMG (2013): China tax for healthcare and life sciences industry  
\textsuperscript{39} PwC (2009): Investing in China’s pharmaceutical industry
scheme in China. A large portion of these experts is applying their experiences in healthcare areas, especially in biotechnology and life science. They also help to train the innovative workforce in order to meet the accumulating innovative labour demand in China.\textsuperscript{40}

MNCs have begun conducting R&D activities and creating their own R&D organizations in China since years. For instance, Bristol-Myers Squibb conducted 17 trials in 2010 in China.\textsuperscript{41} Pfizer established its R&D centers in 2005 and 2010, in strong cooperation with many first class Chinese academic institutions. Novartis operates two pharmaceutical development centers in China and has further invested USD 1 bn in its third biggest biomedical R&D center in Shanghai’s Zhangjiang Hi-tech park with focuses on infectious causes of cancer mainly found in Asia and hepatitis diseases. The goal is to open the park in 2015. Roche’s R&D center in China is positioned in Shanghai’s Zhangjiang Hi-tech park as well. Roche’s center cooperates with the best academic institutions, biotech companies and CROs in China and focuses on the areas of oncology, virology and metabolic diseases. In terms of medical devices, Medtronic for instance has established its innovation center in Shanghai in 2012 as a long-term commitment to China. GE Healthcare has also constructed 5 innovation centers and institutions across China with the intention to increase GE Healthcare’s medical product sales in China.\textsuperscript{42}

Based on these favourable factors, we expect the positive development of R&D investments from both local and international healthcare companies to continue over the coming years.

1.4 Healthcare industry consolidation and integration

The healthcare sector in China is highly fragmented, unlike some state-owned and monopolistic sectors such as energy or telecom. The government’s 12\textsuperscript{th} Five Year Plan for the Healthcare industry has set industry consolidation as an essential target. The goal is to help and support establishing 1~3 companies with over RMB 100 billion market value and 20 companies with hundreds of millions revenue, so that the top 100 enterprises’ sales will make up 50\% of the total healthcare industry.\textsuperscript{43}

The character of the Chinese healthcare sector can be described as fragmented and disorderly. As shown in Table 1-1, there are over 6'000 pharmaceutical companies, where the top 10 companies only represent

\textsuperscript{40}1000plan.org (2014)
\textsuperscript{41}Fierce Biotech (01.11.2012): Drug R&D collaborations in China flower as big pharma focuses on Asia
\textsuperscript{42}Company news releases of Pfizer, Novartis, Roche, Medtronic, GE Healthcare
\textsuperscript{43}W. Ding, Y. Gao, Shanghai Yiyaao 32(7), 345–347 (2011): Analysis of environment and characters of healthcare industry consolidation
around 15% of the total market share. A similar character can also be identified within the medical device and healthcare distribution subsectors. In contrast, the top-ten global pharmaceutical MNCs account for over 40% of the total drug market share.\(^4\)

### Table 1-1 – The highly fragmented local healthcare industry in China

<table>
<thead>
<tr>
<th>Subsector</th>
<th>No of Chinese companies</th>
<th>% Market share</th>
</tr>
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<tbody>
<tr>
<td>Chemical drug</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biological drug</td>
<td>6000</td>
<td>Top 10 has 15.5% in 2011</td>
</tr>
<tr>
<td>Traditional Chinese Medicine (TCM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical devices/ consumable</td>
<td>&gt;15,000</td>
<td>Top 30 has 27%</td>
</tr>
<tr>
<td>Distribution/retail</td>
<td>13,000</td>
<td>Top 10 has 48%</td>
</tr>
</tbody>
</table>

Source: UBS Research (2014); Bioon (2015)

Facing this situation, the Chinese government has issued relevant policies in order to help to promote the industry consolidation. Since 2009, a series of policies are progressively coming into place, such as The New Good Manufacturing Practice (GMP), The New Edition of Pharmacopoeia\(^5\) and Medical Institution Central Bidding and Procurement of Pharmaceuticals etc. The new policies place higher requirements and standards for processes of procurement, manufacturing and packaging.\(^6\) The consequence is higher production costs, which could boost M&A activities and the elimination of uncompetitive and substandard companies. Taking the new GMP standards announced by the Ministry of Health in Feb 2011 as an example, pharmaceutical manufacturers of sterile drugs\(^7\) had to qualify for the new GMP requirements before the end of 2013 and the rest of the drug manufacturers have to be qualified before the end of 2016.\(^8\) In 2013, nearly 40% out of all 1,319 sterile drug producers had to stop manufacturing, as their facilities could not comply with the new GMP standards’ requirements.\(^9\) The new GMP takes related standards of the European Medicines Agency (EMA) and the US FDA as reference, causing high costs of adjustment and improvement. Yibai Pharmaceuticals, for instance, has

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\(^5\) Pharmacopoeia: A book containing directions for the identification of compound medicines, published by the authority of a government or a medical or pharmaceutical society. (Source: Wikipedia)

\(^6\) CFDA (2010, 2011); CHP (2009)

\(^7\) Sterile drugs include blood products, vaccines and injections.

\(^8\) KPMG (2011): China’s pharmaceutical industry – poised for the giant leap

\(^9\) Dingxiangyuan (16.01.2014): Mid- to small-sized pharma companies are confronted with the new GMP standard challenge
invested RMB 271 mn in its plants and equipments to meet the requirements.\textsuperscript{50} The overall impact on large-sized companies is less severe than on middle- to small-sized companies, as smaller companies may have less funding available for the increased operational costs. We believe this will lead to acquisition opportunities within the pharmaceutical industry. Major targets are those companies with valuable existing or pipeline products.

In the first 7 months of 2014, there have been 181 M&A deals within the Chinese healthcare industry, 113 in pharmaceuticals and 68 in medical devices respectively. Medical devices represent the fastest growing subsector in terms of deals.\textsuperscript{51} The CFDA has created various regulation rules for medical devices for enforcement starting in 2014 and intending to strengthen supervision for every step from registration to production, which will further promote the consolidation of China's medical device market.

The trend of larger deals has emerged since 2008. As less small and less attractive targets remain, the average deal sizes have enlarged. In the meantime, with ongoing sector upgrading and consolidation, the valuation of acquirable targets has also climbed up, which serves as another factor to boost the deal size.\textsuperscript{52} (Figure 1-16)

Large local players are aggressively expanding through M&A deals, especially those who face patent cliffs. These companies aim to strengthen their R&D capability by acquiring small-sized and innovative biotech companies. Some local players have acquired overseas companies with the ambition of going out of China by implementing latest technologies and establishing their own brands through international platforms. Many MNCs have completed acquisition deals with local Chinese companies or established joint ventures in order to pool resources and expand their market shares in China. MNCs have entered into new areas, obtained new distribution channels and in the mean time, they have accelerated and strengthened their own pipeline development. (Table 1-2)

We can conclude that the whole industry is experiencing a period of reshuffling, which will help competitive healthcare companies to thrive whilst inferior ones will gradually perish. The result is an optimized resource allocation.

\textsuperscript{50} Bioon (03.01.2014): The new GMP standard stops 40% of the sterile pharma companies
\textsuperscript{51} Bioon (14.08.2014): M&As in the healthcare sector have entered the first three places within all sectors
\textsuperscript{52} Deloitte (2011): The next phase: Opportunities in China’s pharmaceuticals market
Figure 1-16 – M&A deals within the healthcare industry in China

![Graph showing M&A deals and average deal size from 2008 to 2013.]

Source: UBS Research (2014)

Table 1-2 – Examples of M&A deals of MNCs in China

<table>
<thead>
<tr>
<th>Date</th>
<th>Acquirer</th>
<th>Target</th>
<th>Price</th>
<th>Target Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct 10</td>
<td>Sanofi</td>
<td>BMP Sunstone</td>
<td>$520 mn</td>
<td>OTC</td>
</tr>
<tr>
<td>Dec 10</td>
<td>GSK</td>
<td>Meirui</td>
<td>$466 mn</td>
<td>Prostate drugs</td>
</tr>
<tr>
<td>Mar 11</td>
<td>Novartis</td>
<td>Tianyuan Biotech</td>
<td>$125 mn</td>
<td>Vaccination</td>
</tr>
<tr>
<td>Dec 11</td>
<td>Astra Zeneca</td>
<td>Beikang</td>
<td>unexposed</td>
<td>Generics</td>
</tr>
<tr>
<td>Nov 14</td>
<td>Bayer</td>
<td>Dihon Pharmaceutical</td>
<td>$ 580 mn</td>
<td>OTC &amp; TCM</td>
</tr>
</tbody>
</table>

Source: SERICChina (2012); Bayer (2014)
2 Overview of the healthcare system and the related reform in China

2.1 Organization and governance

Healthcare organizations in China consist of hospitals, primary healthcare facilities and specialized public healthcare institutions. In 2013, there were 24'709 hospitals, 915'368 primary healthcare facilities and 31'155 specialized public healthcare institutions in China.\(^53\) Different classifications of hospitals will be discussed in the following part of the report. Primary healthcare institutions, in spite of their smaller size compared to hospitals, count for the biggest part of the healthcare organizations in China. They include village health posts, outpatient clinics, urban community health centers and rural township health centers. Specialized public health institutions consist of centers for disease control, health supervision institutions and hospitals for disease prevention.\(^54\) To be highlighted here is that the primary healthcare system in China is still under development and public healthcare services rely largely on hospitals, especially in urban areas.

![Figure 2-1 – Healthcare organization classification in China](image)


2.2 Chinese hospitals

2.2.1 Classification of hospitals

Hospitals are the main service providers in the Chinese healthcare service market. From a functional perspective, hospitals are classified as general hospitals, specialized hospitals (such as dental hospitals, tumour hospitals, cosmetic surgery hospitals, etc) and Traditional Chinese Medicine (TCM) hospitals.55

The following Table 2-1 illustrates the classification of hospitals by their level, namely by their size, quality of service level and research capability. The smallest group among all classified hospitals with 1624 hospitals is the Level III hospitals, which are the best hospitals in China. Level III hospitals are general or comprehensive hospitals at national, provincial or city level with over 500 beds capacity and integrate the functions of medical treatment, healthcare education and scientific research. Normally Level III hospitals are equipped with the most skilled physicians, the best medical devices and provide high-standard, specialized medical services to multiple regions. In addition to that, they are also responsible for advanced teaching and research projects, mostly in cooperation with universities and research institutions. In contrast, Level II and Level I hospitals are more regional and primary healthcare institutions. In contrast, Level II and Level I hospitals for a relatively fair fee structure. The large patient flows have led to difficulties to see doctors and problems of bed over-utilization in Level III hospitals.

Table 2-1 – Overview of hospital services in China from January to November 2014

<table>
<thead>
<tr>
<th>Level</th>
<th>Number (Nov 2014)</th>
<th>Beds</th>
<th>Bed utilization</th>
<th>No of visits in hospitals (in mn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level III hospitals</td>
<td>1898</td>
<td>&gt;500</td>
<td>102.7%</td>
<td>121.1</td>
</tr>
<tr>
<td>Level II hospitals</td>
<td>6807</td>
<td>100-499</td>
<td>89.7%</td>
<td>104.2</td>
</tr>
<tr>
<td>Level I hospitals</td>
<td>6853</td>
<td>20-99</td>
<td>63.5%</td>
<td>15.7</td>
</tr>
<tr>
<td>Unclassified hospitals</td>
<td>9951</td>
<td>\</td>
<td>\</td>
<td>21.5</td>
</tr>
</tbody>
</table>

Source: NHFPC (2014)

55 NHFPC (25.08.2014)
56 Baidu Baike (2015)
There have long been criticisms of the structural and mechanistic deficiencies of the hospital system in China. Hospital’s reliance on drug sales is considered as one of its major symptoms, which promotes wrong incentives for the hospitals and physicians and results in high financial burden to patients. In 2011, Chinese hospital revenue was divided into 40% drug sales and around 60% medical services as shown in the following chart, while the split of public hospitals is around 45% drug sales and 55% medical services.

2.2.2 Hospital’s reliance on drug sales

Table 2-2 – Medical expenses in public hospitals in 2012

<table>
<thead>
<tr>
<th></th>
<th>Drug</th>
<th>Examination</th>
<th>Drug</th>
<th>Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level III hospitals</td>
<td>126.7</td>
<td>42.7</td>
<td>4521</td>
<td>881</td>
</tr>
<tr>
<td>Level II hospitals</td>
<td>77.9</td>
<td>33.3</td>
<td>2033</td>
<td>352</td>
</tr>
<tr>
<td>Level I hospitals</td>
<td>59.9</td>
<td>14.7</td>
<td>1411</td>
<td>236</td>
</tr>
</tbody>
</table>

Source: NHFPC (2014)

Figure 2-2 – Hospital revenue composites in 2011

Source: Citi Research (2012)

57 Dingxiangyuan (08.05.2014): The analysis of Chinese hospitals’ income and expenses balance and surplus
The reliance of hospital revenues on drug sales can be traced back 65 years, when China was experiencing great economic and financial difficulties. Public hospitals received insufficient annual subsidies from local authorities, ranging from 15% to 35% of their expenditures. Besides, the contribution to hospitals’ income from medical service has always been small due to its unreasonable pricing. In order to resolve the severe underdevelopment of healthcare resources and to reduce government’s heavy fiscal burden, market mechanisms were introduced to public healthcare in the 1980s. Public hospitals have been taking full responsibilities of their own P&L and have been allowed to use the 15% price premium on the procurement costs of drugs to fund their own operations.\textsuperscript{58} Due to the 15% upper limit of the drug price premium, the higher the original drug price, the higher the absolute commission flows to hospitals and doctors. However, according to data provided by the National Development and Reform Committee (NDRC), the actual average mark-ups increased to 42% in 2005. Additionally, 80% of the drug sales in China are generated through the hospital channel.\textsuperscript{59} On the other hand, physician’s compensation remains relatively low. According to a survey, physician’s average annual income was RMB 67516 (USD 10’900) in 2012/2013, which does not correspond to the long educational period required for medical studies and long working hours.\textsuperscript{60} As shown in the following pie chart, physicians’ income is highly linked to the bonus received from the hospital and their own departments. It indicates that the higher the profitability of hospitals and their departments, the higher the benefits that will be returned back to physicians.

\textbf{Figure 2-3 – Components of physicians’ annual income in 2012/2013}

Source: Dingxiangyuan (2013)

\textsuperscript{58} Chinese Health Policy Research Portal (2015): History reviews
\textsuperscript{59} Y. Yang: The empirical study of eliminating hospital reliance on drugs through zero markup on drugs
\textsuperscript{60} Dingxiangyuan (29.11.2013): 2012-2013 Chinese physician compensation survey
Mark-ups on drug prices can lead to wrong incentives for doctors and hospitals to prescribe more expensive drugs, over-prescription, and even corruption activities, which make it difficult to improve the medical service quality and also hinder the use of low price drugs with similar therapeutic efficiency. The high purchase costs for hospitals, together with high drug mark-ups are completely transferred to patients, making the medical costs for many Chinese people hardly affordable.

2.2.3 Public hospital reform

Aiming to establish an accessible and affordable healthcare system and infrastructure for the entire population, the State Council has released the Public Health Development 12th Five Year Plan in 2012 – along with other supportive policies. One of the main aims is to deepen the public hospital reform and to enhance the social welfare function of public hospitals.

The plan’s goal is to set up a reasonable compensation system for physicians and to decouple physicians’ income from drug mark-ups and the operating revenue they generate for the hospitals. Then the plan aims to abandon the drug mark-up policy gradually. Without drug mark-ups, the net profit of many hospitals would slump. Therefore, the government has to increase the subsidies for hospitals and the management of public hospitals has to improve the cost-control efficiency and operational efficiency, in order to compensate the reduced revenue derived from drug mark-ups. At the same time, healthcare insurance institutions and regulatory institutions have to strengthen supervision and regulation on medical cost controls, in order to prevent over-prescription, repetitive examination and corruptive activities.
activities. The goal is to clearly define and emphasize the public hospitals’ responsibilities of providing basic healthcare services and to reverse their current motivation of pursuing profits.61

The second goal to further expand and implement the Essential Drug List (EDL) in China will provide physicians with guidance for using adequate drugs. With a better EDL prescription activities of physicians can be better controlled, as information about effective and fairly-priced drugs becomes more transparent for patients.62

Another step is to further promote the service contribution of grass-roots healthcare institutions, in order to solve the problem of inadequate and overly expensive medical services in hospitals. Treatment for minor diseases will be gradually transferred from hospitals to local grass-roots institutions, which will be equipped with advanced medical devices and progressive professional skills of physicians.63 In some regions in China, grassroots institutions are also trying to attract patients with relative low costs of diagnosis and treatment combined with high reimbursement levels.64 Although reimbursement policies vary from region to region, high level hospitals in general charge higher costs with a lower fraction of reimbursement.

2.3 Healthcare insurance framework

2.3.1 The multi-layered medical insurance system in China

The prime minister of China, Keqiang Li has announced in 2011 the goal of establishing a universal coverage system that provides “safe, effective, convenient and affordable basic healthcare services” covering the whole population by 2020.65 A series of reforms on the basic healthcare insurance system in China has taken place for over two decades. In the late 1990s, the Urban Employee Basic Medical Insurance (UEBMI) was set up for urban residents with formal occupation, followed by the New Rural Cooperation Medical Insurance (NRCMI) for rural residents in 2003. In 2007, the Urban Residence Basic Medical Insurance (URBMI) was built for unemployed or self-employed urban residents, especially for children, students and seniors.66

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61 The PRC Government (19.10.2012): Notification of the Public Health Development 12th Five Year Plan
62 See 61
63 See 61
64 JS Chinanews (08.03.2015): Jiangsu’s pilot for diagnosis classification; Sohu Health (05.06.2014): Reimbursement level for primary healthcare institutions expected to be increased in Guangzhou
The UEBMI, which is characterized by the highest level of funding from employers and individuals, provides the most generous coverage among the three public medical insurance schemes, with deductibles of up to 6 times the employee’s annual salary. Funding from employers and employees is mandatory. The employees’ contribution flows into a personal medical saving account, together with 30% of the employers’ total contribution. The remaining 70% of the employer and a government contribution flow into a pooled fund, which covers mainly inpatient expenditures. The funding is collected in the form of a pay roll tax, whose level varies across regions.67

The second scheme, URBMI is designed to serve urban residents without UEBMI coverage. There are different subsidy and reimbursement levels for different population groups. Since its inception in 2007, the government subsidies flowing into the URBMI fund have accreted sufficiently, while the individual part has remained largely the same. Over 80% of the funding is derived from both local and central governments. The central government subsidy for each individual has increased from RMB 80 in 2009 to RMB 280 in 2013, while provincial contributions differ.68

In the form of family-based funding, families with rural “Hukou” 69 can participate in the NRCMI schemes voluntarily. Government subsidies vary from region to region and make up on average over 85% of the total fund. Government subsidy per capita is planned to climb from RMB 80 in 2009 to RMB 380 in 2015, as announced by the NHFPC.70

In spite of the three public medical insurance schemes targeting basic medical needs, the current structure of China’s multi-layered medical insurance system is complemented by a safety net applied for people with very low income. This Medical Assistance is completely financed by the government, centrally and locally. In addition, a supplementary system including commercial healthcare insurance covers diverse additional needs primarily for upper-middle to affluent classes of the population. However, the commercial healthcare portion is small compared to many western countries. According to McKinsey, commercial healthcare insurance penetration rises with the income status. Currently only approximately 30% of Chinese urban population possesses some kind of commercial healthcare schemes.71

69 Hukou: A household registration system in China. (Urban and rural Hukou)
70 See 68; NHFPC (29.01.2015)
Figure 2-5 – Multi-layered medical insurance system in China

<table>
<thead>
<tr>
<th>Basic Health Insurance</th>
<th>Target Population</th>
<th>Enrolment</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>URBMI</td>
<td>Employees and retirees with regular employment in all institutions</td>
<td>Mandatory</td>
<td>Inpatient: 80-95%</td>
</tr>
<tr>
<td>NRCMI</td>
<td>Rural area residents</td>
<td>Voluntary family-based</td>
<td>Inpatient: 50-70%</td>
</tr>
</tbody>
</table>

Source: Citi Research (2010); Ministry of Health (2014); UBS Research (2014)

Figure 2-6 – Framework of basic medical insurances

<table>
<thead>
<tr>
<th>UEBMI</th>
<th>URBMI</th>
<th>NRCMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urban Employee Basic Medical Insurance</td>
<td>Urban Residence Basic Medical Insurance</td>
<td>New Rural Cooperation Medical Insurance</td>
</tr>
<tr>
<td>Urban individual: different among population groups</td>
<td>Government: RMB 280 per capita per year</td>
<td>Rural individual: RMB 120 per capita per year (2015)</td>
</tr>
<tr>
<td>Government: 6% of employee's income and up to 4% of supplementary insurance</td>
<td>Urban employer: 6% of employee's income and up to 4% of supplementary insurance</td>
<td>Government: RMB 380 per capita per year (2015)</td>
</tr>
<tr>
<td>Urban employee: 2-4% of personal income</td>
<td>Urban individual: different among population groups</td>
<td>Medical Assistance</td>
</tr>
</tbody>
</table>

Source: MOHRSS (2014); Citi Research (2012); Baidu Baike (2014)
Based on data released by the Ministry of Human Resource and Social Security of the PRC (MoHRSS), the current period surplus of the four basic social insurances, namely basic pension insurance, basic medical insurance, work-related injury insurance and maternity insurance, has reached RMB 590 bn by the end of 2014, aggregating to a total surplus of RMB 4380 bn.\textsuperscript{72} In spite of the relative large and stable surplus, the growth rate of the funds’ income has been revised downward, which is in line with a slowdown in GDP growth in China. As illustrated in Figure 2-8 and Figure 2-9, the growth rates of annual funds raised and paid of NRCMI, UEBMI and URBMI have decelerated over time, while the expenditure of the basic medical insurance funds exceeded their income most recently. As the population aging problem aggravates, pressure on the funding balance is growing.

\textsuperscript{72} MoHRSS (06.02.2015)
2.3.2 Key problems and drawbacks of the healthcare insurance system

The effort of the Chinese government in establishing universal coverage has achieved significant progress over the last decade. Compared to the coverage rate of only 34.4% in 2004, as social health insurance began to expand, the basic medical insurance system has expanded widely and has realized coverage of over 95% of the total population by 2013. \(^{73}\) The enrolled rural population in NRCMI has been

increased from 80 mn in 2003 to 805 mn in 2012, while 75% of the urban population, ca. 536 million has been covered by either UEBMI or URBMI in 2012.  

Nevertheless, goals of addressing the difficulties of medical costs for patients have not been completely achieved yet. Firstly, the actual figure of the covered population might be lower due to the overlaps, meaning that people covered by more than one type of public basic healthcare insurance are counted more than once. This problem roots in the separated regulation and management system of the three insurance schemes by mutually independent governmental institutions. A unified information system has not been established yet, which enables multiple registrations. This problem has resulted in roughly 10% overlapping enrolments, translating into unreasonable usage of funding resources of an estimated amount of RMB 20 bn. Medical insurance schemes and related beneficial policies are neither consistent nor well connected at provincial, municipal and county level, which makes medical services received outside of the individual's location of origin difficult to be recognized and reimbursed.

Secondly, there are also uncovered areas among the various schemes. With the process of reforms on “Hukou” in China, it has become more difficult to clearly distinguish urban and rural residents. The marginal population, especially the migrant workers and their families originally from rural regions, are largely ignored within the URBMI, as their employment status and location vary over time.

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74 NHFPC (2014)
75 Xinhuanet (15.08.2014): Overlapped population over 100 million
Thirdly, there are huge disparities between the benefits and reimbursement levels received by urban employees and other groups. The geographic distribution of healthcare resources is literally uneven. In addition, the insured population is still inadequately protected from high medical expenditures. On average, 35% of the total healthcare spending remains out-of-pocket payments. This is one of the main reasons why Chinese people keep money in their saving accounts. Out-of-pocket expenses of most inpatient costs and outpatient therapies for serious chronic diseases such as diabetes can even exceed the average annual income.  

2.3.3 Healthcare insurance reform

Facing the previously listed obstacles and drawbacks of the medical insurance system in China, the State Council has announced the “Proposal about reform in the healthcare and medical system during the period of the 12th Five Year Plan” in March 2012. The first step is to further expand and optimize healthcare coverage and improve reimbursement levels. Broader coverage especially focuses on migrant families, flexible employment worker, retirees of bankrupt enterprises etc. The 12th Five Year Plan has outlined targets of improving government subsidy per capita for both URBMI and NRCMI and the reimbursement level to 75% for any covered range of inpatient expenditures by all three insurance policies (UEBMI, URBMI and NRCMI) by 2015. Hence, personal out-of-pocket payments should be limited to 30% of the total healthcare spending. However, severe diseases normally require a large proportion of a family’s disposable income and are not completely covered under the basic insurance schemes. The Prime Minister, Keqiang Li has reiterated in a leader meeting in 2012 that the coverage for severe diseases has not been established yet, which gives rise to heavy financial burden on the patients and their families. The solution is to enhance government inputs to raise the upper limit of basic medical insurance reimbursement for severe diseases on one hand. On the other hand, it is necessary to bolster the function of commercial medical insurance for the effective and professional management of severe diseases reimbursement. The goal is to integrate basic medical insurance, commercial medical insurance, medical assistance to cover severe diseases whilst ensuring the quality of the coverage.  
The next essential step is to manage and regulate the three basic medical insurance schemes in a consistent and efficient way and thus integrate the three schemes gradually, including establishing a nation-wide unified healthcare pricing system, integrating management and charging platforms. In terms

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76 A. Ng, C. Dyckerhoff, F. Then, McKinsey (2012): Private health insurance in China: Finding the winning formula
77 The PRC Government (21.03.2012): Proposal about reform in healthcare and medical system during the period of the 12th Five Year Plan
78 Ifeng News (19.07.2012): Ke Qiang Li: Determined to include severe disease insurance into basic medical insurance
of cross regional treatment, instant settlement in different localities should be realized within provincial range by the end of 2015.\textsuperscript{79}

Thirdly, the current fee-for-service method has driven hospitals and doctors to overprescribe high price premium drugs, to over-diagnose and over-treat. The government is conducting currently three new payment methods in pilot regions, namely Diagnosis Related Groups (DRG), total budget prepay and capitation. Diagnosis-based methods such as DRG calculate reimbursement caps according to disease categories rather than treatment methods. The DRG method provides a solution to reduce incentives of seeking side payments and thus reduces patients’ out-of-pocket payments. DRG has shown its positive impacts on standardizing pricing and improving the quality of care in the pilot regions. However, due to highly differentiated treatment costs and quality of service at different hospital levels and locations, collecting effective clinical information and costs remains an obstacle in implementing DRG in China. Nevertheless the trend seems irreversible.\textsuperscript{80}

<table>
<thead>
<tr>
<th>Table 2-3 – Pilot payment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Payment method</strong></td>
</tr>
<tr>
<td>DRG</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total Budget Prepay</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Capitation</td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Source: Deloitte (2014)

The fourth step is to encourage and to support the commercial health insurance institutions to actively develop and enrich their product portfolio. The expenditure of the commercial healthcare insurance subsector is expected to make up a larger proportion of the total healthcare spending in China by 2020, while covering more disease and service areas. According to the China Insurance Regulatory Commission (CIRC), the expenditure of commercial healthcare insurance only made up 1.07% of the total healthcare spending in 2012, whereas the proportion of commercial healthcare insurance in western countries

\textsuperscript{79} Xinhuanet (09.03.2014): When can be interregional reimbursement realized?

\textsuperscript{80} X. Lu Boynton, O. Ma, CSIS (2012): Payment system reform in China’s healthcare reform
amounts to around 10%. The premiums collected by commercial health insurance institutions have reached RMB 159 bn in 2014, which have risen at a growth rate of 41% from RMB 112 bn in 2013. This lies far beyond that of the total insurance industry’s growth rate of 17.4%. The premiums for commercial health insurances will increase at an estimated CAGR of 28% to 37% in the coming 10 years. A variety of commercial health insurances is expected to integrate and coordinate with the basic public health insurance schemes on one hand. On the other hand, given the flexibility of its reimbursement policies based on different patient demands, commercial health insurance can control costs more effectively through negotiation with providers and by ensuring appropriate use of funds. The State Council encourages commercial health insurance institutions to cooperate with hospitals and participate in their operation and management processes. This will help easing the issues of information asymmetry and consequential conflicts between physicians and patients. In addition, with the opening up of the Shanghai Free-Trade Zone in 2013, the CIRC is also supporting foreign health insurance institutions to commence their business, indicating that high-end commercial health insurance is in the interests of the rising newly affluent Chinese people. Despite high coverage, as we have elaborated, challenges remain within the health insurance system in China. However, we believe that China is on the right track to develop a transparent, sustainable and diversified health insurance market.

2.4 Pharmaceutical regulatory system

2.4.1 The process of drug registration and approval

Similar to the US FDA, the China Food and Drug Administration (CFDA) is in charge of the implementation and enforcement of pharmaceutical laws, the regulation for food, drug, medical devices and cosmetics in China, as well as the approval of drugs. The CFDA is operated under supervision of the Ministry of Health (MOH). Among all CFDA departments, the Center for Drug Evaluation (CDE), the National Institutes of Food and Drug Control (NIFDC), the Center for Certificate of Drugs (CCD) and the Center for Drugs Reevaluation (CDR) play the most important roles in the regulatory processes for drug registration and manufacturing (Figure 2-11). For instance, CDE is taking responsibility for the technical evaluation of applications on chemical, biological and TCM drugs.

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81 China Securities Research (2014): Commercial insurance frees huge domestic demand
82 CIRC (26.01.2015)
83 Xinhuandan (03.09.2014): The State Council pushed the development of commercial healthcare insurance twice within half month
84 The PRC Government (17.11.2014): Opinions on accelerating the development of commercial healthcare insurance
85 Ernst & Young (2014): 2014 EV Asia-Pacific insurance outlook
Before digging into the drug registration and approval details, it is meaningful to have a look at drug classifications in China. Defined by the CFDA, there are 6 registration categories for chemical drugs (small molecule), 15 for biologics and 9 for TCM, covering innovative drugs to generics (Table 2-4). Regarding drug application registration, there are 3 different types, namely the Domestic New Drug Application, the Domestic Generic Drug Applications and the Imported Drug Registration. Application of category 1 to 5 of chemical drugs and category 1 to 14 biologics are sorted into the Domestic New Drug Application, which requires a deepened registration process and more strict regulations compared to the other types. Category 1 drugs represent the most innovative ones, which have never been approved for marketing in any country.\(^{86}\)

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\(^{86}\) Tigermed (2015): Overview of Chinese regulatory framework
Table 2-4 – CFDA drug registration categories for chemical and biological drugs

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>New drugs never approved for marketing at home or abroad</td>
</tr>
<tr>
<td>Category 2</td>
<td>Drugs with new administration route not yet being approved for marketing at home or abroad</td>
</tr>
<tr>
<td>Category 3</td>
<td>Drugs marketed in other countries but not yet in China</td>
</tr>
<tr>
<td>Category 4</td>
<td>Drugs based on salts marketed in China with changes in acid or alkaline radicals or metallic elements, without changing the original pharmacological effects</td>
</tr>
<tr>
<td>Category 5</td>
<td>Drugs marketed in China with changes in drug dosage form, without changing the administration route</td>
</tr>
<tr>
<td>Category 6</td>
<td>Generic form of drugs with existing national standards in China</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Biological</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>New biological products never approved for marketing at home or abroad</td>
</tr>
<tr>
<td>Category 2</td>
<td>Monoclonal antibodies</td>
</tr>
<tr>
<td>Category 3</td>
<td>Gene and human somatic cell therapy and their products</td>
</tr>
<tr>
<td>Category 4</td>
<td>Allergy products</td>
</tr>
<tr>
<td>Category 5</td>
<td>Biologically active multi-component products extracted from human or animal tissues or body fluids, or prepared from the fermentation processes</td>
</tr>
<tr>
<td>Category 6</td>
<td>New compound products from biological products being marketed</td>
</tr>
<tr>
<td>Category 7</td>
<td>Biological products marketed in China but not yet abroad</td>
</tr>
<tr>
<td>Category 8</td>
<td>Probiotic products containing unapproved bacteria</td>
</tr>
<tr>
<td>Category 9</td>
<td>Biological products without exactly the same structure as products not yet being marketed at home or abroad</td>
</tr>
<tr>
<td>Category 10</td>
<td>Biological products with different preparation processes as products being marketed</td>
</tr>
<tr>
<td>Category 11</td>
<td>Biological products with DNA recombinant technology for the first time</td>
</tr>
<tr>
<td>Category 12</td>
<td>Biological products not yet marketed at home or abroad, changing administration route from non-injection to injection, or from local to systemic medication</td>
</tr>
<tr>
<td>Category 13</td>
<td>Biological products marketed with changes in dosage form, without changing the administration route</td>
</tr>
<tr>
<td>Category 14</td>
<td>Biological products with changes in administration route (not including category 12)</td>
</tr>
<tr>
<td>Category 15</td>
<td>Biological products with existing national standards in China</td>
</tr>
</tbody>
</table>

Source: CFDA (2014); Standard Charted Research (2014)
An application of a new drug has to pass two steps: first is the application to conduct clinical trials, namely the Clinical Trial Application (CTA), and second is the application to market or import drugs. CTA is comparable to Investigational New Drug (IND) and the marketing application is similar to the New Drug Application (NDA) required by the US FDA respectively.

Similar to an IND, a three-phase clinical evaluation framework is required for a CTA to ensure drug safety and efficacy. A reviewer team with a professional background is responsible for the evaluation process, with cooperation and communication with external experts and drug developers. Nevertheless, in contrast to US companies, Chinese companies have first to apply for due diligence of related application materials and for site inspection for sampling at provincial authorities, which lasts 3 months, before the application is handed over and being technically reviewed by the CDE department of the CFDA. Then it takes 10 to 13 months for the CDE and the CFDA to conduct their CTA process before issuing the approval. The same process only takes about 30 days for the FDA in the US and 60 days for the European Medicines agency (EMA). After CTA approval, applicant companies should commence clinical trials within 3 years before the approval goes invalid. After successful clinical trials applicant companies submit a NDA for CFDA review. The CDE and the NIFDC review separately the dossier which lasts at least 12 months altogether. In average, it takes 3 to 4 years longer in China for a drug from being developed in the labs to obtaining approval to launch the drug in the market, which gives rise to a substantial drug lag compared to developed markets such as the US, Europe and Japan. Given the more complex nature of biological drugs, both CTA and NDA process last longer than for chemical drugs.

The longer timeline for CTA and NDA can be traced back to a lack of professional workforce at the CDE, which hinders the effectiveness of drug review and evaluation processes. The CDE has 115 employees, of which only 89 are involved in the review and evaluation processes. From 2011 to 2014 for instance, the number of new applications for evaluation received has increased by 24%, while the CDE employment capacity has remained unchanged. Until the end of 2014, the pending evaluation tasks have exceeded 18'500, referring to an increment of 4'362 in comparison to the end of 2013 according to the CDE. Although the CDE has completed more drug reviews in 2014 with the help from industrial professionals,

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88 Pharmaceutical Product Development (2013): Optimizing drug registration in China: Category I Route
89 Sina Finance (18.12.2014): Chinese drugs face the market 3 to 4 years later than in other countries due to the drug approval process
90 CDE (13/03/2015)
its effort of accelerating reviews and shortening the time lag for new drugs to enter the market has not worked out as expected.91

Another reason for the delays of new drug approvals is that the drug approval system in China was established on a large generics manufacturing basis instead of innovative drugs. Although the related regulation standards have been updated four times over the last years, it will still take a long time to fully readjust the regulatory environment for the rising number of new drug applications.92

Unlike the relatively simple structure of the US FDA, there are different departments such as the provincial CFDA, the CDE, the CCD and the NIFDC involved in the review and approval processes in China. This multi-department structure of the CFDA requires multi-party communication for the applicants and thus adds complexity and bureaucracy to the drug review and approval processes.

Imported drugs make up a large portion of drugs approved for marketing in China. However, the timeline from application to marketing for imported drugs takes over 5 years on average, being included in the reimbursement drug list will add on another 1 to 3 years. Essential time to treat patients in need is lost and extra drug development costs are added, which is often being criticized.93 According to the Drug Administration Law of the People’s Republic of China (Order 28), imported chemical drug developers have to either apply for CTA of Category 3 chemical drugs in Chinese subjects, or for a full development process of Category 1 chemical drugs like other new drugs being developed domestically.94 These regulatory processes are not required by many other countries. Taking the Direct-Acting Antiviral Medications (DAA) for HCV as an example, there are currently at least three DAA drug applications under review by the CFDA, which are estimated to get to the market at the soonest in 2017.95 We expect that China could participate in the ICH96 conference in the near future, which aims to reduce repeated clinical trials for innovative drugs in different countries.

91 Fiercepharma (13.03.2015): China says backlog of drug approvals soared 33% last year as new application jumped; CDE (13.03.2015): 2014 drug approval report
94 Dingxiangyuan (15.01.2015): Why are the imported drugs in China so expensive?
95 Pharmaceutical Product Development (2013): Optimizing drug registration in China: Category I Route
96 Netease (16.12.2014): Drugs for millions of HCV patients are outside the door
96 The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
Figure 2-12 – Drug registration and approval process for Clinical Trial Application (CTA) in China

Source: CFDA (2004); Citi Research (2012)

Figure 2-13 – Approval process for New Drug Application (NDA) in China

Source: Abbott (2012); Citi Research (2012)
2.4.2 Drug application and approval trends

Drug R&D in China has entered a new era characterized by the increasing number of science driven companies and institutions involved in innovative drug research, instead of mainly focusing on generics in the past. As mentioned previously, the current regulatory system and approval processes in China present unique challenges to the industry, pushing the CFDA to take action.

Over the last years, some major changes have been taking place to meet the global standards of drug approval. In the near future, more efficiency and transparency are still expected to add to the approval processes to encourage drug innovation. Since 2009, the CFDA has adapted a series of changes in its review and approval mechanisms for supporting new innovative drug registration, including “early involvement, propriety review, dynamic submission of supplemental information and multi-channel communication”\(^97\). At the beginning of 2013, the CFDA proposed “Opinions regarding deeper reform on drug review and approval for further encouraging drug innovation”, which illustrates an accelerated drug approval process (fast track) for innovative chemical and biological drugs and new treatments for serious or life-threatening diseases such as cancer, as well as for diseases without available treatment. The opinions also demonstrate CDE’s orientation on new drugs with high clinical value, for instance drugs for serious diseases and rare diseases, pediatric drugs etc.\(^98\) Companies who address unmet clinical needs will benefit most from fast track approvals.

As demonstrated in Figure 2-14, the absolute number of both new chemical drugs and generics applications is rising. However, the applications for new chemical drugs have been accelerating at a much advanced growth rate since 2012, while generics application growth is decreasing. The overlapping registrations and applications for the same kind of generics remain severe, leading to an enormous waste of the very limited evaluation resources of the CDE. Ca. 43% of all 2427 NDA applications in 2013 had already received over 20 historical approval numbers.\(^99\) The CFDA is reacting and has announced the “List of Excessive Overlapping Drug Categories” in September 2014 for the first time, intending to remind companies of the costs and risks of related R&D decisions.\(^100\)

\(^{97}\) CFDA (09.01.2009)
\(^{98}\) CFDA (22.02.2013)
\(^{99}\) CDE (06.03.2014)
\(^{100}\) CFDA (12.09.2014)
As approval standards and criteria tend towards higher and stricter, generics approvals for both clinical trials and for marketing have been reduced significantly. (Figure 2-15; Figure 2-16)

With the Chinese government’s dedication, we expect further reforms being implemented within the regulatory system.

**Figure 2-14 – Trend of acceptance for chemical drug applications by the CDE**

Source: Insight – China Pharma Data (2015)

**Figure 2-15 – Number of CFDA approvals for clinical trials for chemical drugs**

Source: Insight – China Pharma Data (2015)
2.4.3 Essential Drug List and National Reimbursement Drug List

Building a comprehensive essential drug system is one of the priorities supporting the government’s objective of establishing a universal healthcare system with easy access and affordable healthcare services and products by 2020, as announced in the national Healthcare Reform Plan for 2009-2012. The Ministry of Health in China has first introduced the Essential Drug List (EDL) in 2009, which contains 2 parts. The first part is intended for use in the primary healthcare system, namely community healthcare institutions in urban areas and township healthcare facilities in rural areas. The second part is for other healthcare institutions including higher level city hospitals.

In March 2013, China’s Ministry of Health (MOH) released the new essential drug list (“2012 EDL” version). This new version is outlined with significant changes and additional therapeutic focuses such as oncology and blood diseases, while the 2009 version mainly covers basic needs. The number of drugs within the list has also been increased from 307 to 520, which includes a series of MNC’s drugs like Sanofi’s Plavix, Novo Nordisk’s Novolin and Novartis’s Diovan. Essential drugs’ prices are determined through provincial tendering. The drug mark-up is capped at 15% when being supplied by primary healthcare institutions. In order to expand the usage of the EDL, the Chinese government has placed requirements on healthcare institutions regarding the revenue share of the EDL, namely 100% for grassroots healthcare institutions, over 50% for county hospitals, 40% to 50% for Level II hospitals and 25% to 30% for Level III hospitals. In order to solve the problem of overloaded patient flows at high level hospitals and

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MOH Department for drug policies and EDL system (15.03.2013); IMS (2013): Exploring impacts of the revised EDL and associated policies
to encourage more patients visiting primary healthcare institutions, patients who visit lower levels of healthcare institutions are provided with higher reimbursement rates for medical treatment and EDL prescriptions accordingly. By the end of 2013, the EDL market size in China has reached RMB 190 bn, representing around 15% of the total revenue of the pharmaceutical market according to the CFDA. With the further implementation and expanded coverage of the 2012 version EDL, the EDL market size is expected to grow at a CAGR of 31% from 2013 to 2015 to RMB 400 bn by the end of 2015, reaching 35% to 40% of the total prescription pharmaceutical market size.

The NRDL stands for the list of drugs reimbursed by the two public basic healthcare insurance schemes, UEBMI and URBMI, and is thus only available for insured people. The NRDL is divided into two categories, namely category A and B. Category A is the superset of EDL, which is fully reimbursable. Category B is composed of more innovative and patented drugs with a price premium partially reimbursable. The reimbursement policies for category B vary from 70% to 80%, depending on each provincial policy based on the local economic conditions and healthcare needs. The 2009 updated version of the NRDL has included many innovative drugs from MNCs, such as Sebivo and Aclasta of Novartis and Baraclude of BMS. As a result, the majority of sales of the top ten MNCs comes from NRDL drugs.

Table 2-5 – NRDL and EDL

<table>
<thead>
<tr>
<th>Type</th>
<th>Applicable insurance</th>
<th>Applicable number of drugs</th>
<th>Applicable reimbursement policies</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Reimbursement Drug List (NRDL)</td>
<td>UEBMI and URBMI</td>
<td>Type</td>
<td>Class A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemical &amp; biologics</td>
<td>349</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TCM</td>
<td>154</td>
</tr>
<tr>
<td>Essential Drug List (EDL)</td>
<td>URBMI and NRCM</td>
<td>Type</td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemical &amp; biologics</td>
<td>317</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TCM</td>
<td>203</td>
</tr>
</tbody>
</table>

Source: Zhi-en corporation

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102 Deloitte (2014): Unlocking access across China
103 ChinaIRN (20.01.2014): China’s EDL market is expected to be doubled under the new edition of EDL
104 Bioon (11.09.2013): The EDL market size is expected to reach RMB 400 bn by the end of 2015
105 IMS(2009): The 2009 revision of the National Reimbursement Drug List (NRDL)
Drugs on the NRDL and the EDL face a two-sided situation. On one hand, the NRDL and EDL drugs can win much broader market coverage as they are generally much easier added to physicians’ prescription lists and thus more affordable for patients. One the other hand, they are also confronted with intense generic competition and government’s price control. Essential drugs are likely targets for price cuts. Drug manufacturers can produce the NRDL and EDL drugs at relatively lower costs and preserve their gains, if they can sell those drugs with higher volume, which is possible given the expanding needs from grass-roots markets. However, pricing pressure and an over-focus on the price in the drug tendering processes have raised concerns about insufficient supply of some essential drugs with low prices in the market, as well as neglecting the quality of the drugs. The No. 16 document released by the Minister of Health in 2013 illustrates that regulators will place more focus on the quality side and further push to improve the quality control by implementing the new GMP standards, pushing essential drug manufacturers to enhance the quality of their products. The EDL and the NRDL are updated every three and every five years respectively. The next revision of the NRDL is expected to include more innovative drugs with partial reimbursement, which is aligned with the implementation of the Critical Illness Insurance Program (CIIP) in 2012. The goal of CIIP is to improve the reimbursement of medical costs for the most serious 20 diseases to at least 50%. In January 2015, the NHFPC has declared its key tasks for the year 2015, which include evaluating the 2012 version EDL and initializing the revision of the “Management Measures for the National Essential Drug List”. Hence, we expect the updated version of EDL to come in the near future.

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106 MOH Department for drug policies and EDL system (15.03.2013): Notification on implementing the 2012 version EDL
107 Deloitte (2014): Unlocking access across China
108 NHFPC (23.01.2015): Notification on releasing the 2015 key tasks of NHFPC
3 Healthcare subsectors with future growth potential

3.1 The Pharmaceutical market

China’s importance to the global pharmaceutical market is rising. Defined by IMS, the pharmerging countries contain 21 countries and represent the fastest growing pharmaceutical market in the world with an estimated CAGR of 13% from 2012 to 2017. China contributes alone almost half of the rapid growth.109

Figure 3-1 – Global versus Pharmerging markets sales

As discussed in the first section, drivers for China's healthcare market such as the aging population, rising awareness and increasing total and per capita expenditure on healthcare will obviously boost the growth of the pharmaceutical market. Our view on the future of China’s pharmaceutical market is positive. However, we expect the growth rate to be volatile year over year.

China’s pharmaceutical market has exploded in the last decades, climbing from the world’s fifth place in 2006 to the third largest pharmaceutical market worldwide after the US and Japan in 2013. According to IMS estimates, China’s pharmaceutical market size will exceed USD 180 bn and overstep Japan by 2017, based on an annual growth rate of 14-17% from 2013 to 2017.110 This volume-based growth will be driven by government’s efforts to expand the EDL and the NRDL and to further improve healthcare insurance

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109 IMS (2013): Pharmerging markets – Picking a pathway to success
110 IMS (2013): The global use of medicines: Outlook through 2017
coverage. However, compared to the CAGR of 23.5% from 2008 to 2013, lower growth rates are partly due to the slow-down in GDP growth, as well as continuing price cuts in the pharmaceutical market. With nearly 200 companies, the healthcare sector stands at the third place among all subsectors with the largest amount of listed companies in China’s A-share markets, representing 5% of the total market value. As shown in Figure 3-2. TCM and chemical companies together are representing over 60% of the healthcare A-share market, followed by biological drug companies. 30 years ago, there were solely state-owned drug manufacturers of API and generics. Today, although generics still dominate the market, innovative drugs and biologics are winning a higher degree of attention and more market share. In this part of the report, we will focus on our preferred subsectors of the Chinese pharmaceutical market, namely biological drugs and Traditional Chinese Medicine (TCM).

Figure 3-2 – Total market value distribution of the China-based A-share listed HC companies

Source: Bioon (2015)

3.1.1 Biological drugs

With the ongoing global surging wave of biological drugs, China also places a focus on the development of biologics. China has huge unmet medical needs in many therapeutic areas such as diabetes, cancer, HBV and HCV, where biological drugs can provide more effective and successful treatments. Imported patented drugs are often delayed due to the CFDA approval process, which we have discussed in the previous part. As a consequence, many top innovative biological drugs like monoclonal antibody drugs and interferons are not yet available to Chinese patients. There were over 800 biopharmaceutical

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112 Bioon (27.04.2015): Ranking list of 196 listed healthcare companies
companies in China in 2014.\textsuperscript{113} Most of them are manufacturing biosimilars. Among the innovative biological drugs in China, the majority is still coming from MNCs. Local Chinese companies are targeting MNCs' drugs with biosimilars, which is also in line with the demand of low-cost drugs based on the large population size. For instance, the second generation recombinant insulin products are facing fierce competition from local manufacturers such as Tonghua Dongbao Pharmaceuticals, whose human insulin product Ganshuling costs RMB 59.9 per 400iu/10ml compared to Novo Nordisk's Novolin with RMB 73 in Jiangsu province.\textsuperscript{114} There are some changes taking place in China's insulin market currently. The third generation insulin products are penetrating first-tier cities, while second generation products are gradually replacing the first generation in grass-roots markets. Now that MNC's insulin products are better penetrated in first-tier cities, local companies enjoy bigger opportunities in expanding their coverage in grass-roots markets. Due to favourable pricing, domestic-made insulin products can be included in many provincial supplementary EDL's and have better reimbursement levels.\textsuperscript{115} Longer term the third generation insulin products will replace the second generation products. In 2013, the third generation insulin products have grown at 27.9\% yoy, exceeding the growth rate of 23.5\% of the whole insulin market. Chinese companies such as Ganlee Pharmaceuticals are dedicated in bringing their third generation insulin products at lower prices to the market in the upcoming years.\textsuperscript{116}

Unlike those in developed countries, many biotech companies in China are partially or wholly state-owned, in order to promote the cooperation between these companies and universities. For instance, students from Shanghai jiao Tong University can earn their PhD title while working with a local biotech company called Shanghai Genomics. On the other hand, collaborations between local biotech companies and pharmaceutical companies are traditionally weaker, given the fact that local pharmaceutical companies focus mainly on generics and have less expertise and experiences in developing innovative biologic drugs.\textsuperscript{117} Local biotech companies tend to eye abroad and seek collaboration opportunities with small- to middle- sized foreign biotech companies. In 2014, within all disclosed collaborations, 90\% show a trend of Chinese companies buying innovative technologies or products from foreign biotech companies, which are mostly in early stages of development. The focus is mainly on the oncology area.\textsuperscript{118} We expect that local pharma-biotech mergers will also increase over the coming decade, as big local

\textsuperscript{113}CEIC (2014)
\textsuperscript{114}Yaozh Data (2014)
\textsuperscript{115}Strept (2013): Analysis of China's insulin market capacity and prices
\textsuperscript{116}CN Health (04.06.2014): Four companies share the third generation insulin market
\textsuperscript{118}Dongxiangyuan (07.01.2015): Chinese pharma companies became more mature in new drug collaborations
pharmaceutical companies intend to strengthen their innovative pipelines and seek diversification opportunities for their product portfolios.

The Chinese government is very supportive for the development of new therapeutic biologic fields such as gene therapy and stem cells. On top of the 11th 5 Year Plan in 2006, a series of policies supporting biopharmaceutical and related innovative capabilities of Chinese biopharmaceutical companies have been released. The 12th Five Year Plan has identified biotechnology, including biologic drugs and other biologic products for agriculture and energy, as one of the seven Strategic Economic Industries in China. The following Table 3-1 shows some of these commitments, which aim to accelerate biopharmaceutical developments.

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120 The PRC government (20.07.2012): Notification of 12th Five Year Plan on development of the national new strategic industries
Table 3-1 – Examples of government policies for promoting biotechnology / biopharmacy developments

<table>
<thead>
<tr>
<th>Policy</th>
<th>Chinese name</th>
<th>Issuer</th>
<th>Key points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opinions to Promote the Development of Biotechnology industry</td>
<td>促进生物产业加快发展的若干意见</td>
<td>State Council (2009)</td>
<td>To support the establishment of some multinational big biopharmacy enterprises and many innovative small- and middle-sized companies in the biopharmacy industry between 2006 and 2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>To support innovation for treating cancer, HIV, diabetes, viral hepatitis diseases, etc</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>To implement beneficiary tax policies in innovative biotechnology companies</td>
</tr>
<tr>
<td>12th Five Year Plan for Biotechnology Development</td>
<td>“十二五”生物技术发展规划</td>
<td>Ministry of Science and Technology (MoST) (2011)</td>
<td>3 focus areas: Gene engineering, Monoclonal antibody, Vaccines</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>To develop 30 innovative drugs and add 300’000 R&amp;D personnel</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Central government funding: USD 8 bn; local government funding: USD 5 bn; self-funding: USD 11 bn</td>
</tr>
<tr>
<td>Biotechnology Industry Development Plan</td>
<td>生物产业发展规划</td>
<td>State Council (2012)</td>
<td>To support the total output of the biopharmacy industry to grow at a CAGR of 20% over 2013 to 2015.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>To promote the consolidation of biopharmacy industry and improve its share in the global market.</td>
</tr>
<tr>
<td>Pharmaceutical Industry 12th Five Year Plan</td>
<td>医药工业“十二五”规划</td>
<td>Ministry of Industry and Information Technology (MIIT) (2012)</td>
<td>To implement 100% new GMP compliance on drug production lines</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>To increase R&amp;D expenses over 5% of sales for key pharmaceutical companies</td>
</tr>
<tr>
<td>Technical guidance for developing and evaluating biosimilars</td>
<td>生物类似药研发与评价技术指导原则(征求意见稿)</td>
<td>Center for Drug Evaluation (CDE) (2014)</td>
<td>The first biosimilar guidance for improving safety, effectiveness and quality control</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>To standardize application procedures, registration classification and application materials for biosimilars</td>
</tr>
</tbody>
</table>

Source: The PRC Government documents
The CAGR of biological drugs was around 25% from 2008 to 2013, growing 1% faster than the total pharmaceutical market. However, biologic drugs only accounted for 13.3% of the total Chinese pharmaceutical market by 2013 with a value of RMB 238 bn.\textsuperscript{121}

Figure 3-3 shows the favourable trend toward more innovative drugs, as the year over year growth rate of new drug sales in China has exceeded the existing drugs by over 10% on average. The proportion of new drugs has increased from 11.3% in 2007 to 15.3% in 2011. Although chemical drugs still dominate new drugs, we believe that biological drugs will make up a larger part of the market in the coming decade, given their treatment efficacy for chronic diseases, strong governmental support, as well as the rising R&D capability and willingness of Chinese companies.\textsuperscript{122}

The key challenges for the biological drugs sector remain the drug lag due to regulatory conditions and limited reimbursement policies of the medical insurance schemes. In addition, despite of the well-educated and transnational talent pool, obstacles remain on the biopharmaceutical workforce side, such as the lack of practical training programs. Facing this situation, many companies, local ones and MNCs are implementing on-job training. Taking Novartis Institutes for Biomedical Research in Shanghai as an example, they help newly hired scientists to get to know the latest technologies and to implement the concept of mechanism-based medicine by offering continuous learning and team-work opportunities.\textsuperscript{123}

\textsuperscript{121} X. Ji, S. Tong, UBS Research (2014): China healthcare: Where to position for growth
\textsuperscript{122} See 121
\textsuperscript{123} G. Wong, Nature Biotechnology 26, 353 – 354 (2008): Developing China’s home grown biotechnology workforce
3.1.2 Traditional Chinese Medicine

Traditional Chinese Medicine (TCM) can be traced back to 2000 years ago. TCM has developed a unique system of disease diagnosis and treatment. The diagnosis is based on the so-called “Four Steps”, namely inspection, olfaction, inquiry and palpation ("望闻问切"). The treatment is related to herbal medicine used in formulas composed of combinations of single herbal elements being kept and practiced generation by generation. Herbal elements are composed of primarily plants, as well as some mineral and animal sourced products.

The TCM pharmaceutical market refers to intermediate herb pieces and finished TCM drugs. The former can be also directly sold to customers as health products such as herbal tea. Instead of using the traditional method of boiling the medicine herbs and then drink the soup, the finished TCM drugs are produced with modern technology of extracting effective elements from the raw materials, often in form of capsules, granules, powders, as well as injections. As with western medicines, modern TCM drugs require clinical trials, while manufacturing and marketing of finished TCM drugs also need the CFDA approval.¹²⁴

TCM plays an important role in China’s healthcare industry. In 2012, 30% of the total pharmaceutical market revenue came from TCM drugs. Compared to the concentrated sales of chemical drugs to hospitals, TCM has a wider coverage in the retail pharmaceutical market and made up 44% of the retail pharmaceutical market share, with 32% for prescription TCM drugs and 12% for non-prescription (OTC) TCM drugs in 2013.¹²⁵ From 2008 to 2012, the TCM subsector has grown at a CAGR of 27%, which has exceeded the growth of the pharmaceutical industry average by around 4%.¹²⁶ However, in 2014, the growth rate of the TCM subsector has slowed down gradually to 12.5% in Q3 2014, below the pharmaceutical sector average for the first time, according to IMS. This was mainly due to price controls for the pharmaceutical sector and the related total reimbursement ratio control of the public medical insurances.¹²⁷ TCM drugs for cardio-vascular diseases are the best selling products within the prescription TCM drug market. In terms of the retail market of TCM drugs, drugs for respiratory system diseases have the biggest contribution to the total market revenue with over 35% share.¹²⁸

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¹²⁴ I. Wang, Z. Zhou, Credit Suisse Research (2014): China TCM sector
¹²⁵ IMS (2013): IMS 13th viewpoints
¹²⁶ S. Zhang, Standard Chartered Equity Research (2014): China health care
¹²⁸ IMS (2013): IMS 13th viewpoints
Chinese people have a traditional preference for TCM products to prevent and treat diseases. It is commonly accepted that TCM drugs can improve one’s health condition by promoting inner body harmony and have less side effects than western drugs. Especially the elder generations, who suffer from chronic diseases such as cardio-vascular diseases believe in the effectiveness and safety of TCM drugs, as the improvement is slowly and stable. Compared to western medicine, TCM provides more personalized diagnosis and treatment, while western medicine has more detailed and reliable clinical research results. The Chinese government listed integrative medicine and the popular trend for mixed treatment methods as an important research area, using both western and TCM drugs for chronic diseases. The integrative way shows positive results. Most hospitals in China offer an integrative medicine department.

Due to the relatively low entry barriers, there were over 2515 TCM companies in 2012, with the majority being small- to middle-sized companies.\(^\text{129}\) However, based on the special character of TCM formulas that enjoy high differentiation in herbal components, ranging normally from 5 to 20 ingredients, TCM exclusive drugs with patent face less competition from generics. The recent average price cut required by the government for exclusive TCM drugs was limited to 2% to 7%, much lower when compared to a price cut of 10% to 21% for non-exclusive drugs.\(^\text{130}\)

In addition, thanks to its relatively low costs and the prescription habits of rural doctors, the development of the TCM sector benefits from reimbursement policies of the public medical insurances in China. TCM drugs make up 39% of the EDL and 46% of the NRDL. As lower tier hospitals have to prescribe more EDL drugs according to government policies, TCM drugs have higher usage in rural areas.\(^\text{131}\)

Strongly supported by all the factors, we believe that the TCM sector will enjoy continued high growth, despite price controls. However, it is also essential for TCM companies to increase the R&D investments and to improve their clinical research standards, in order to provide more plausible clinical data for winning international recognition. In addition, with the implementation of the new GMP standards, the overall quality and regularization of the TCM industry will be further improved. Establishing a quality standard system for TCM drugs could also help to win recognition and approvals at international level. TCM companies are increasingly eager to bring their products to the international market. We believe

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\(^{129}\) Yiyaojie (15.01.2015): The trend and perspective of the Chinese TCM industry  
\(^{130}\) I, Wang, Z. Zhou, Credit Suisse Research (2014): China TCM sector  
\(^{131}\) See 130
that the penetration of TCM to broader international markets is an important future growth driver for this subsector.

3.2 Medical devices

China has become the third biggest market for medical devices worldwide. However, in terms of the medical device density (MDD), which measures the relative availability of medical devices in a country by the average expenditure per capita, China merely stands at USD 6, while the top ranking country Switzerland has a MDD of USD 369.\textsuperscript{132} The market share of the medical device sector represents 19.2% of the total healthcare market in China.\textsuperscript{133} China’s medical device market has experienced a period of rapid development over the last decades, where the total industry output value has increased at a CAGR of around 19% from USD 8 bn in 2006 to USD 26 bn in 2013. The growth rate in 2014 has turned to slow down essentially due to the fierce anti-corruption campaign in the same year, which is expected to continue into 2015 but with milder impact on the medical device market.\textsuperscript{134}

Similar to other fragmented subsectors within the healthcare industry, medical device companies face fierce competition for small portions of market share. By the end of 2013, 80% of over 15,000 medical device manufacturers are small- to middle-sized companies with low content of technology involved, whose annual revenues are less than RMB 13 mln.\textsuperscript{135} The medical device market is divided into 25% high-end market and 75% middle to low-end market. Within the 25% high-end market, over 70% of the market share is in the hand of MNCs, mainly GE, Siemens and Philips.\textsuperscript{136} High-end medical devices are largely imported. Chinese local medical device companies have a smaller size and focus mainly on the middle to low-end market. On the other hand, products for exporting traditionally centre on basic and disposable medical consumables. As some local big players are emerging, medical diagnostic and therapeutic equipment have gradually become the leading export products with a double-digit yoy growth rate in 2013.\textsuperscript{137} In the first half of 2014, local medical devices companies exported to 214 countries

\textsuperscript{133} X. Ji, S. Tong, UBS Research (2014): China healthcare: Where to position for growth
\textsuperscript{134} J. Hsu, Deutsche Bank Research (2014): China healthcare: 2015 outlook
\textsuperscript{135} Bioon (10.03.2015): 2014 Blue Book of China Medical Devices Industry Development
\textsuperscript{136} ChinaIR (25.11.2013): The import substitution analysis of China’s high-end medical devices
\textsuperscript{137} Bioon (14.02.2014): Medical device exports stepped into stable growth period
and regions, whereas USA, Japan and Germany remain the biggest export destinations with a total portion of 40%.

Table 3-2 – Comparison of local medical device companies with international peers

<table>
<thead>
<tr>
<th></th>
<th>Chinese local companies</th>
<th>International companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market share</td>
<td>20% ~ 30%</td>
<td>70% ~ 80% (USA, DE, JP)</td>
</tr>
<tr>
<td>Company size</td>
<td>Small- to mid caps</td>
<td>Large caps</td>
</tr>
<tr>
<td>Market focus</td>
<td>Mid- to low-end markets</td>
<td>High-end markets</td>
</tr>
<tr>
<td>R&amp;D as % of sales</td>
<td>3%</td>
<td>&gt;15%</td>
</tr>
<tr>
<td>Future strategies</td>
<td>Development of high-tech devices</td>
<td>Penetration in mid- and low-end markets</td>
</tr>
</tbody>
</table>

Source: CFDA (2014); HKTDC Research (2014); Bioon (2015)

Today, local companies intend to expand their market coverage to high-technology products with enhanced quality. However, domestic medical device companies have overall weaker R&D capabilities and the R&D to sales ratio lies far behind MNCs. Product homogenization and relative poor after-sales services are other key challenges for China’s medical device players. As a result, the overall profit margin remains at around 10% to 12% despite increasing revenues. Differentiation and diversification with innovative products will be critical in the future.

Based on the rapid rising aging population in China, we anticipate favourable growth opportunities for home-care medical devices such as blood glucose meters, blood pressure meters and hearing aids, which are widely demanded by aging people. Surveys show that each household in China now owns on average 1 to 2 homecare medical devices. Portable medical devices designed for remote patient monitoring or health status data recording and analyzing can bring convenience to aging people and also help improving the diagnosis quality, accuracy and efficacy.

With the rapid development of private hospitals, domestic medical device manufacturers can take the chance to expand into those hospitals that are more cost-sensitive. As announced in the "Healthy China 138 Bioon (22.09.2014): Report about medical devices in H1 2014 139 Medtec China (16.12.2014): Domestic high-end medical devices face difficulties 140 Sinopharm United Medical Device Co (27.10.2014): Homecare medical devices are about to boom
2020 Strategy Research Report, around USD 18 bn out of the USD 66 bn total governmental investment to be spent on seven subsectors within the healthcare system will flow into county level hospital constructions, where MNCs are less present. We believe that this investment will fuel demand for medical devices, since county level hospitals purchase primarily middle to low-end medical equipments due to budget constraints. The Chinese government has also carried out a series of favourable policies to boost the development of local players. In August 2014 for instance, the director of the National Health and Family Plan commission (NHFPC) pointed out that the government will encourage the usage of domestic devices on different levels of HC organizations, especially Level III hospitals, as expensive imported diagnostic devices further intensify the financial burden of medical services. An agent from the Ministry of Industry and IT (MIIT) also indicated that the government has planned to support the development of advanced technologies and key components for high-end domestic devices and to invest RMB 1.5 bn in the sector with focus on in vitro diagnostics, medical imaging devices and therapeutic equipment.

We forecast that China’s medical device market will continue to grow in the next 5 years, however, at a more stable pace of around 14%. Local players have started going abroad in acquiring foreign medical device companies, as well as in exporting devices to emerging markets, especially to Russia, India and Brazil. Although exports to emerging markets are presently still limited, we believe this trend will continue given the enhanced product safety and quality, stronger R&D capability and relatively lower costs of Chinese medical devices.

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141 Economic Information (18.08.2014): Two ministries push the development and application of domestic medical devices
142 Finance China (18.07.2013): New supportive policy fell on medical devices
When classifying hospitals by their ownership, 58% of the hospitals in China are public, including state-owned and indirect state-owned ones, the other 42% are private. 96% of Level III and 91% of level II hospitals are public-owned (Figure 3-5). As a result, 90% of Chinese patients choose to visit public hospitals. Private hospitals in China only account for around 10% of the service volume and for 14% of beds while being operated at a lower level.\textsuperscript{143} The picture in the US is nearly the opposite, where public hospitals make up 15% of total hospitals and only 27% of patient visits.\textsuperscript{144}

\textbf{Figure 3-5 – Hospital ownership and ranking overview (2012)}

Source: NHFPC (2014)

\textsuperscript{143} NHFPC (2014)

\textsuperscript{144} X. Ji, S. Tong, UBS Research (2014): China healthcare: Where to position for growth
Key challenges for the development of private hospitals in China include low patient recognition and insufficient skilled and reputable doctors. In addition, according to a survey with executives of healthcare companies in China, those who are directly involved in hospital operations believe that the second most important factor is whether private hospitals can be developed to designated reimbursement hospitals.\textsuperscript{145}

In recent years private hospitals have yet experienced strong growth. According to the NHFPC, from September 2013 to September 2014, the number of private hospitals has increased by 1,168, while public hospitals shrunk by 86. From 2008 through 2014, the number of private hospitals has grown at a CAGR of 14%, while the number of public hospitals has shown a decreasing trend. (Figure 3-6) In the mean time, visits of patients to private hospitals have increased by 12.5% from Q3 2013 to Q3 2014, overstepping the growth of visits to public hospitals which have accreted at 7.9% on a quarter to quarter basis.\textsuperscript{146}

**Figure 3-6 – Comparison number of public and private hospitals in China**

<table>
<thead>
<tr>
<th>Year</th>
<th>No of public hospitals</th>
<th>No of private hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept 2011</td>
<td>13'685</td>
<td>7'716</td>
</tr>
<tr>
<td>Sept 2012</td>
<td>13'427</td>
<td>9'295</td>
</tr>
<tr>
<td>Sept 2013</td>
<td>13'427</td>
<td>10'795</td>
</tr>
<tr>
<td>Sept 2014</td>
<td>13'341</td>
<td>11'963</td>
</tr>
</tbody>
</table>

Source: NHFPC (2014)

The State Council has set a goal to increase both the private hospital beds and patient volume contribution to 20% by 2015 from less than 10% in 2011, meaning an incremental flow of 400 mn patients to private hospitals compared to 2011.\textsuperscript{147} A series of policies that have been released since 2009, have shown the government’s dedication for the development of private hospitals by easing entry

\textsuperscript{145} J. Hu, Deutsche Bank Research (2014): China healthcare: 2015 outlook
\textsuperscript{146} NHFPC(2014)
\textsuperscript{147} NHFPC (2014); C. Wu, Y. Tian, J. Wong, BCG (2013): Investing in China hospital market
requirements and improving the business environment. For instance, the government’s No.58 document in 2010 about further encouraging and conducting social capital to run private hospitals covers more detailed practical beneficial policies for running a private hospital and allows foreign capital to establish medical institutions by lowering the entry barrier. In order to bring more efficiency and advanced management concepts into the process of public hospital reform, some local governments have released pilot public hospitals for privatization.\textsuperscript{148}

Growth in the private healthcare services sector is being driven by overall market demand, favourable policies and also diversification and specialization. The private specialty hospital chain model is currently in favour of investors and market entrants, especially dental, ophthalmology and plastic surgery hospital chains, as well as diagnostic labs and centers, whose customized services may generate higher margins. Investors with various backgrounds are entering China’s private hospital market. As demonstrated in Figure 3-7, foreign hospital chain investors, such as Chindex have built up high-end chain hospitals in smaller size in China. Local financial investors, real estate companies and pharmaceutical companies are mostly targeting at mid-end market and specialty hospitals. Pharmaceutical companies such as Shanghai Fosun Pharmaceutical Group aim at broadening their value chain and boost selling of their own drugs by establishing hospitals or participating in public hospital privatization.\textsuperscript{149}

\textbf{Figure 3-7 – Private hospital ownership breakdown in 2012}

![Private hospital ownership breakdown in 2012]

\textit{Source: Roland Berger (2014)}

\textsuperscript{148} The PRC government (03.12.2010): Notification on further encouraging and leading social capital to participate in healthcare institutions

\textsuperscript{149} Roland Berger (2014): Entering China’s private hospital segment
The market is expecting further beneficial policies such as accelerating approval processes for physicians to practice at multiple sites, which has also been seen as an ideal transition layer to the free practice model. Unlike western markets, skilled doctors prefer to stay with hospitals instead of running independent clinics due to the uninsured welfare and pension benefits, limited research resources, higher costs and extremely complicated application procedures. With regard to the insurance coverage, there are enormous opportunities of cooperation between commercial insurances and private hospitals. In spite of the continuing domination of public hospitals in the near future, we believe that with the government’s commitment and the preferential environment, the private hospital sector is poised for rapid growth in the coming years. In the mean time, the development of private hospitals will put pressure on public hospitals and push them to improve their service quality and operational efficiency.

150 Netease (17.03.2015): Multi-site practice hardly to be put into practice
4 Outlook

In 2015, China's economic development faces challenges and slowdowns as a result of its transition from an investment-driven to a consumption-driven model. With the rising healthcare demand and the relevant total healthcare spending, pressure on the medical insurance funding will become more critical. Headwinds from drug pricing erosion during the provincial tendering processes, reforms on reimbursement price control and policy uncertainties bring along other challenges. However, we remain bullish on the long-term growth perspectives of China's healthcare sector, as the fundamental conditions stay favourable.

On the demand side, Chinese people are getting wealthier and thus can better afford healthcare products and services. In the light of an aging population, a higher prevalence of chronic or non-communicable diseases has gained increasing attention and Chinese people's spending on healthcare grows over-proportionally to rising incomes. In a long-term perspective, the demographic shift and urbanization will act as drivers for the healthcare industry in China, fueled by the Chinese government's commitment to strengthen the healthcare safety net with broad healthcare insurance coverage, enhanced reimbursement levels and reduced personal out-of-pocket healthcare spending. China will already be the second largest country regarding total healthcare expenditures in the near future.

Similarly on the supply side, tremendous changes are taking place: Chinese companies are gaining market share, investments in research and development increases as innovation plays a more and more important role for domestic companies; international companies' investments in China's healthcare market have become more extensively and diversely and accelerated consolidation of the highly fragmented healthcare industry is supported by improving product standards, stricter regulation and increasing international cooperation.

On top of these, the Chinese government intends to implement reforms on the healthcare industry, ranging from establishing an effective and safe drug system to promoting reforms on public hospital systems and primary care institutions. Reforms on China's healthcare system have shown the dedication and ambition of the Chinese government in upgrading this industry and have brought about significant changes and developments. We expect that the government will continue supporting the domestic healthcare industry, especially the domestic pharmaceutical and medical device companies.
Companies who can withstand the hard transition period driven by regulatory upgrades will be well prepared and positioned for the new episode of healthcare market opportunities in China. Due to the large unmet medical needs and lagging development in primary healthcare markets, companies with the capability of penetrating the market with effective and cheaper medical treatments and products will be able to deliver sustainable and faster growth compared to the total market.

The additional focus on expanding the private healthcare service market will promote the service contribution of private hospitals and the market share of private commercial insurance, which will help to distribute the patient flows efficiently and supplement the uncovered reimbursement areas of basic medical insurances.
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Lin Niu, equity analyst, joined Kieger in 2014. She focuses mainly on the healthcare sector in Asia. Lin Niu earned a Bachelor of Arts degree in German Language and Literature from Xi’an International Studies University in China, a Bachelor of Science degree in Economics from the University of Bonn in Germany and a Master of Science degree in Financial Markets & Investments from Skema Business School in France.

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At the University of Liechtenstein he completed a Bachelor’s Degree in Financial Services and a Master’s Degree in Banking & Financial Management. He is also a CFA Charterholder.
## Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAGR</td>
<td>Compound Annual Growth Rate</td>
</tr>
<tr>
<td>CCD</td>
<td>Center for Certificate of Drugs</td>
</tr>
<tr>
<td>CDE</td>
<td>Center for Drug Evaluation</td>
</tr>
<tr>
<td>CDR</td>
<td>Center for Drugs Revaluation</td>
</tr>
<tr>
<td>CFDA</td>
<td>China Food and Drug Administration</td>
</tr>
<tr>
<td>CIIP</td>
<td>Critical Illness Insurance Program</td>
</tr>
<tr>
<td>CIRC</td>
<td>Chinese Insurance Regulatory Commission</td>
</tr>
<tr>
<td>CIT</td>
<td>Corporate Income Tax</td>
</tr>
<tr>
<td>CPC</td>
<td>Chinese Pharmacopoeia Commission</td>
</tr>
<tr>
<td>CRO</td>
<td>Contract Research Organisation</td>
</tr>
<tr>
<td>CTA</td>
<td>Clinical Trial Application</td>
</tr>
<tr>
<td>DAA</td>
<td>Direct-Acting Antiviral Medications</td>
</tr>
<tr>
<td>Diabetes type 1</td>
<td>Diabetes mellitus type 1 (also known as type 1 diabetes, or T1DM; formerly insulin-dependent diabetes or juvenile diabetes) is a form of diabetes mellitus that results from the autoimmune destruction of the insulin-producing beta cells in the pancreas.</td>
</tr>
<tr>
<td>Diabetes type 2</td>
<td>Diabetes mellitus type 2 (formerly noninsulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes) is a metabolic disorder that is characterized by hyperglycemia (high blood sugar) in the context of insulin resistance and relative lack of insulin.</td>
</tr>
<tr>
<td>DRG</td>
<td>Diagnosis related groups</td>
</tr>
<tr>
<td>EDL</td>
<td>Essential Drug List</td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GDP</td>
<td>Gross Domestic Product</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>HBV</td>
<td>Hepatitis B is an infectious disease caused by the hepatitis B virus (HBV) which affects the liver.</td>
</tr>
<tr>
<td>HCV</td>
<td>Hepatitis C is an infectious disease affecting primarily the liver, caused by the hepatitis C virus (HCV).</td>
</tr>
<tr>
<td>Helicobacter pylori</td>
<td>Helicobacter pylori, previously named Campylobacter pylori, is a Gram-negative, microaerophilic bacterium found in the stomach, and may be present in other parts of the body, such as the eye.</td>
</tr>
<tr>
<td>HPV</td>
<td>Human papillomavirus (HPV) is a DNA virus from the papillomavirus family that is capable of infecting humans. Like all papillomaviruses, HPVs establish productive infections only in keratinocytes of the skin or mucous membranes.</td>
</tr>
<tr>
<td>IGT</td>
<td>Impaired glucose tolerance</td>
</tr>
<tr>
<td>IND</td>
<td>Investigational New Drug</td>
</tr>
<tr>
<td>MDD</td>
<td>Medical Device Density</td>
</tr>
<tr>
<td>MIIT</td>
<td>Ministry of Industry and IT</td>
</tr>
<tr>
<td>MNC</td>
<td>Multinational Corporation</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MoHRSS</td>
<td>Ministry of Human Resources and Social Security of the People Republic of China</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>Mergers &amp; Acquisitions</td>
</tr>
<tr>
<td>NDRC</td>
<td>National Development and Reform Committee</td>
</tr>
<tr>
<td>NHFPC</td>
<td>National Health and Family Plan Commission</td>
</tr>
<tr>
<td>NIFDC</td>
<td>National Institutes of Food and Drug Control</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>NRDMI</td>
<td>New Rural Cooperation Medical Insurance</td>
</tr>
<tr>
<td>NRDL</td>
<td>National Reimbursement Drug List</td>
</tr>
<tr>
<td>OTC</td>
<td>Over-The-Counter</td>
</tr>
<tr>
<td>RMB</td>
<td>The official currency of the People's Republic of China</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research &amp; Development</td>
</tr>
<tr>
<td>TCM</td>
<td>Traditional Chinese Medicine</td>
</tr>
<tr>
<td>UEBMI</td>
<td>Urban Employee Basic Medical Insurance</td>
</tr>
<tr>
<td>URBMI</td>
<td>Urban Residence Basic Medical Insurance</td>
</tr>
<tr>
<td>VAT</td>
<td>Value Added Tax</td>
</tr>
</tbody>
</table>

The official currency of the People's Republic of China.
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