

## **The rising Chinese pharmaceutical industry: local champions vs global players**

Francesca Spigarelli  
Hao Wei

### ABSTRACT

This paper is an exploratory study on main features and challenges of the Chinese pharmaceutical market. Dramatic changes in the market are due both to the Government policies, changing consumer habits and behaviour, and to the growing competition at firm level. From a demand side perspective, consumptions of pharmaceutical products are booming thanks to a combined effect of economic growth, aging population, urbanization and health system reforms. Key forces shaping the demand are examined in the chapter, with a specific attention to health care reforms as well as to new habits and confidence of Chinese people towards the Western medicine. In this regard, import and export trends, consumption, and expected evolution of the market are examined. From a supply side perspective, two main trends can be highlighted: the increasing interest of foreign investors, and the effort of Chinese pharmaceutical firms to compete in the national market. To better understand the ongoing changes we look at market characteristics, key players, as well as trends and motivation of inward FDI to China are examined. On the basis of this general picture, the paper focuses on IP related aspects, to understand who are the main actors of patenting trends (foreign vs local firms) and for which kind of products patents are registered (raw materials vs basic products vs drugs). Analyzing patent trends and the role of Chinese vs Western firms, we try to define how China is taking its role and position into the national and – potentially - international pharmaceutical market.

Keywords: China, pharmaceutical industry, patents

Francesca Spigarelli  
Università degli Studi di Macerata  
spigarelli@unimc.it  
Hao Wei  
Beijing Normal University

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## **1. Introduction**

China is becoming a strategic player in the pharmaceutical market, both as a consumer country and as a growing and upgrading industrial platform.

The Government has been embracing a large reform in the healthcare system to upgrade the quality and coverage of healthcare assistance of Chinese people. Multiple strategies are promoted, both on the demand and on the offer side. A key issue in this process is related to the transformation of the Chinese pharmaceutical industry: the Government is planning to build an innovative system, led by research-based companies. Integration of local firms with international companies has been encouraged; new specific measures were issued to stimulate foreign investments, improving the market access.

To grasp knowledge, know how and best practices, the Government is willing to attract not only the manufacturing and marketing division of foreign firms, but it is also promoting the transfer of some of their critical business operations, core technologies and research development to China.

The growth of the size of the “industry” is also due to an increased order in the market, to the exit of small and irregular competitors, to more stability in drug regulation and to an improved intellectual property (IP) protection. IP issues, in particular, play a fundamental role for the development of the market. In recent years, pharmaceutical is the industrial sector which has applied the highest number of patents in China: domestic firms are actually the main force, but patent applications and granted patents of foreign enterprises are increasing.

The aim of the chapter is to give a general overview of the current characteristics of the Chinese pharmaceutical market, of its main trends, as well as of main changes and expected evolution of the demand and of the supply in the industry. We also look at the balance between foreign and national firms’ position in the market, in term of Western interests for Chinese traditional knowledge and culture as well. We try to build a general picture of the industry and of main competitors to evaluate and grasp future research opportunities in this area in an International Business perspective.

The chapter is structured as follows. Paragraph 2 is focused on main trends in the Chinese pharmaceutical market: consumptions, production, import and export flows. Features of the industry and main competitors are described in Paragraph 3, while Paragraph 4 analyses the motivation of the increasing presence of global pharmaceutical players in China. Paragraph 5 is focused on IP trends and on the role of national firms *vs* foreign competitors.

Before starting the analysis, a clarification is fundamental. The Chinese pharmaceutical market is a comprehensive industry, for manufacturing and sale of: synthetic chemicals and drugs, the so-called Western drugs, including OTC –over the counter medicine and prescription medicine; traditional Chinese medicines (TCM); medical devices, apparatus and instruments; hygiene materials; and pharmaceutical machinery. In this chapter we chose to focus only on Western and TCM drugs, for which the patenting issues are more relevant and seem to fit best our research goals.

## 2. The evolution of the market: a demand side perspective

China is the world's third-largest pharmaceutical market in term of sale (IMS, 2010), but it should become the second by 2020, behind only the United States (Yan, 2009). Several data and trends can help understand the speed and scope of changes undergoing in China. The market grew by 17% in 2010, reaching a value of \$25.7 billions and accounting for 18.6% of the Asia-Pacific pharmaceutical market.

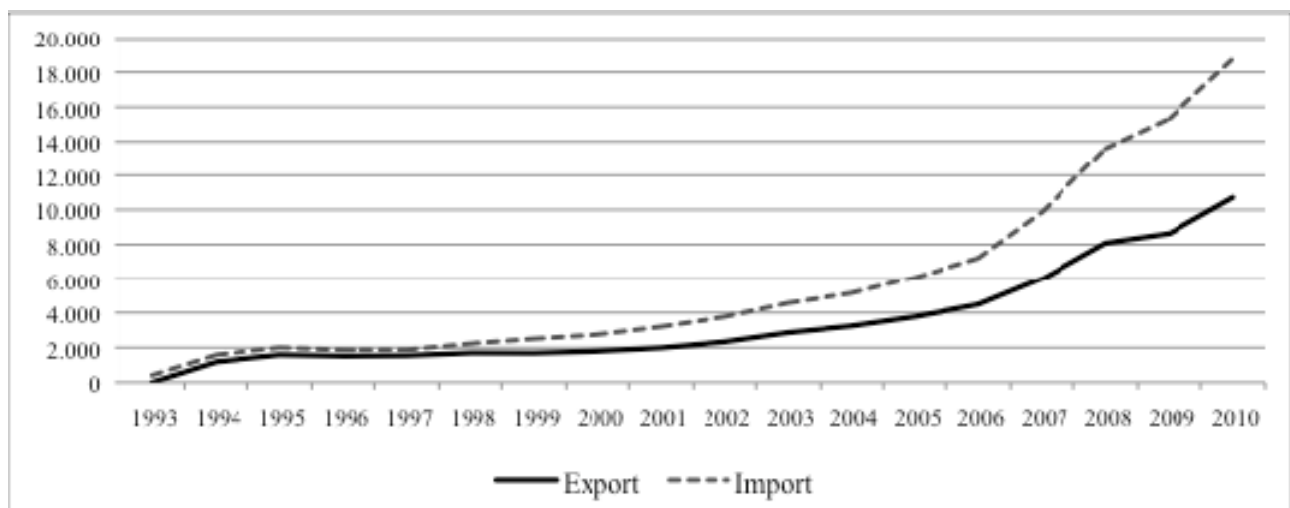
Expenditure on health care is expected to increase from 4.7% of GDP to 6%-7% in the next few years. China should reach a total amount of healthcare expenditure of \$705.74 by 2015 (Frost, Sullivan, 2011, p. 4), while per capita expenditure should be set at a level of \$437 in 2016, compared to \$109.5 in 2007 (Deloitte, 2011, p. 10). Pharmaceutical sales are spreading out as well: from 2007 to 2010 the compound annual growth rate was 25.9%, while through 2015 it should be 15.5% (Deloitte, 2011, p. 6).

As a result of such facts and figures, the Chinese pharmaceutical market is becoming increasingly attractive to Western firms. It is considered one of the World's most important emerging pharmaceutical areas (Business Monitor International Ltd, 2011).

At the moment, sales from generics dominate the market (61.4% of the market share in 2009), but newly patented products are expected "to gain shares from a huge and rapidly growing absolute value market" (Jan-Willem, 2011, p. 2).

Data on imports of pharmaceutical products show a strong expansion (+195% of the value of flows from 2006 to 2010), and in parallel, exports are accelerating (+135% over the same period). See Exhibit 1.

Exhibit 1. Import and Export trade in Medical & Pharmaceutical Product sector (data in million US dollars)



Source: own calculation on data provided by CeSif, Fondazione Italia Cina - Ceic

From a demand-side perspective, demographic factors can be considered as one of the most relevant drivers of the growth of China's pharmaceutical market.

China is the most populous country in the World, thus resulting in a large size potential market. At the same time, the population is ageing, also as a consequence of the one-child policy. Many observers consider this

issue the country's Achilles heel: the total fertility rate is well below the replacement rate<sup>1</sup>, and the share of young population is decreasing rapidly<sup>2</sup>. Elderly people require appropriate, specific and long-term health care assistance, whose costs are much higher compared to those absorbed by young country population. Estimated increase of drug prescription market is between 23% and 40%, while the increase for the OTC market should be between 40% and 50% (Deloitte, 2010, p. 2).

The higher sensitivity of Chinese on healthcare services and products can also be related to higher living standards (Yuanijia, 2007, p. 296). As the income per capita heightens, people can put more money in taking care of their health needs, upgrading the typical expenditure structure of consumption from basic good to more sophisticated goods. More and more high quality healthcare services are going to be requested by healthier Chinese people.

Urbanization is another important aspect to take into account: mass migration to the cities, from the agricultural areas, is resulting in a growing demand for pharmaceuticals (Yuanijia, 2007, p. 296). People is becoming more used to new lifestyles and has an easy access to retail pharmacies. The strong commitment made by the Government towards the upgrading of rural infrastructure should supports this trend (Deloitte, 2011, p. 4).

Beside from the demographic perspective, the rising consumption of pharmaceuticals is also related to the evolution of the typical needs/requests of the Chinese healthcare consumer. High longevity, combined with environmental and pollution problems are increasing chronic diseases like respiratory illnesses, cancer, diabetes, as well as obesity (Jan-Willem, 2011). New lifestyles are considered the cause of those diseases, sometimes called "lifestyle disease" – for which the use of lifestyle drugs are booming. Consumption of OTC is increasing as well, as a result of a new attitude towards self-medication. As reported by several surveys (Yuanjia, 2007, pp. 297-298), self medication is becoming more and more popular among Chinese people (Deloitte, 2011, p. 15). Since without a medical prescription, patients can only have access to OTC drugs, a relevant increase in this market is expected in the future.

Last sign of the evolving Chinese consumer habits is the booming sales of drugs on line, because of the increasing attitude towards online shopping and the diffusion of internet<sup>3</sup>.

The cultural and social revolution that is taking place in the healthcare habits of Chinese people has a lot to do with institutional issues. In 2009 the government launched new plans to reshape the National health-care system (Rein, 2009; RDPAC, 2008). According to the *Guidelines on Deepening the Reform of Health-care System* (Ye, Guocheng, 2009), the first phase of the reform aims to: increase the Basic Medical Insurance (BMI) to reach a 90% of population coverage by 2011; revise the reimbursable medicine under BMI, i.e. of the Essential Drugs List; set a more restrict regulation on prices by the National Development and Reform

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<sup>1</sup> "Over the past 30 years, China's total fertility rate - the number of children a woman can expect to have during her lifetime - has fallen from 2.6, well above the rate needed to hold a population steady, to 1.56, well below that rate. Because very low fertility can become self-reinforcing, with children of one-child families wanting only one child themselves, China now probably faces a long period of ultra-low fertility, regardless of what happens to its one-child policy". See *The Economist*, April 21<sup>st</sup> 2012.

<sup>2</sup> "People above the age of 60 now represent 13.3% of the total, up from 10.3% in 2000. In the same period, those under the age of 14 declined from 23% to 17%". See *The Economist*, May 5<sup>th</sup> 2011.

<sup>3</sup> China has more online shoppers (193 million) than any other country in the world. US has 170 million online consumers (Jingting, 2012). "By 2015, China will add nearly 200 million users, reaching an Internet population of more that 700 million-almost double the combined number of Japan and the US" (see: Michael et al., 2012).

Commission (Deloitte, 2011, p. 3). The second phase of the reform should bring into effectiveness a universal health care system, providing “safe, effective, convenient and affordable” health services to urban and rural residents (Ye, Guocheng, 2009). The 12th Five-Year Plan (2011-2016), released in 2011, has also put strong attention to health care and pharmaceutical industries (Tung, 2011; Deloitte, 2011).

### **3. The changing shape of the Chinese pharmaceutical industry**

Healthcare reforms, while affecting consumptions, habits, and behaviours of Chinese people are having a significant impact on the industry, which is still highly fragmented (Yuanjia, Ung et al., 2007) and with strong rivalry. National firms compete and cooperate with foreign companies that have a direct presence in the market<sup>4</sup>. The three major firms - one Chinese and two big Western multinationals - share only 10% of the market. Yangtze River Pharmaceutical Group is the leading player (3.6% of the market’s value), AstraZeneca PLC controls 3.4% and Pfizer Inc. 3.0% (Datamonitor, 2010, p. 2). Bayern is gaining importance, as well.

Distribution is highly fragmented. It is often criticised for its inefficiency and lack of transparency. China’s top three distributors - Sinopharm Group, Shanghai Pharmaceutical, and Guangdong Jiuzhoutong Pharmaceutical - had in combination less than 20% of overall market share in 2009. In the U.S., the top three pharmaceutical commerce companies together held a 96% market share (Deloitte, 2011).

Above this general picture, in recent years, Chinese pharmaceutical market has made remarkable development, and its scale has increased rapidly. In 2010, the gross output of Chinese pharmaceutical market was \$183.57 billions: \$118.25 billions more compared to 2005. The industrial added value was \$ 69.25 billions, with an annual growth rate of 15.4%, larger than that of GDP and national industrial average growth. Total profit increased as well, at a rate higher than that of production value<sup>5</sup>. What’s more, from 2000 to 2010, the number of pharmaceutical enterprises above the “designated size”<sup>6</sup> increased from 3,301 to 7,039; the value added tax was \$1.39 billion in 2000, and increased to \$ 8.08 billion in 2010. From 2000 to 2010, revenues from principal business changed from \$19.66 billion to \$168.66 billion (see Exhibit 1).

The number of firms has more than doubled from 2000 to 2010 and their scale has been also increasing. State-owned enterprises, foreign enterprises and private enterprises compete in the market (see Exhibit 2). Even if the number of private firms has more than doubled in only 6 years, their average size is much lower than SOEs and foreign firms. SOEs, on their side, have been experiencing a period of reorganization and rationalization: their number decreased from 1.500 to 500, but their average size grew significantly, as well as their gross domestic output.

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<sup>4</sup> From a geography perspective, most firms are located in the south-eastern zone, including two well developed areas (Zhejiang and Guangdong provinces) and three underdeveloped areas (Hebei province, Heilongjiang province and Sichuan province). The motivation of this concentration can be found in the economic factors that draw the growth in last years. (Yuanjia, Ung et al., 2007, p. 19).

<sup>5</sup> See Ministry of Industry and Information Technology of the People’s Republic of China, *12th five-year plan of Chinese pharmacy market*. See: <http://news.pharmnet.com.cn/news/2012/01/20/352022.html>.

<sup>6</sup> As stated by the National Bureau of Statistics of China, the relevant size is reached when revenue from principal business is more than 5 million yuan. 5 million yuan equal to 0.7386 million \$ in 2010.

Exhibit 1 - Manufacture firms in the pharmaceutical industry, above designated size

Year	n. of enterprises	Gross industrial output value (\$100 millions)	Total assets (\$100 millions)	Revenue from principal business (\$100 millions)	Total profits (\$100 millions)	Value Added Tax Payable (\$100 millions)	Annual average n. of employees (10,000 persons)
2000	3301	215.18	338.10	196.59	16.50	13.94	83.00
2001	3488	246.57	396.41	232.50	20.30	16.03	82.00
2002	3681	287.36	446.25	275.46	24.33	18.14	82.00
2003	4063	349.16	521.50	332.33	31.37	20.35	115.40
2004	4397		579.70	388.19	33.78	22.41	118.51
2005	4971	518.87	677.49	490.72	41.29	26.77	123.44
2006	5368	629.59	769.77	591.94	46.73	30.68	130.28
2007	5748	836.65	909.59	784.74	76.44	40.47	137.34
2008	6524	1133.89	1134.90	1065.83	114.17	57.34	150.75
2009	6807	1382.42	1367.49	1330.26	145.51	66.39	160.48
2010	7039	1734.44	1642.13	1686.58	196.63	80.82	173.17

Source: China Statistical Yearbook, several years.

Exhibit 2 - The number and average size of pharmaceutical firms

year	Foreign Pharmaceutical Enterprises			State-owned Pharmaceutical Enterprises			Private Pharmaceutical Enterprises			Other Kind of Enterprises <sup>7</sup>		
	n. units (a)	Gross industrial output value (\$100 mil) (b)	Average Size (\$100 mil) (b/a)	n. nits (a)	Gross industrial output Value (\$100 mil) (b)	Average Size (\$100 mil) (b/a)	n. units (a)	Gross Industrial Output Value (\$100 mil) (b)	Average Size (\$100 mil) (b/a)	n. units (a)	Gross Industrial Output Value (\$100 mil) (b/a)	Average Size (\$100 mil) (b/a)
2000	542	48.8	0.09	1496	106.78	0.07	-	-	-	-	-	-
2001	568	54.73	0.1	1341	110.43	0.08	-	-	-	-	-	-
2002	604	63.43	0.11	1180	116.71	0.1	-	-	-	-	-	-
2003	701	76.84	0.11	1001	128.43	0.13	-	-	-	-	-	-
2004	743	100.4	0.14	939	241.28	0.26	-	-	-	-	-	-
2005	890	127.93	0.14	676	124.27	0.18	1573	81.79	0.05	1832	184.98	0.10
2006	955	159.44	0.17	590	124.94	0.21	1940	121.93	0.06	1883	223.26	0.12
2007	1035	214.1	0.21	559	150.32	0.27	2198	171.75	0.08	1956	300.43	0.15
2008	1144	307.12	0.27	527	175.09	0.33	2669	261.05	0.1	2184	390.57	0.18
2009	1144	386.18	0.34	508	175.38	0.35	2911	334.8	0.12	2244	486.01	0.22
2010	1140	468.42	0.41	507	223.06	0.44	3118	449.81	0.14	2274	592.99	0.26

Source: China Statistical Yearbook, several years.

Pushed by factors of market growth, technical progress, increased investment and mergers and reorganization, some large-scale enterprises are appearing in China and they are becoming leaders in basic drugs supply. There was only 1 pharmaceutical firm with more than 10 billion yuan (\$1.22 billion) sale proceeds in 2005, while in 2010 they were 10. In 2010, 1,125 out of the 7,039 pharmaceutical firms in the market were large and medium-sized<sup>8</sup>, controlling 694.8 billion yuan (\$102.64 billion) of the pharmaceutical industrial output value (59.17% of total value). Pharmaceutical enterprises with more than 5 billion yuan

<sup>7</sup> Other Kind of Enterprises includes: collective-owned enterprises, share-holding cooperative enterprises, share-holding enterprises.

<sup>8</sup> Large-sized industrial enterprises means that the number of employed persons is more than 2000, the sale revenue is more than 300 millions yuan (44.31 millions \$ in 2010), the total assets is more than 400 millions yuan (59.09 millions \$ in 2010). Medium-sized Industrial Enterprises means that the number of employed persons is between 300 and 2000, the sale revenue is between 30 and 300 millions yuan (4.43-44.31 millions \$ in 2010), the total assets is between 40 and 400 millions yuan (5.91-59.09 millions \$ in 2010).

(\$0.61 billion) sales were 17 in 2010, while only 3 in 2005<sup>9</sup>. Among them, Yangtze River Pharmaceutical Group, Harbin pharmaceutical Group, China Shijiazhuang Pharmaceutical Company, TongRenTang, Guangzhou Pharmaceuticals Corporation, Weigao Holding Co. Ltd are gaining market shares.

At the same time, new enterprises, such as Jiangsu Hengrui Medicine Co., Zhejiang Hisun Pharmaceutical Co. Ltd., Tasly Group, Shineway Pharmaceutical Group, Mindray, are developing rapidly. Some backbone enterprises, such as China National Pharmaceutical Group Corporation, Shanghai Pharmaceutical Co.,Ltd., Sino-Swed Pharmaceutical Corp.Ltd., are also growing rapidly by merger and acquisition, achieving integration of industry chain, enhancing their competitiveness.

Enterprises listed in Exhibit 3 were the top 20 firms in Chinese pharmacy market. Yangtze River Pharmaceutical Group is the first as for prime operating revenue, while Shanghai Pharmaceutical (group) Co. Ltd had most gross assets. Looking at total profit, China National Pharmaceutical Group Corporation ranked first.

*Exhibit 3 – Financial and economic data: ranking the top 20 firms in 2011*

Ranking	Prime operating revenue	Gross assets	Total profit
1	Yangtze River Pharmaceutical Group	Shanghai Pharmaceutical (group) Co.,Ltd.	China National Pharmaceutical Group Corporation
2	Xiuzheng Pharmaceutical Group Co. Ltd.	China Shijiazhuang Pharmaceutical Company	Weigao Holding Company Limited
3	Shanghai Pharmaceutical(group) Co. Ltd.	Tasly Group	Shanghai Pharmaceutical(group) Co.,Ltd.
4	Harbin pharmaceutical group	Harbin pharmaceutical group	Shandong Buchang Pharmaceutical Co., Ltd.
5	China Shijiazhuang Pharmaceutical Company	Kangmei Pharmaceutical Co.,Ltd	Yangtze River Pharmaceutical Group
6	Tasly Group	China National Pharmaceutical Group Corporation	NHU Group Co., Ltd.
7	Weigao Holding Company Limited	Weigao Holding Company Limited	Harbin pharmaceutical group
8	Yunnan Baiyao Group Company Limited	Yangtze River Pharmaceutical Group	Yunnan Baiyao Group Company Limited
9	China National Pharmaceutical Group Corporation	Sichuan Kelun Pharmaceutical Co., Ltd.	Tasly Group
10	Guangzhou Pharmaceuticals Corporation	Qilu Pharmaceutical CO.,LTD.	Qilu Pharmaceutical CO.,LTD.
11	Bayer Group	Zhejiang Jianfeng Pharmaceutical Holdings	Hangzhou Sainuofei Anwante Minsheng Pharmaceutical Co., Ltd.
12	Taiji Group Co., Ltd.	Xiuzheng Pharmaceutical Group Co.,Ltd.	Guangzhou Pharmaceuticals Corporation
13	Northeast Pharmaceutical Group Co., Ltd.	Guangzhou Pharmaceuticals Corporation	Sichuan Kelun Pharmaceutical Co., Ltd.
14	Tianjin Zhongxin Pharmaceutical Group Corporation Limited	Yunnan Baiyao Group Company Limited	Kangmei Pharmaceutical Co.,Ltd.
15	HeiLongJiang ZBD Pharmaceutical Co.,Ltd.	Furen Medicine Group	Zhejiang Medicine Co., Ltd.
16	Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.	NHU Group Co., Ltd.	Jiangsu Hengrui Medicine Co., Ltd.
17	Sichuan Kelun Pharmaceutical Co., Ltd.	Taiji Group Co., Ltd	China Resources Dongeejiao Co.Ltd
18	Beijing Double-Crane Pharmaceutical Business Co., Ltd.	Zhejiang Hisun Pharmaceutical Co.,Ltd.	Xiuzheng Pharmaceutical Group Co.,Ltd.
19	Shanghai Roche Pharmaceutical Co., Ltd.	Northeast Pharmaceutical Group Co., Ltd	China Shineway Pharmaceutical Group
20	Shandong Buchang Pharmaceutical Co., Ltd.	Lunan Pharmaceutical Group Corporation	Jiangsu Chia-tai Tianqing Pharmaceutical Co., Ltd.

Source: Ministry of Industry and Information Technology of the People's Republic of China, The rank of manufacture firms in the pharmaceutical industry in 2011, <http://xfps.miit.gov.cn/n11293472/n11295176/n11298973/14522230.html>.

There are more and more foreign enterprises in China and their size is also increasing. From the absolute value of indicators, we can find that there were only 542 enterprises in 2000, while in 2010 they were 1,140.

<sup>9</sup> Ministry of Industry and Information Technology of the People's Republic of China, 12th five-year plan of Chinese pharmacy market, <http://news.pharmnet.com.cn/news/2012/01/20/352022.html>.

The total assets they hold moved from \$6.4 billions to \$44.34 in 2010. In 2010, revenues from principal business reached 44.77 billion (ten times of that in 2000), while total profit was about 6 billion in 2010 (15 times of that in 2000). See Exhibit 4.

*Exhibit 4 - Main Indicators of foreign firms in the Chinese market*

Year	n. unit	Gross industrial output value (\$100 million)	Total assets (\$100 million)	Revenue from principal business (\$100 million)	Total profits (\$100 million)	Value added tax payable (\$100 million)	Annual average number of employees (10,000 persons)
2000	542	48.77	64.00	44.19	3.97	3.64	-
2001	568	54.76	70.11	51.05	4.69	4.17	-
2002	604	63.41	78.68	59.82	5.58	4.92	-
2003	701	76.84	93.34	69.67	8.37	5.29	16.92
2004	743	-	100.35	76.96	9.16	5.50	16.63
2005	890	127.92	145.06	118.05	12.60	8.27	22.62
2006	955	159.44	169.67	148.84	14.78	9.55	25.29
2007	1035	214.11	218.87	198.40	24.81	12.87	27.40
2008	1144	307.19	303.03	287.39	37.45	18.71	31.77
2009	1144	386.23	375.34	372.69	48.31	22.20	34.77
2010	1140	468.47	443.41	447.74	60.75	26.72	38.21

Source: China Statistical Yearbook, several years.

In 2010, firms from abroad produced 27.01% of gross industrial output value, 26.55% of prime operating revenue, 30.89% of total profit, and 27.1% of total assets (Exhibit 5). Anyway, despite the importance of foreign companies, their share in the market is not overtaking national firms, that are keeping their role and competitive position.

Competition and rivalry among foreign firms and Chinese companies is going to be strongly affected by the changing landscape in proprietary technology. At the moment, foreigners hold the monopoly in many proprietary technologies. In the insulin market only, Novo Nordisk, Eli Lilly and Sanofi controlled more than 90% of the sales in 2010<sup>10</sup>. This situation is going to change rapidly. In fact, more than 10 of the world's best-selling drugs, including Pfizer's cholesterol-lowering Lipitor and Lilly's antipsychotic Zyprexa, lost patent protection in 2011. This is expected to directly result in a nearly US\$5 billion reduction in those global pharmaceutical companies' revenue. Furthermore, it is estimated that more drugs valued at about 77 billion \$ in total are going off patent within the next five years. Generic drugs are the mainstay of China's pharmaceutical industry, and are likely to remain so for a long time (Deloitte, 2011). In this regard, foreign enterprises should play a more and more important role in Chinese non-Generic drugs market, while Chinese state-owned firms and private companies should have a relevant market share in the generic drug market.

*Exhibit 5 - The role of foreign enterprises in the pharmaceutical market (% of total market)*

Year	Number of Enterprises	Gross industrial output value	Total assets	Prime operating revenue	Total profit
2000	16.42	22.66	18.93	22.48	24.06
2001	16.28	22.21	17.69	21.96	23.08
2002	16.41	22.07	17.63	21.71	22.92
2003	17.25	22.01	17.90	20.97	26.69
2004	16.90	---	17.31	19.82	27.13
2005	17.90	24.65	21.41	24.06	30.52
2006	17.79	25.32	22.04	25.15	31.62
2007	18.01	25.59	24.06	25.28	32.46
2008	17.54	27.09	26.70	26.96	32.80
2009	16.81	27.94	27.45	28.02	33.20
2010	16.20	27.01	27.00	26.55	30.89

Source: China Statistical Yearbook, several years.

<sup>10</sup> See: China Medical Association, *The Development of Insulin Market in China*, <http://www.chinamsr.com/2011/0124/21748.shtml>.

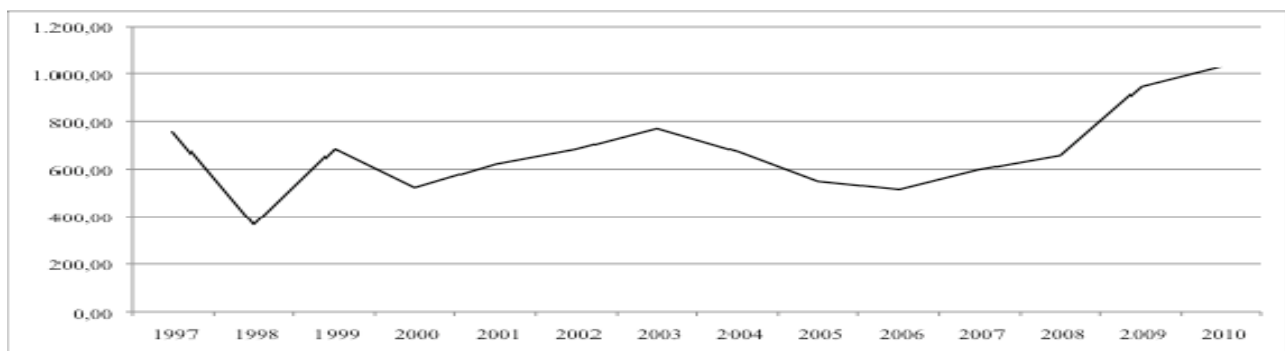


#### 4. The foreigners' hunger for China

As shown in the previous paragraphs, foreign firms play an increasing role in China. Most of them have made collaborative partnerships with Chinese companies to start manufacturing plants, business operations facilities, marketing divisions, and research facilities.

As a result of the *Open Door Policy*, China has been attracting huge flows of FDI and has become the first recipient of FDI among emerging market, the second after the US in absolute term (Unctad, WIR, 2011). The Chinese pharmaceutical industry has been one of the most interesting target for foreign investors. At the end of 1998, there were 1,500 pharmaceutical firms with foreign ownership (Jiang, 2005, p. 22). Since 2000, investments have nearly doubled (see Exhibit 6). Large multinational groups from North America, Western Europe, and Asia were attracted to China, as a result of a more friendly and favourable business and institutional environment. Operating in the Chinese market is still considered high-risky, time-consuming and expensive compared to other emerging markets due to stringent regulations concerning safety and efficacy. Anyway, the interest for China is increasing and several factors can explain this trend.

Exhibit 6. Inward FDI in China in the Medical & Pharmaceutical Product sector (million US dollars)



Source: own calculation on data provided by CeSif, Fondazione Italia Cina - Ceic

First of all, China is an important sales market for the internal, booming demand (Jiang, 2005)<sup>11</sup>. As mentioned above, China is supposed to become the second world largest pharmaceutical market by 2020, as a result of demographic changes, improved life standards, government actions. Upgrading health care behaviours and consumptions, Chinese people are changing their attitude towards Traditional Chinese Medicine practices. Western medicines are considered more effective, especially as for life-saving drugs are concerned, antibiotics most of all.

China is also strategic for Western companies to reach other nearby Asian emerging markets: as operating in the country can offer a logistic and commercial platform to penetrate them.

Second factor, China is a market for delocalizing the production of high quality and price competitive raw materials. In some specific market segment (antibiotics, cephalosporin o other high chemical substances),

<sup>11</sup> In the study developed by Jiang (2005) on determinants of FDI into China, the author found out that FDI were pushed mainly by China's specific location factors. China's market size and its potentials played the most important role. Other relevant motivations were: rapid economic development and growth, China's Open Door Policy and relatively stable political conditions.

producing in China is a necessity. In the West, in fact, environmental and safety rules make it impossible to set up fermentation and chemical plants associated with pharmaceutical plants.

The delocalization phenomenon is not recent. Internationalization in China began in the middle 80's, when important pharmaceutical groups settled fermentation plants in the North of the country to produce basic products for antibiotics. During the '90, production in China evolved, including more sophisticated products/materials. Nowadays, China is the world leader in the production of pharmaceutical base materials, that are then re-imported in the Western markets to produce finished goods (medicines). This phenomenon could justify the huge increase in imports and exports volumes, as well. See exhibit 2.

Third aspect, China is the frontier to develop applied research programs. Big players such as Novartis, Pfizer, Merck Serono, AstraZeneca, Roche have established research centres in China (see box 1 and Exhibit B in Appendix). The strategic idea is to leave good R&D departments in the country of origin to develop basic programs. The implementation phases and applied research activities are carried out in China, to reduce time for drug improvement and to cut costs (Datamonitor, 2009, p. 13). The core phases related to market entry of a new drug are left in the West, partly because of stringent rules of trials required by the U.S. and European agencies<sup>12</sup>. All other, subsequent, trials and market extension activities are developed in China, where skilled labour workforce, talented scientists and leading University research centres are available (Tung, 2011).

China is more and more considered as a platform to develop innovative drugs (Choy et al., 2011, p. 6). The booming success of Chinese Contract Research Organizations (CROs) - the backbone of Chinese R&D - is a proof of this phenomena. They support the pharmaceutical and biotechnology industries on a contract basis, providing specific services: biopharmaceutical development, preclinical research, clinical research, as well as clinical trials management<sup>13</sup>.

Chinese CROs are expanding the activity of the value chain that they can serve (see Exhibit A in Appendix), and thus upgrading their role in the Chinese pharma industry. They range from large and global organizations to niche specialty groups, offering reduced costs and high flexibility. "Almost every global biopharma company outsources at least some of its R&D activities to China" (BCG, 2011, p. 2). Industry projections forecast an increase role of CROs as high quality service providers, both for longlasting cooperation and for a "one-stop" shop approach. CRO are considered as a valuable source of innovation for Western pharmaceutical companies to develop strategic alliances to boost both research and development of new products. At the same time, CRO are economic and effective way for buying "on demand" innovation to face specific and/or unplanned needs.

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<sup>12</sup> "The globalisation process of industry-sponsored clinical trials is growing. More and more study sites are located outside North America and Europe, especially phase III trials. From the latest analysis, there are now more phase II-III trial sites in the rest of the world (ROW) than Europe; 27.0% versus 24.6%, respectively. [...] The major emerging regions are still Eastern Europe, Asia and Latin America". Cfr. Karlberg, Speers, 2010, p. 58.

<sup>13</sup> At the end of 2007 the value of R&D outsourced to China, mostly through CROs, was worth \$550 million (Shen, 2008).

### *Box 1 - Major Western pharmaceutical R&D centers in China*

#### *AstraZeneca*

Innovation Center China (ICC) opened its lab facilities in Zhangjiang Hi-tech Park in October 2007. ICC's presence is traced back to the announcement, in May 2006, of a large \$100 million R&D investment in China. The initial concentration is on cancer through the development of knowledge about Chinese patients, biomarkers and genetics. Researchers at the facility work on the identification, development and validation of new biomarkers. The centre also draws on the extensive alternative compound resources of AstraZeneca to analyse and select suitable drugs for Chinese patients. These also provide useful data for further decision-making in clinical trials (<http://en.astrazeneca.com>)

#### *Bayern*

Bayer, a leading healthcare product manufacturer, has been developing an investment plan in China since 2009 to establish a research and development (R&D) center in Beijing, the company's first foot in Asia. "China is home to a large pool of skilled medical and scientific talents. Our goal is to work closely together with our Chinese partners to support China conducting their own R&D activities and at the same time we will be able to strengthen our own R&D capabilities" (<http://www.bayer.cn/index.php/NewsCenter/newsDetail/id/161?l=en-us>).

#### *Merck Serono*

Merck Serono has recently established a global R&D center in Beijing, supported by a four year investment of \$225 million. The center, which will eventually house 200 employees, will be the fourth major R&D center for the company (<http://seekingalpha.com>).

#### *Novartis*

Novartis, in 2009, announced its five year plans to invest \$1.25 billion in its two Chinese R&D centers. In 2007 the Novartis Institute of BioMedical Research was opened in Shanghai ([http://www.businessweek.com/globalbiz/content/nov2009/gb2009113\\_520982.htm](http://www.businessweek.com/globalbiz/content/nov2009/gb2009113_520982.htm)). Two years later another center was established in Changshu, near Shanghai, to develop and manufacture active pharmaceutical ingredients (API). In March 2011, Novartis expanded its presence in the Chinese vaccine market by acquiring an 85 percent stake in Zhejiang Tianyuan Bio-Pharmaceutical Co Ltd, one of the largest private vaccine companies in China (Tung, 2011).

#### *Pfizer*

Pfizer recently has been undertaking a series of initiatives in China to tap the expertise of Chinese academics and professionals. The aim is to enhance its capabilities in the research and development field. Pfizer has grown its work force at its Shanghai R&D center to 342 from the 14 hired in 2005, when the center was established (Yan, 2009). After Shanghai, in 2010, Pfizer completed a greenfield scientific center in Wuhan in China's midwest region, in the Biolake scientific park.

#### *Roche*

Roche has established the R&D Centre China LTD (RRDCC) in 2004 in Zhangjiang Hi-Tech Park in Shanghai, for pharmaceutical R&D, employing about 100 people (Burkitt, 2010). The group also controls in China: Roche Holding Shanghai, Roche Diagnostics (Shanghai) Limited, Shanghai Roche Pharmaceuticals Limited.

Part of the interest of key Western pharmaceutical companies into the Chinese market can also be related to the potentials of Traditional Chinese Medicine – TCM (Shen, 2008, p. 22).

The popularity of alternative or holistic medicines has increased significantly in recent years within the general public (Datamonitor, 2010, p. 15). Annual global trade in herbal medicine has surpassed \$40 billion, with an annual growth rate of 10 percent (Zhang, 2011). Chinese companies do not have a primary role in this market. China had nearly 4,700 herbal medicine companies by the end of 2010, with annual output worth 1.2 trillion yuan (\$186.5 billion). The sector is fragmented, with the top 10 formulated TCM companies accounting for 14% of total market share. Local companies, including many state-owned enterprises dominate the internal Chinese market (PWC, 2009, p. 4).

Most of China's herbal medicine companies have a low internationalization profile (Zhang, 2011). Only about 3 percent of the global TCM market is in the Chinese's hands. There is therefore huge space for partnership and alliances by Western companies that could help pushing the Chinese firm in the international arena. One of the key problems in expanding abroad is related to intellectual property rights, trademark

registration and patent applications. Chinese companies are still weak in promoting their products on the global market (Zhang, 2011)<sup>14</sup>.

## 5. Patenting trends

Technological innovation achievements in the Chinese pharmaceutical market are remarkable. 3 billion \$ were invested in innovation medicine by government in the form of “significant new drug”, attracting also non-public funds into the sector. More than 50 state-level technical centers were built up in the form of “Industry-University-Institute” Cooperation programs. Innovative Medicines, such as Antofloxacin hydrochloride and recombinant *Helicobacter pylori* vaccine, were approved. Some Monoclonal antibody agents, such as Recombinant Human Tumor Necrosis Factor, had achieved industrialization. Breakthrough was made in cells culture in a large scale and biocatalysis and so on. The production technology of some products, such as amoxicillin and Vitamin E, was enhanced. Achievements were made in the area of product and technology development<sup>15</sup>.

In such a flourishing environment, China has been very active in patent applications. According to the statistics from WIPO in 2011, the quantity of Chinese patent applications was increasing rapidly compared with other leading countries. China applied 10,894 patents in 2010, which was 7 times of that in 2000. China became the second largest patent application country after US exceeding Japan and German in 2005 (see Exhibit 7).

*Exhibit 7 - The pharmaceutical patent application by leading countries (2000-2009)*

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
The United States of America	9,989	11,386	15,069	16,877	18,584	21,872	22,155	21,884	20,957	19,497
China	1,347	2,509	3,445	4,178	4,689	8,385	9,578	11,157	10,962	10,894
Japan	2,949	3,240	3,814	4,514	5,112	5,528	5,694	5,358	5,165	5,297
Germany	2,708	2,990	3,965	4,428	4,727	5,236	4,814	4,229	3,899	3,649
Switzerland	854	1,129	1,504	1,993	2,598	2,991	2,839	3,098	3,332	2,992
France	1,647	1,667	1,875	1,881	2,134	2,159	2,174	2,234	2,326	2,488
Britain	1,933	1,866	1,944	2,122	2,306	2,268	2,203	2,215	2,184	2,103
The Republic of Korea	518	648	880	1,089	1,140	1,295	1,186	1,149	1,342	1,842

Source: WIPO Statistics Database, 2011, based on the WIPO IPC-Technology concordance table.

Considering the industrial sectors involved in patenting in China, from 2000 to 2008, pharmaceutical has been the industrial sector that applied the highest number of patents (see Exhibit 8).

<sup>14</sup> The case of European market is significant. It is the second world’s largest market for herbal medicine, after China. The position of Chinese companies is neglectable. Consider that after the European directive in 2004, regulating herbal medicines, a company must demonstrate that a herbal medicine has been in use for at least 30 years, including 15 years in the EU. “It must also get a certificate that it meets standards for quality and safety. In the seven years following adoption of the regulation, none of the 350 newly authorized herbal medicines came from China” (Zhang, 2011).

<sup>15</sup> Ministry of Industry and Information Technology of the People’s Republic of China: 12th five-year plan of Chinese pharmacy market. <http://news.pharmnet.com.cn/news/2012/01/20/352022.html>.

*Exhibit 8 - Patent applications published by field of Technology from 2000 to 2009, in China*

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Pharmaceuticals	1,347	2,509	3,445	4,178	4,689	8,385	9,578	11,157	10,962	10,894
Telecommunications	270	534	933	1,697	2,376	3,560	5,679	7,190	10,055	6,782
Computer technology	778	1,156	1,740	2,683	3,346	4,710	5,226	7,336	9,645	11,818
Biotechnology	428	2,570	2,198	1,343	1,561	2,329	2,472	2,787	3,873	4,574
Chemical engineering	428	578	692	1,053	1,131	1,877	2,191	2,884	4,061	4,785
Environmental technology	344	477	656	862	1,030	1,688	1,967	2,308	3,232	4,020

Source: WIPO Statistics Database, 2011, based on the WIPO IPC-Technology concordance table.

Domestic firms lead the patent application market (see Exhibit 9). Taking medicine manufacturing industry as an example, there were only 273 patent applications in 1995, and this number increased to 8,601 in 2009 which was almost 30 times of that in 2000. There were only 183 patents granted in 1995, and this number increased to 6,017 in 2009. In the meantime, the patent applications and granted patents of foreign enterprises were also increasing. From 23 patent applications made by foreign enterprises in 1995, the number increased to 923 in 2009, while granted patents increased from 19 in 1995 to 986 in 2009.

Patents are becoming more and more popular also for TCM. The Chinese State Intellectual Property reported that since 1985, more than 68,000 TCM patents were registered. Over 66,000 of them were from domestic applicants (Jingjing, 2010). At the same time, China has applied for 3,000 TCM patents in foreign countries, but foreign countries applied for more than 10,000 TCM patents in China. Big pharmaceutical players have not a significant “place” in this market yet. Consider that only GlaxoSmithKline has registered in 1997 a TCM patent on “a pharmaceutical composition for the prevention and treatment of gastrointestinal diseases, and its preparation method”<sup>16</sup>, while Roche has registered two TCM patents: on “the use of erythropoietin and iron preparations for producing pharmaceutical combination preparations for treating rheumatic diseases” and the other on “hedgelog protein medicinal composition and its use/a protein solution and its use”. Other Western important players do not appear in the database of Traditional Chinese Medicine patents (Spigarelli, Farah, Filippetti, 2012).

*Exhibit 9 - Patent application and patent granted in Chinese manufacturing industry (1995-2000)*

Year	Total		Foreign enterprises		Foreign enterprises (proportion, %)	
	Patent application	Patent granted	Patent application	Patent granted	Patent application	Patent granted
1995	273	183	23	19	8.42	10.38
1996	168	113	67	54	39.88	47.79
1997	257	134	38	25	14.79	18.66
1998	275	224	95	62	34.55	27.68
1999	283	232	30	16	10.60	6.90
2000	547	414	87	168	15.90	40.58
2001	735	308	139	62	18.91	20.13
2002	999	484	70	64	7.01	13.22
2003	1,305	459	208	91	15.94	19.83
2004	1,696	902	354	145	20.87	16.08
2005	2,708	1,134	594	273	21.94	24.07
2006	2,383	1,965	575	495	24.13	25.19
2007	3,056	2,482	589	747	19.27	30.10
2008	3,917	3,170	863	853	22.03	26.91
2009	8,601	6,017	923	766	10.73	12.73
2010	5,767	5,672	841	986	14.58	17.38

Source: China Statistical Yearbook On High Technology Industry, several years.

<sup>16</sup> See <http://chmp.cnipr.cn/englishversion/help/help.html>.

Chinese consumers have high confidence in foreign patented brands, that – as a result - are expected to win drug customers away from the domestic generic brands, causing their proportional market shares to shift accordingly. Sales of patented drugs, which rocketed upward at a CAGR of 35.7 percent from 2007 through 2010, are forecast to continue growing at just over 25 percent from 2010 through 2015 (Deloitte, 2011).

The increasing role of foreign enterprises in patent applications and granted patents can be considered a combined consequence of improved IP protection made by the Government and of the booming pharmaceutical demand in China.

The Government has adopted industrial and regulatory policies, such as preferential drug pricing and hospital drug procurement policies, that favour research-based MNCs and large domestic enterprises. At the same time, it has improved market access for foreign companies and taken steps to strengthen intellectual property protection to foster innovation. A huge effort has been made also to regulate and approve APIs and audit drug production facilities (Shen, 2008, p. 21).

Despite such policies, however, foreign companies remain concerned with certain areas of IP protection in the pharmaceutical sector. Specifically, the central government has not (Shen, 2008) yet clearly defined “new chemical entity” in a drug, which would make ensuring data exclusivity during drug registration difficult. More over, it has not adequately protected against unfair commercial use of undisclosed test and other data submitted by pharmaceuticals companies. A more robust system of patent linkage under which the filing of a lawsuit will automatically suspend the registration process of a product suspected of infringement is missing. At the same time, there is a lack of a system of patent-term restoration to help innovative companies recover patent-term losses due to long development time and regulatory delays.

## **6. Conclusions**

Major players of the World pharmaceutical market are investing in China, where they can have access to a rapidly growing market to sell Western products, as well as to incentives and facilities to develop high level R&D activities.

An R&D driven re-evolution of the market is taking place, thanks to the Government’s policies aiming at building a friendly environment for Western firms, attracted in China not only to be partners of local actors and grasp knowledge from them, but also to become customers of a more and more qualified R&D oriented supply. At the same time, the Government is supporting the growth of global-national champions, reorganizing SOEs and pushing new private pharmaceutical firms. The rise of Chinese innovative and large multinationals is promoted (Shen, 2008, p. 21).

The role of industrial policies is thus fundamental to understand the scope of changes undergoing in China. Huge efforts in R&D is resulting in booming patents in the field: pharmaceuticals is the industrial sector which applied the highest number of patents in recent years. Domestic enterprises are the main force, but patent applications and granted patents of foreign enterprises are increasing as well. Acquisition of distinctive knowledge (as far as TCM is involved) does not seem to be strategic, for Western companies entering the Chinese market. TCM industry and patents are currently dominated by national firms.

In sum, Chinese market seems to be evolving into a highly competitive marketplace, where Chinese firms are training not only to keep market shares compared to Western firms, but also to conquer an active and strategic position in the global value chain of the World pharmaceutical market.

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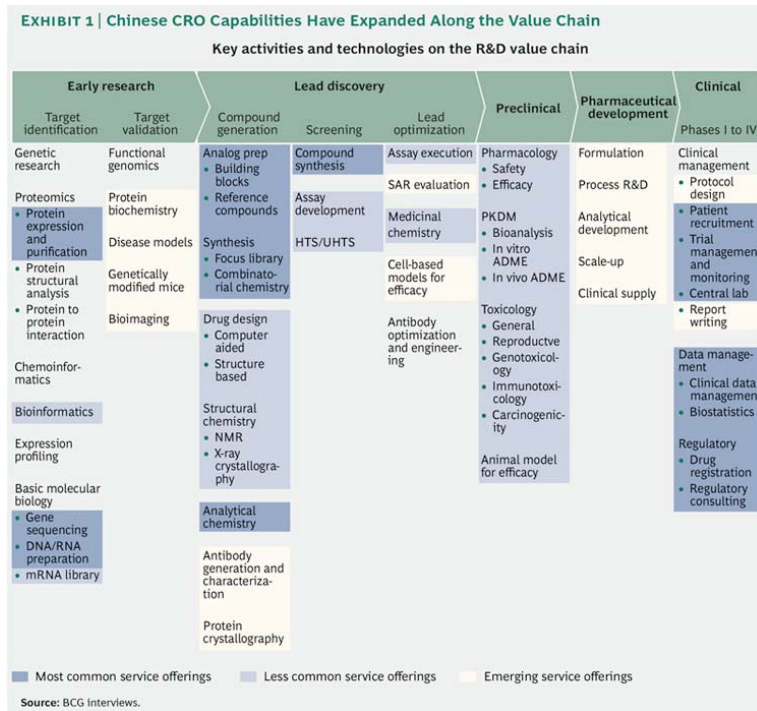
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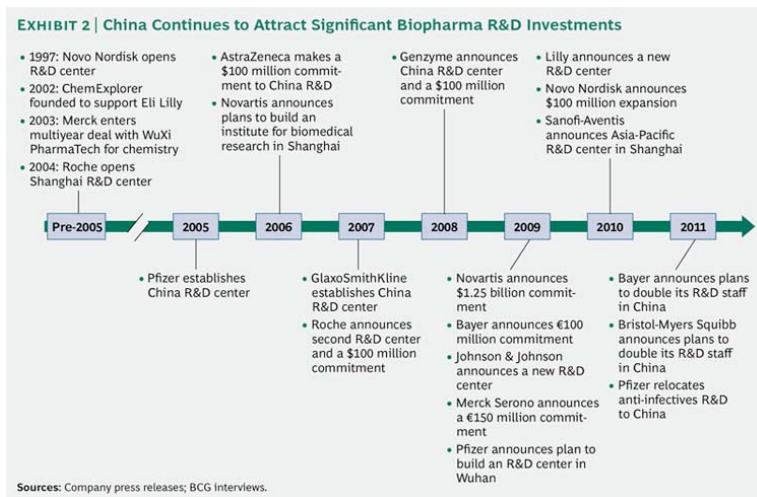
## Annex

### Exhibit A Chinese CROs: their role in the industry value chain



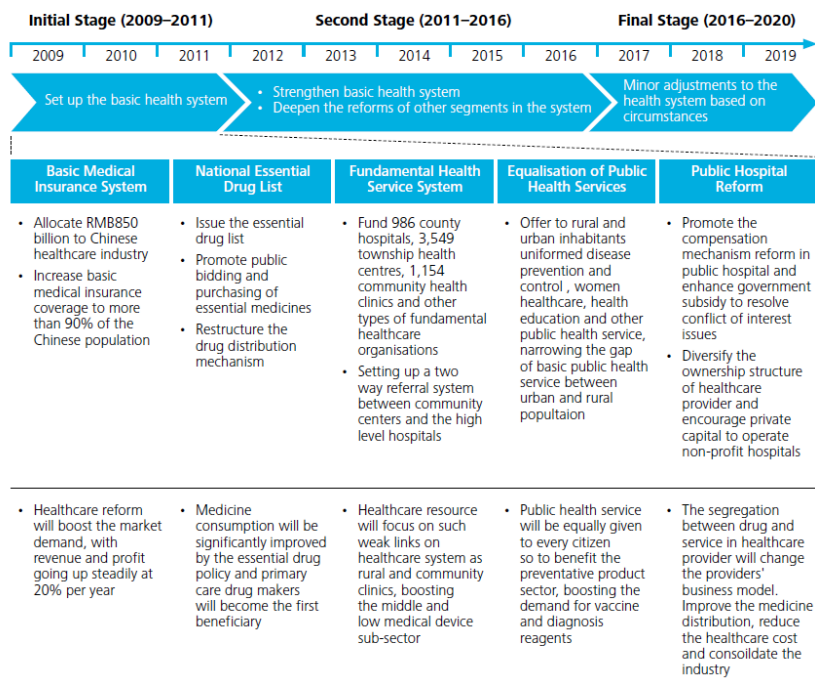
Source: BCG, 2011.

### Exhibit B Main foreign investment initiatives in China in the R&D sector



Source: BCG, 2011.

## Exhibit C Main Steps in the Chinese Healthcare reform



Source: Deloitte, 2011, p. 3.