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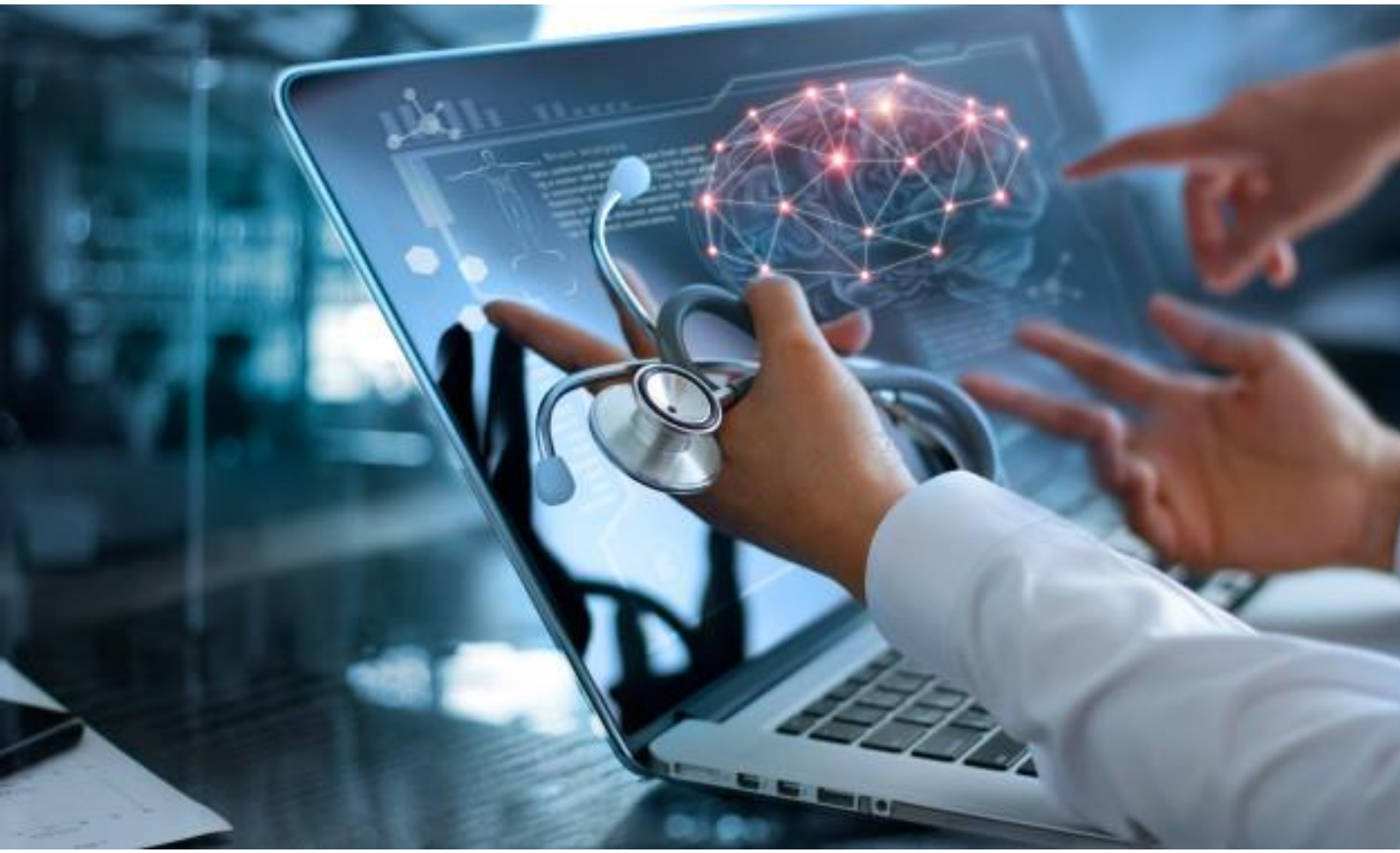
The Healthcare Market in China



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Executive summary

In 2019, China's healthcare import and export volumes both saw an increase from the previous year, reaching the highest levels since 2011. Europe, Asia, and North America were China's top three continental partners for healthcare foreign trade. In terms of countries, the US continued to be China's number one trading partner, followed by Germany, Japan, India, and Ireland. Under the Belt and Road Initiative, there have been higher rates of overseas investment, M&A, and both in- and out-licensing. Developing healthcare reform in China continued to unleash new market opportunities, while international registrations and certifications acquired by Chinese companies were also on the rise.[1]

The global outbreak of COVID-19 has placed the healthcare and life sciences industries under the spotlight. As a result of the pandemic, the public are now paying more attention to topics such as early warning and prevention of infectious diseases, vaccine research and development, medical equipment, and online medical services.

In March 2021, the 14th Five-Year Plan (2021-2025) was published, putting forward a detailed plan for the development of the healthcare and life sciences industries in China. The plan covers a range of areas, including overall planning and reimbursement for medical insurance, the multi-tiered healthcare system, social medical services, remote medical treatment, traditional Chinese medicine, and chronic disease management, providing a wide variety of development prospects for these industries.[2]

This report will provide an overview of the healthcare sector in China. The first chapter focuses on the key factors and drivers that are shaping the sector in China, especially the increasingly supporting role of the Chinese government in issuing key development plans and regulations, as well as the rapidly ageing Chinese population. The second chapter provides a deeper analysis of China's healthcare providers, in particular the number of public vs private healthcare institutions, services, beds and personnel. The third chapter is the core section of the report: it provides up-to-date information on the market, regulations, key players and market entry requirements for three subsectors: (i) pharmaceuticals; (ii) medical devices; and (iii) healthcare services. The last chapter of the report summarises the main opportunities, challenges and key success factors that European SMEs should bear in mind when exploring the highly-competitive and difficult Chinese healthcare market.

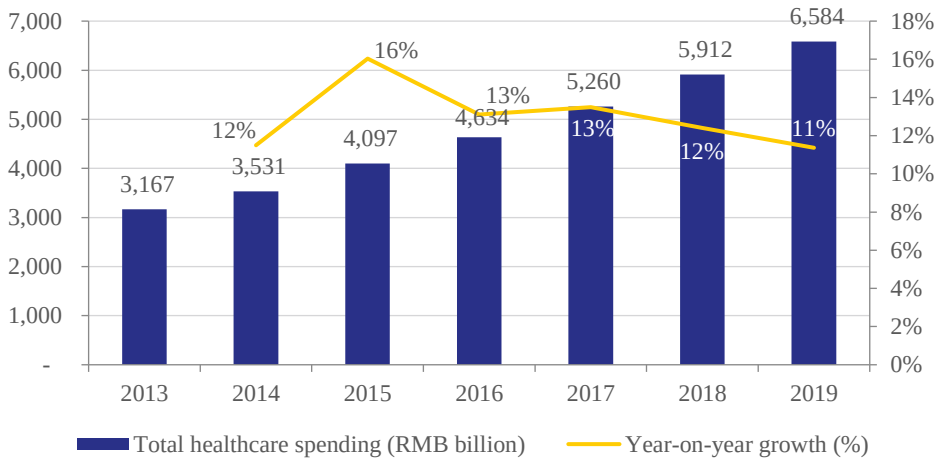
[1] *http://www.cccmhpie.org.cn/Pub/1757/176093.shtml (accessed: 29 June 2021).*

[2] *KPMG report: https://home.kpmg/cn/en/home/insights/2021/01/14th-five-year-plan-industry-impact-outlook.html (accessed: 29 June 2021).*

1. Sector overview

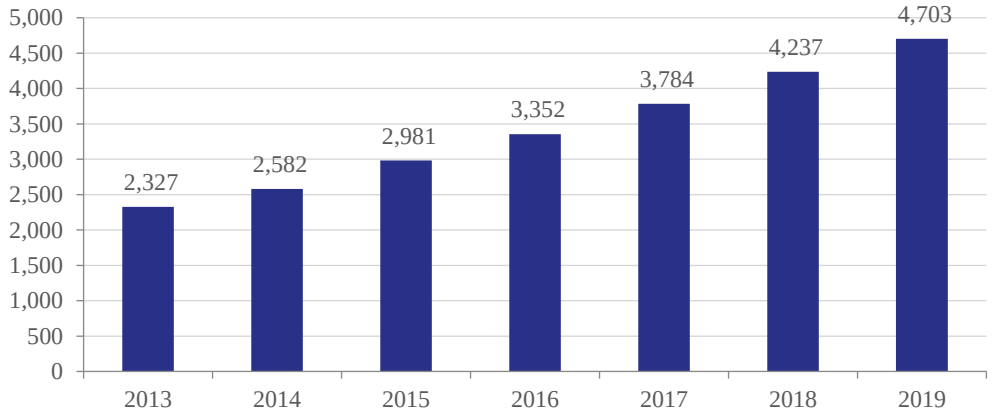
According to data from the National Bureau of Statistics, [3] China's total healthcare spending – including expenditure from the government, companies, social organisations, and individuals –stood at RMB 6.58 trillion (€850 billion [4]) in 2019, accounting for approximately 6.6% of the country's GDP that year. In the United States, the total healthcare spending in the same year accounted to 17% of its GDP.

Figure 1: China's healthcare expenditure, 2013-2019, RMB billion[5]



From 2013 to 2019, China's healthcare spending increased from RMB 3.17 trillion (€0.4 trillion) to RMB 6.58 trillion (€0.85 trillion), with the highest year-on-year growth in 2015.

Figure 2: China's healthcare spending per capita, 2013-2019, RMB[6]



In 2013, an average of RMB 2,327 (€301) per capita was spent on healthcare needs; this value more than doubled between 2013 and 2019, reaching RMB 4,703 (€608) in 2019. This figure, together with China's total healthcare spending, is expected to increase further as China's population ages, resulting in more elderly relatives to support within many families.

[3] *Source: National Bureau of Statistics, http://www.stats.gov.cn/english/ (accessed: 30 June 2021).*

[4] *€1 = RMB 7.73*

[5] *Ibid.*

[6] *Ibid.*

1.1. Government support

Large-scale healthcare reform in China was initiated by the Chinese government in 2009. The goal at the time was to "provide affordable and equitable basic health care for all by 2020".[7] Specifically, the reforms aimed to increase public healthcare insurance coverage through three public insurance channels:

- Urban Employee Basic Medical Insurance (UEBMI) for the urban workforce and the retired; [8]
- Urban Resident Basic Medical Insurance (URBMI) for urban residents who are not in the workforce;
- New Cooperative Medical Scheme for rural residents.

Other highlights of the reforms included improving public health services, expanding the number of general practitioners, and lowering the price of pharmaceuticals. An Essential Drug List (EDL) was introduced by the then National Health and Family Planning Commission (now known as the National Health Commission or NHC) in 2009, allowing patients to be reimbursed when purchasing drugs listed. The EDL is updated on a regular basis: the latest version is from 2018 and includes 685 medicines.[9]

Healthy China 2030

On 25 October 2016, the Central Government and the State Council issued the *Outline of the Healthy China 2030 Plan*, which is the national medium- and long-term strategic plan for the health sector.[10] *Healthy China 2030* aims to increase life expectancy, decrease the death rate, optimise healthcare resources, improve the medical insurance system, and improve the living environment. The implementation of *Healthy China 2030*, with key indicators set by the Chinese government summarised in Table 1, draws on the strength of China's health science and technology innovation and helps improve the quality and level of health service delivered across the country, which will contribute to the development of the healthcare and life science industry in China and provide opportunities for stakeholders in these sectors.

The 14th Five-year Plan

On 11 March 2021, the 14th Five-Year Plan (FYP) was announced, laying out the national strategic development plan for 2021 to 2025. Regarding the healthcare sector, the 14th FYP states that the government will further promote the construction of a "Healthy China". Specifically, the action plan includes the following: [11]

- Establish a strong public health system;
- Deepen the reform of the medical and health sectors;
- Improve the medical insurance system for all people;
- Promote the inheritance and innovation of traditional Chinese medicine;
- Build up a sports-strong country;
- Carry out a patriotic health campaign.

[7] *https://www.euro.who.int/en/publications/abstracts/pharmaceutical-policy-in-china-challenges-and-opportunities-for-reform-2016 (accessed: 29 June 2021).*

[8] *http://www.hnjh.gov.cn/4/444/447/2758/content_2291192.html (accessed: 29 June 2021). Urban residents are those who hold the urban household registration certificate (urban* hukou*), and rural residents are those under the rural household registration certificate (rural* hukou*).*

[9] *http://www.nhc.gov.cn/ewebeditor/uploadfile/2018/10/20181025183346942.pdf (accessed: 29 June 2021).*

[10] *http://www.gov.cn/zhengce/2016-10/25/content_5124174.htm (accessed: 29 June 2021).*

[11] *http://www.xinhuanet.com/2021-03/13/c_1127205564_14.htm (accessed: 29 June 2021).*

Table 1: Key indicators for the implementation of Healthy China 2030 [12]

	Indicator	2015	2020	2030
Health conditions	Average life expectancy (years)	76.34	77.3	79.0
	Infant mortality rate (‰)	8.1	7.5	5.0
	Under-five mortality rate (‰)	10.7	9.5	6.0
	Maternal mortality rate (per 100,000)	20.1	18.0	12.0
	Percentage of people meeting the fitness standards defined in the national physical fitness standards (%)	89.6 (2014)	90.6	92.2
Healthy living	Health literacy (%)	10	20	30
	Number of people regularly doing physical exercise (million)	360	435	530
Health services and health security	Premature mortality rate due to major chronic diseases (%)	19.1 (2013)	Decreased by 10% from 2015	Decreased by 30% from 2015
	Number of licensed doctors and assistant licensed doctors per 1,000 people	2.2	2.5	3.0
	Proportion of personal health expenditure to total health expenditure (%)	29.3	Approximately 28	Approximately 25
Living environment	Ratio of days with good air quality in cities at and above the prefectural level (%)	76.7	>80	Keep improving
	Ratio of surface water quality reaching Class III Standard (%)	66	>70	Keep improving
Healthcare industry	Total market size of healthcare service industry (RMB trillion)	——	＞8	16

Along with the action plan, the 14th FYP also proposes a National Health Security Project relating to building different facilities – summarised in Table 2. With the implementation of this project, medical device producers and relevant service providers could benefit from it.

Table 2: National Health Security Project [13]

National Health Security Project	
Disease prevention and control	Start the Phase II project of the China Disease Prevention and Control Centre; based on current disease prevention and control institutions, build 15 regional public health centres and upgrade 20 national major disease prevention and control bases and 20 national emergency medical rescue bases.

[12] *https://www.sahealth.sa.gov.au/wps/wcm/connect/d39abd8041032c76a711ff1afc50ebfc/1645+Ning+Zhuang.pdf?MOD=AJPERES (accessed: 29 June 2021); http://www.gov.cn/zhengce/2016-10/25/content_5124174.htm (accessed: 29 June 2021).*

[13] *Ibid.*

National Health Security Project	
National medical centres	Strengthen the construction of national medical centres for cardiovascular diseases, respiratory diseases, oncology, trauma, paediatrics, and others; build several high-level medical and medical innovation centres.
Regional medical centres	Encourage high-level medical institutions to build regional medical centres in provinces with limited healthcare resources; complete building of regional medical centres in Hebei, Henan, Shanxi, Liaoning, Anhui, Fujian, Yunnan, and Xinjiang provinces.
County-level hospitals	Encourage the distribution of advanced healthcare resources to support the development of county-level hospitals and seek to improve the quality of healthcare services and facility conditions to the level of Class 3 hospitals for 500 county-level hospitals (including traditional Chinese medicine hospitals).[14]
Traditional Chinese medicine development	Build 20 national inheritance and innovation centres for traditional Chinese medicine, 20 flagship hospitals of traditional Chinese and Western medicine, 20 traditional Chinese medicine disease prevention and rescue bases, and 100 key hospitals featuring traditional Chinese medicine.
Facilities for fitness	Build and/or rebuild 1,000 sports parks, and build facilities for outdoor sports, fitness, and other activities; promote the construction of football fields and running tracks.

1.2. Demographic change

With a rapidly growing economy and improving healthcare services, living standards and life expectancy in China have dramatically increased in recent decades. According to the China Health Statistics Yearbook 2019,[15] China's average life expectancy reached 77 years in 2018, only 2 years lower than the target set by *Healthy China 2030*.

According to the seventh national census report published on 11 May 2021, [16] China has a total population of 1,443,497,378, reflecting a 5.38% increase compared with data in 2010, with an average annual growth rate of 0.53% since 2010. The growth of the population has decelerated in recent years, mainly resulting from the falling number of births. In contrast, the ageing population in China is rising. There are 264,018,766 people in total aged 60 and above, accounting for 18.70% of the total population and growing by 5.44% since 2010; similarly, there are 190,635,280 people aged 65 and above, accounting for 13.50% of the total population.[17] Since 2000, the number of people aged 60 and above has increased by 8.4%, and it is believed that China's population will age more rapidly in the coming decades.[18]

[14] *http://www.nhc.gov.cn/cms-search/xxgk/getManuscriptXxgk.htm?id=4d84820f321144c290ddaacba53cb590 (accessed: 29 June 2021); http://www.nhc.gov.cn/fzs/s3576/201808/f674e82257a2471a9a68f5c369403042.shtml (accessed: 29 June 2021). Three-tier system: public hospitals in China are categorised into three classes – Class 1, Class 2, and Class 3, with Class 3 being the highest tier – according to standards including the facilities and doctors in the hospital. Each level is further categorized into three levels – Grade A, Grade B, and Off-specification, with Grade A being the highest level – according to a further set of standards.*

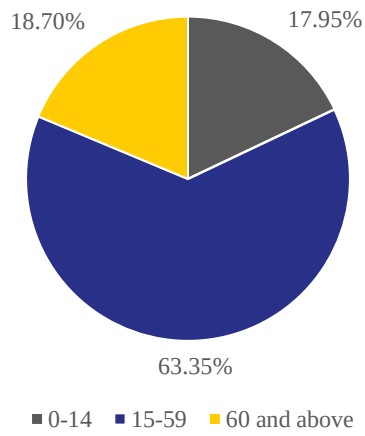
[15] *Source: China Health Statistics Yearbook 2019, https://www.yearbookchina.com/navibooklist-n3019102807-1.html (accessed: 30 June 2021).*

[16] *http://www.stats.gov.cn/tjsj/zxfb/202105/t20210510_1817178.html (accessed: 29 June 2021).*

[17] *http://www.stats.gov.cn/tjsj/zxfb/202105/t20210510_1817181.html (accessed: 29 June 2021).*

[18] *http://www.stats.gov.cn/tjsj/sjjd/202105/t20210512_1817336.html (accessed: 29 June 2021).*

Figure 3: Population structure by age, 2020[19]



Since implementing the reform and opening-up policy in the 1980s, China's urban population has increased from 191 million in 1980 to 902 million in 2020.[20] However, the urban population in China are not all permanent urban residents. Many inequalities exist between the wealthy eastern coastal cities and inland cities, with blue-collar and white-collar workers frequently migrating between their smaller and lower-tiered cities to the coastal cities where they work. Bound by the Chinese household registration system (*hukou*), a large proportion of migrant workers are ineligible to take full advantage of urban public healthcare insurance, posing a challenge to the Chinese healthcare system.

1.3. Future outlook

Since *Healthy China 2030* was issued in 2016, the Chinese government has formulated a series of guiding policies to achieve its targets, including:

- *Healthy China Action 2019-2030* [21]
- *Opinion on Implementing Healthy China Action* [22]
- *Implementation and Appraisal Programme of Healthy China Action* [23]
- *Healthy China Action - Prevention and Treatment Programme of Cancer 2019-2022* [24]

These four policies include more detailed information and set the phase-based action plans for achieving the goals set in *Healthy China 2030*. The focal points mentioned in these policies are:

- Undertaking the prevention and treatment of chronic non-communicable diseases, including cardiovascular and cerebrovascular diseases, chronic respiratory diseases, cancer, and diabetes;
- Undertaking the prevention and control of endemic and communicable diseases;
- Maintaining full-life circle health management, covering the health situations of maternity and infants, students, employees, and elderly people;

[19] http://www.stats.gov.cn/tjsj/zxfb/202105/t20210510_1817181.html *(accessed: 29 June 2021).*

[20] http://www.stats.gov.cn/tjsj/zxfb/202105/t20210510_1817183.html *(accessed: 29 June 2021).*

[21] http://www.gov.cn/xinwen/2019-07/15/content_5409694.htm *(accessed: 29 June 2021).*

[22] http://www.gov.cn/zhengce/content/2019-07/15/content_5409492.htm *(accessed: 29 June 2021).*

[23] http://www.gov.cn/zhengce/content/2019-07/15/content_5409499.htm *(accessed: 29 June 2021).*

[24] http://www.gov.cn/gongbao/content/2020/content_5483906.htm *(accessed: 29 June 2021).*

- Full-intervention into all factors that impact the health of people, including wide-spread communication of health management knowledge and promotion of fitness activities nationwide, tobacco control, mental health, and healthy environments.

The COVID-19 pandemic brought great challenges to China's disease prevention system, which made the Chinese government determined to build up a strong disease prevention system in the future. In June 2020, President Xi Jinping gave a speech at a forum for experts and scholars, revealing the post-pandemic agenda for disease prevention. The main points from this talk included: [25]

- Improving disease prevention and public health services;
- Optimising the functions of disease prevention institutions;
- Strengthening the ability of national disease prevention institutions and building up the pool of talent and technology;
- Building up the talent pool for disease prevention and updating mechanisms for talent cultivation;
- Prioritising capacity strengthening for early monitoring and early warning and improving related mechanisms;
- Gradually promoting the formulation of regulations for communicable disease prevention and responding to emergent public health issues.

In May 2021, the National Disease Prevention and Control Administration was established in order to deepen reform for the disease prevention system and establish a strong public medical system.[26]

[25] *http://www.gov.cn/xinwen/2020-06/05/content_5517338.htm (accessed: 29 June 2021).*

[26] *http://www.gov.cn/guowuyuan/2021-05/13/content_5606207.htm (accessed: 29 June 2021).*

2. Overview of healthcare providers in China

2.1. Healthcare resources

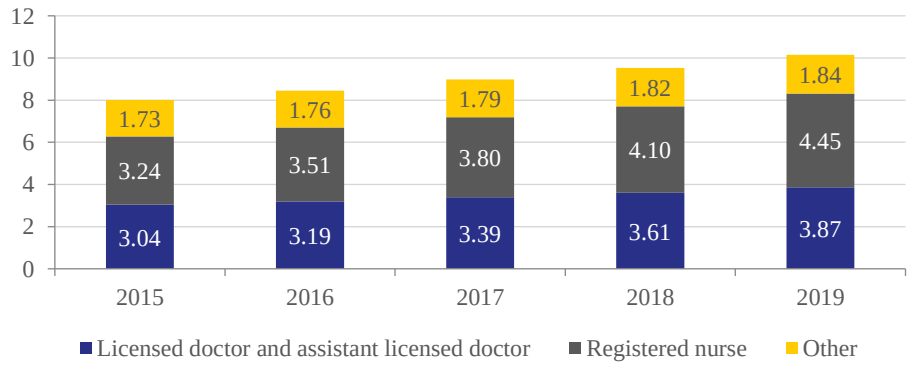
According to official statistics,[27] in 2019, there were total of 1,007,545 medical institutions nationwide, increasing by 10,112 from the previous year. Among these institutions, there were 34,354 hospitals, 954,390 grass-roots medical institutions (defined in Section 2.3), and 12,924 specialised public medical institutions. In 2019, there were also 8.81 million beds provided in medical institutions in total, increasing by 4.8% on a year-on-year basis. More specifically, there were 6.87 million beds (78%) in hospitals, 1.63 million beds (18.5%) in grass-roots medical institutions, and 285,000 beds (3.2%) in specialised public health institutions.

Table 3: The number of different types of medical institutions and beds provided in each institution type, 2018-2019

Types	Number of institutions		Number of beds	
	2018	2019	2018	2019
Hospital	33,009	34,354	6,519,749	6,866,546
Public hospital	12,032	11,930	4,802,171	4,975,633
Private hospital	20,977	22,424	1,717,578	1,890,913
Grass-roots medical institution	943,639	954,390	1,583,577	1,631,132
Specialised public medical institution	18,033	15,924	274,394	285,018
Other [28]	2,752	2,877	26,358	24,260
Total	997,433	1,007,545	8,404,078	8,806,956

Regarding the number of health personnel, in 2019, there were 12.93 million health workers, an increase of 628,000 (5.1%) from the previous year. Within this figure, 10.15 million were professional health personnel (up 6.6% from the previous year), including 3.87 million licensed doctors and assistant licensed doctors and 4.45 million registered nurses.

Figure 4: The number of professional health personnel in China, 2015-2019 (millions)



[27] http://www.gov.cn/guoqing/2021-04/09/content_5598657.htm *(accessed: 29 June 2021).*

[28] *"Other" refers to medical institutions other than hospitals, grass-roots medical institutions, and specialised public medical institutions. For example, physical examination institutions.*

2.2. Healthcare services

According to official statistics,[29] in 2019, there were a total of 8.72 billion visits to healthcare institutions nationwide, increasing by 410 million (4.9%) from the previous year. This included 3.84 billion visits to hospitals, while 4.88 billion visits were to grass-roots and other medical institutions. Among the visits taking place in hospitals, 3.27 billion visits were in public hospitals and 5.7 million visits were in private hospitals.

Regarding inpatients, there were 265.96 million inpatients in China in 2019, among which 211.83 million were in hospitals, 42.95 million in grass-roots medical institutions, and 11.18 million in other medical institutions. For inpatients in hospitals, there were 174.87 million inpatients in public hospitals, accounting for 82.6%, and there were 36.96 million inpatients in private hospitals, accounting for only 17.4%.

Furthermore, among public hospitals in Class 2 and above in 2019,[30] 59.1% of them conducted remote medical services, and 91.6% of them took clinical pathway management.

2.3. Grass-roots healthcare services

Apart from the state of healthcare providers at the nationwide level, grass-roots healthcare services, which are provided in rural areas and communities, are also significant in China. According to official statistics,[31] across 1,881 counties (county-level cities) in 2019, there were 16,175 county-level hospitals, 1,903 county-level maternal and child healthcare institutions, 2,053 county-level disease prevention and control centres, 1,724 county-level health supervision centres, and 3.23 million health personnel among the above four types of county-level health institutions.

By 2019, 35,013 community-based health service centres and stations had been set up, and there were 611,000 health personnel in these community-based institutions. In these health service centres, there were 690 million visits and 3.40 million inpatients, while in the community-based stations, there were 170 million visits.

2.4. Traditional Chinese medicine services

According to official statistics,[32] in 2019, there were 65,809 medical institutions specialising in providing traditional Chinese medicine services, with an increase of 5,071 from the previous year, and there were 1.33 million beds provided in traditional Chinese medicine institutions. 98.3% of the community-based health service centres provided traditional Chinese medicine services. That year, the total visits to traditional Chinese medicine institutions reached 1.16 billion.

[29] *http://www.gov.cn/guoqing/2021-04/09/content_5598657.htm (accessed: 29 June 2021).*

[30] *More details about China's three-tier system for hospitals in footnote 15.*

[31] *http://www.gov.cn/guoqing/2021-04/09/content_5598657.htm (accessed: 29 June 2021).*

[32] *Ibid.*

3. Overview of pharmaceutical, medical device, and healthcare service providers

3.1. Pharmaceutical

Market information

In 2019, China's pharmaceutical industry generated RMB 2.614 trillion (€0.34 trillion) in revenue, increasing by 8% compared to 2018.[33] The pharmaceutical industry in China can generally be divided into eight sub-sectors:

- Chemical preparations manufacturing;
- Chinese proprietary medicine (granules, pills, capsules) manufacturing;
- Raw materials manufacturing;
- Biomedicine manufacturing;
- Medical devices manufacturing;
- Chinese raw herbal processing;
- Hygienic materials and medical supplies manufacturing;
- Pharmaceutical equipment manufacturing.

Table 4: 2019 Chinese pharmaceutical industry revenue breakdown [34]

Sector	Total revenue (RMB billion)	Percentage (%)	Year-on-year growth (%)
Chemical preparations manufacturing	857.61 (€110.97B)	32.80	11.5
Chinese proprietary medicine manufacturing	458.7 (€59.36B)	17.54	7.5
Raw materials manufacturing	380.37 (€49.22B)	14.55	5.0
Biomedicine manufacturing	274.92 (€35.57B)	10.51	10.3
Medical devices manufacturing	271.48 (€35.13B)	10.38	11.6
Chinese raw herbal processing	193.25 (€25.01B)	7.39	-4.5
Hygienic materials and medical supplies manufacturing	178.14 (€23.05B)	6.81	5.3
Pharmaceutical equipment manufacturing	17.23 (€2.23B)	0.66	12.6
Total	**2,614.74 (€338.35B)**	—	**8.0**

The highest revenue-generating sub-sector in 2019 in the pharmaceutical industry was the chemical preparations manufacturing sector, which generated RMB 857.61 billion (€110.97 billion) in revenue. The Chinese proprietary medicine manufacturing sector was the second highest revenue-generating sub-sector, while the raw materials manufacturing sector generated the third highest revenue in the pharmaceuticals industry with RMB 380.37 billion (€49.22 billion). It is also noteworthy that in 2019, the manufacturing of pharmaceutical equipment had the highest year-on-year growth of 12.6%. The fixed-asset investment in the pharmaceutical industry grew by 8.4% in 2019 compared to 2018. In recent years, the Chinese government has strongly encouraged and supported innovation in the pharmaceutical industry, working towards improving the quality of generic drugs. As a consequence, pharmaceutical companies have increased investment in the R&D of new medicines and consistency evaluation, hence driving the growth of fixed-asset investment.

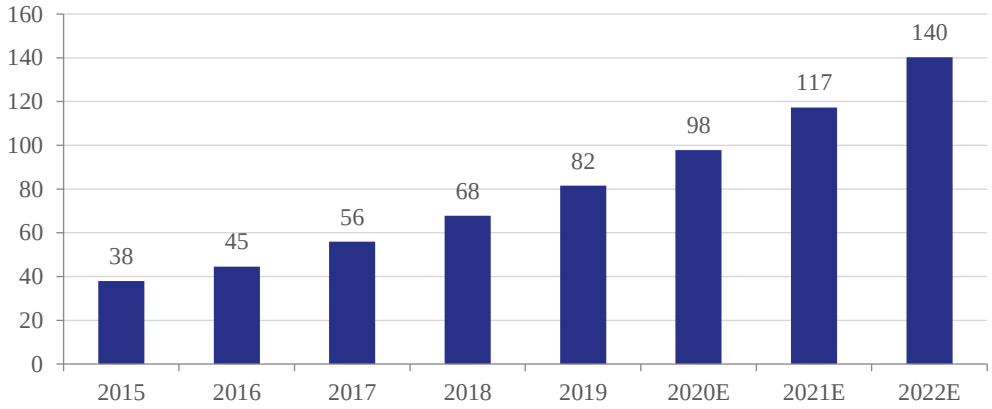
[33] *https://www.qianzhan.com/analyst/detail/220/201016-59cdc81f.html (accessed: 29 June 2021).*

[34] *Ibid.*

Contract research organisations (CROs)

The CRO industry in China has developed rapidly in recent years. In 2019, the CRO market in China was worth RMB 82 billion (€11 billion), and it is estimated that the market size will grow to RMB 140 billion (€18 billion) in 2022.[35]

Figure 5: CRO industry market size in China, 2015-2022E, RMB billion



Since 2017, the Chinese government has issued many policies to promote innovation in the pharmaceutical industry, which will be further expanded during the 14th FYP in order to upgrade and optimise the production of drugs. In 2020, 1,975 drugs were undergoing preclinical and clinical research in China, increasing by 30.3% compared to 2019. There were 177 venture capital/private equity (VC/PE) deals that took place in the innovative drug area in 2020, with the total value of deals reaching RMB 41.09 billion (€5.3 billion), growing by 110.0% compared to 2019.[36] It is expected that more investments in R&D for new drugs and government support will drive the development of the CRO industry, providing opportunities for CRO service providers.

Regulatory policies

In 2018, the State Council completed an institutional reform: many former regulatory bodies relating to the pharmaceutical sector were restructured and/or renamed. Table 5 presents a list of major governing authorities for the pharmaceutical industry and their responsibilities within the industry following the reform.

Table 5: Major authorities governing the pharmaceutical industry and their responsibilities post-institutional reform

Authority	Responsibility
National Health Commission (NHC) ***(formerly known as the National Health and Family Planning Commission (NHFPC); renamed to NHC after the 2018 institutional reform)***	▪ Drafts policies and regulations on national health. ▪ Promotes medical system reform and provides suggestions. ▪ Formulates drug policies and national essential drug systems, as well as participates in formulating the *Chinese Pharmacopoeia.* ▪ Formulates the administrative measures for the management of medical institutions and the medical service sector. ▪ Promotes the construction of elderly care service systems, as well as drafts policies regarding the ageing population. ▪ Guides the construction of grass-roots healthcare systems and maternity and child healthcare systems, as well as the cultivation of general practitioners.

[35] *https://www.askci.com/news/chanye/20210210/1412461359147.shtml (accessed: 29 June 2021).*

[36] *http://data.eastmoney.com/report/zw_industry.jshtml?infocode=AP202102261465968559 (accessed: 29 June 2021).*

Authority	Responsibility
National Medical Products Administration (NMPA) ***(formerly known as the China Food and Drug Administration (CFDA); renamed as NMPA after the 2018 institutional reform)***	▪ Supervises the drug, medical device, and cosmetic industries. ▪ Responsible for the safety supervision of the drug, medical device, and cosmetic industries. ▪ Responsible for standard management of the drug, medical device, and cosmetic industries. ▪ Responsible for registration management of the drug, medical device, and cosmetic industries. ▪ Responsible for quality and risk management of the drug, medical device, and cosmetic industries. ▪ Responsible for the licensing administration of licensed pharmacists.
National Administration of Traditional Chinese Medicine (NATCM)	▪ Formulates development plans for Chinese medicine. ▪ Drafts policies regarding Chinese medicine. ▪ Supervises and coordinates work combining Chinese and Western medicine. ▪ Sets up relevant technology standards.
National Development and Reform Commission (NDRC)	▪ Sets up drug prices and pricing policies. ▪ Supervises drug price fluctuations. ▪ Designs overall drug policy goals. ▪ Formulates and implements policies for the medical device industry. ▪ Lays out development plans for healthcare industries.
National Healthcare Security Administration (NHSA) ***(newly established following the 2018 institutional reform)***	▪ Drafts policies and administrative measures for the management of healthcare security. ▪ Formulates procurement policies for drugs, medical devices, and healthcare services. ▪ Formulates the payment standard and basic medical insurance catalogue for drugs, medical devices, and healthcare services.

Below are some key topics and policies relevant to the pharmaceutical industry in China today.

The consistency evaluation of the quality and efficacy of generic drugs

The *Opinions on Performing Consistency Evaluation of the Quality and Efficacy of Generic Drugs*, issued by the State Council in 2016, officially marked the start of evaluation procedures. Following this, the NMPA issued an *Announcement on Matters Concerning the Consistency Evaluation of the Quality and Efficacy of Generic Drugs* in 2018, and an *Announcement on Performing Consistency Evaluation of the Quality and Efficacy of Generic Chemical Injections* in 2020: both are aimed at further promoting consistency in evaluation. By the end of 2019, the NMPA had approved the consistency evaluation applications of 134 types of drug and approved 81 types of generic drug in accordance with the new registration classification. This evaluation may present an opportunity for overseas companies by reducing competition from low-quality generic drugs. However, in the long term, if local drugs pass the evaluation, these may be seen as substitutes for the original drugs, therefore potentially posing a significant threat to foreign companies.[37]

[37] http://mpa.gd.gov.cn/ztzl/fzypjzl/zcfg/content/post_2962389.html *(accessed: 29 June 2021).*

Centralised procurement

In 2019, the *Pilot Plan of National Centralised Procurement and Use* was issued by the State Council.[38] According to the plan, prior to starting centralised procurement, the procurement price of drugs would first be set based on the estimated procurement volume of all public medical institutions in the pilot cities, namely Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu, and Xi'an. In other words, this means that the government will carry out a strategy of bulk buying at a low price, in which hospitals purchase a large amount of drugs and in return sellers provide the drugs at a lower price – a process that is also referred to as volume-based centralised procurement. The centralised procurement of drugs is now promoted nationwide, and by the end of April 2021, four rounds of procurement had been finished: the first three rounds of procurement involved 112 types of drug, and the average price of the products that won bids for contracts was 54% of the previous procurement price. In January 2021, the State Council issued the *Opinion on the Normalisation and Institutionalisation of Centralised Volume-based Procurement of Drugs*, which indicates that more drugs and medical institutions will be involved in the centralised procurement scheme.[39]

Two-invoice policy

The two-invoice policy was launched in 2016 by the Chinese government. This introduced the two-invoice system, which is designed to optimise the process of drug distribution, only allowing two invoices at most to be issued when drugs are distributed between drug manufacturers and medical institutions: the drug manufacturer issues an invoice to its distributor, and the distributor issues a second invoice to the medical institution. An exclusive distributor of imported drugs, which can be considered the drug manufacturer, is one of the exceptions of two-invoice policy. The system aims to greatly reduce the costs of pharmaceutical products and medical devices, by cutting out intermediaries. In 2017, the NHC issued the *Opinions on the Implementation of the "Two-invoice System" in Drug Procurement by Public Medical Institution (for Trial Implementation)*, indicating the application nationwide of the two-invoice policy for drug procurement in public medical institutions.[40]

According to the *Work Focus in 2016 on Special Rectification of the Misconduct in Drugs Procurement and Medical Services* issued by the NHC, the two-invoice system is also expected to be applied to the procurement of medical consumables. However, according to the NHSA's submission to the China's National People's Congress in December 2019, further study and discussions will be needed for the two-invoice policy before it can be implemented for high-value consumables on a nationwide basis, due to the complexities of clinical practices and after-sales services related to use of medical consumables.

Key players

In 2019, there were more than 4,000 active pharmaceutical ingredient and preparation manufacturing companies registered with the NMPA in China. Large Chinese enterprises dominate the market in terms of revenue. Table 6 provides an overview of the top 25 pharmaceutical companies in China, ranked by revenue in 2019 (the latest data available).

In 2019, the innovative drugs market was worth US$1.33 trillion (€1.11 trillion), accounting for approximately 56% of the total drug manufacturing market, while the generic drug and biosimilars market was valued at

[38] *http://www.gov.cn/zhengce/content/2019-01/17/content_5358604.htm (accessed: 29 June 2021).*

[39] *http://www.gov.cn/zhengce/content/2021-01/28/content_5583305.htm (accessed: 29 June 2021).* For more information about centralised procurement, European SMEs can visit: *http://www.smpaa.cn/*.

[40] *http://www.nhc.gov.cn/tigs/s2906/201701/b64ca4c3d5c64a4c860316437d6eb787.shtml (accessed: 29 June 2021).*

US$1.04 trillion (€0.88 trillion), making up approximately 44% of the total market.[41] It is estimated that by the end of 2021, the innovative drug and generic drug and biosimilars markets will grow to be worth US$1.54 trillion (€1.29 trillion) and US$1.11 trillion (€0.93 trillion), respectively.[42] This rapid growth is rooted in the Chinese government's promotion of innovation in the healthcare sector in recent years, as innovation in the pharmaceutical industry was included as a goal in the 13th FYP (2016-2020) and now the 14th FYP. To achieve this goal, many policies have been issued, including the aforementioned consistency evaluation of the quality and therapeutic effect of generic drugs, which is a significant step towards reaching these goals.

Table 6: Top 25 pharmaceutical companies in China by revenue, 2019 [43]

Ranking	Company	Ranking	Company
1	Yangtze River Pharmaceutical Group	14	Pfizer
2	Guangzhou Pharmaceuticals	15	Sichuan Kelun Pharmaceutical
3	Sinopharm Group	16	CTTQ Pharma
4	CR Pharmaceutical	17	Roche Holding Shanghai
5	Xiuzheng Pharmaceutical Group	18	AstraZeneca
6	Shanghai Pharmaceuticals	19	Buchang Pharmaceuticals
7	Fosun Pharma	20	Novo Nordisk (China)
8	Bayer Healthcare China	21	Zhuhai United Laboratories
9	China Grand Enterprises	22	Lunan Pharmaceutical Group
10	Jiangsu Hengrui Medicine	23	Sanofi (Hangzhou)
11	Jiangxi Jemincare Pharmaceutical	24	Tianjin Pharmaceutical Group
12	Qilu Pharmaceutical	25	HEC Group
13	CSPC Pharmaceutical Group		

Roadmap for entering China as an SME

Foreign pharmaceutical companies that seek to enter the Chinese market should first examine the following regulations and policies:

- *Drug Administration Law of the People's Republic of China (2019 Revision);*[44]
- *Regulations for the Implementation of the Drug Administration Law of the People's Republic of China (2019 Amendment);*[45]
- *Measures for the Administration of Drug Registration (2020).*[46]

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[41] https://www.nmpa.gov.cn/zhuanti/ypzhcglbf/ypzhcglbfzhcwj/20200630180301525.html *(accessed: 29 June 2021). According to the classification for chemical drugs from the NMPA, "innovative drug" refers to drugs of a chemical compound with new molecular structure and clinical value that have not been approved to market at home and abroad.*

[42] https://www.askci.com/news/chanye/20201130/1452121297216.shtml *(accessed: 29 June 2021);* https://www.askci.com/news/chanye/20210402/1705351407039.shtml *(accessed: 29 June 2021).*

[43] http://finance.sina.com.cn/stock/relnews/cn/2020-09-09/doc-iivhvpwy5776293.shtml *(accessed: 29 June 2021).*

[44] http://www.npc.gov.cn/npc/c30834/201908/26a6b28dd83546d79d17f90c62e59461.shtml *(accessed: 29 June 2021).*

[45] http://www.gov.cn/zhengce/2020-12/26/content_5573533.htm *(accessed: 29 June 2021).*

[46] http://www.gov.cn/zhengce/zhengceku/2020-04/01/content_5498012.htm *(accessed: 29 June 2021).*

The NMPA oversees overall drug registration matters in China. The Centre for Drug Evaluation of the NMPA is responsible for handling the evaluation of drug clinical trial applications, new drug registration applications, foreign drug re-registration applications, and other relevant matters.

The fundamental registration process for new drugs follows the *Measures for the Administration of Drug Registration (2020)*.[47] It basically follows three main steps, summarised in Table 7.[48] Foreign pharmaceutical companies should appoint entities registered in China, which could be either enterprises or drug developing institutions, to take charge of drug registration matters.

Table 7: Fundamental registration processes for new drugs

Non-clinical safety testing
Before the applicant proceeds to clinical trial, non-clinical safety testing should be completed first, and it should be conducted in institutions with Good Laboratory Practice (GLP) certification
Clinical trial
The applicant applies to the NMPA for the approval for clinical trial. The clinical trial should be conducted within three years of being approved by the NMPA
Drug registration
The applicant applies to the NMPA for the approval to market after finishing non-clinical safety testing and a clinical trial. A Drug Registration Certificate will be issued to applicant by the NMPA once the drug is approved for the market

3.2. Medical devices

Market information

The medical device industry in China has been rapidly growing. In 2016, the industry was valued at RMB 370 billion (€48 billion). The total market for medical devices in China was worth RMB 637 billion (€83 billion) in 2019, reflecting a compound annual growth rate of 19.8% from 2016 to 2019, as illustrated in Figure 6.[49]

In terms of trade partners, the United States, Germany, Japan, Mexico, and Singapore were the largest exporters of medical devices to China in 2019, accounting for 62.7% of total imported registered medical devices. Imported medical devices in China were valued at a total of US$ 26.79 billion (€22.47 billion) in 2019, indicating a 21.5% year-on-year increase. The major imported product types in 2019 were biochemical analysers, immunoassay analysers, chromosome spectrum analysers, colour ultra-sound equipment, rehabilitation devices, and surgical implants.[50]

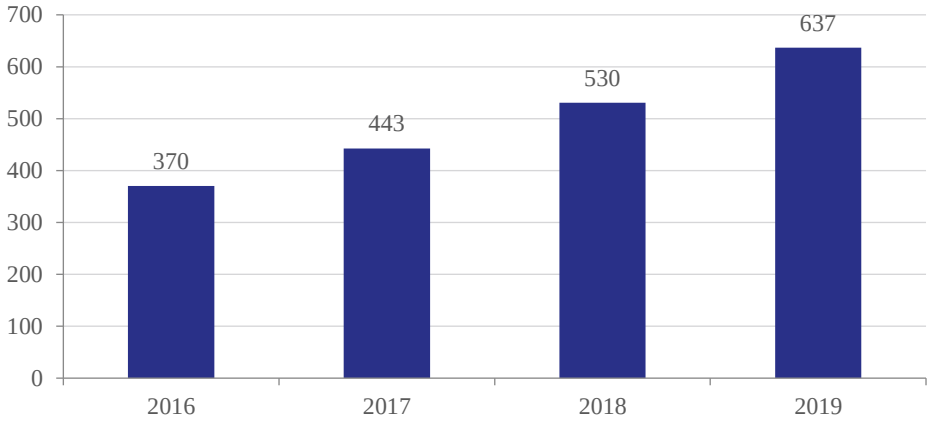
[47] *http://www.gov.cn/zhengce/zhengceku/2020-04/01/content_5498012.htm (accessed: 29 June 2021).*

[48] *An infographic, in Chinese, of the drug registration process, is available at: https://baijiahao.baidu.com/s?id=1683618346750081349&wfr=spider&for=pc (accessed: 29 June 2021).*

[49] *https://www.askci.com/news/chanye/20210317/1447211388909_3.shtml (accessed: 29 June 2021).*

[50] *http://www.camdi.org/news/9379 (accessed: 2 July 2021).*

Figure 6: Medical devices market size in China, 2016-2019, RMB billion



Regulatory policies

The medical device industry in China is generally overseen by the NMPA, which is mainly responsible for drafting industry standards and classifications, as well as regulating pricing and sales channels. There are three key regulations in China that medical device providers need to be aware of:

- *Regulations on Supervision and Administration of Medical Devices*; [51]
- *Administrative Measures for the Registration Medical Devices*; [52]
- *Administrative Measures for the Registration of In Vitro Diagnosis (IVD) Reagents*.[53]

Classification of medical devices

The NMPA classifies medical devices in China under three categories according to their risk level. [54] A device's risk level is determined based on its intended purpose, structural features, contact with the body during use, and method of use:

- Class I medical devices are deemed to have low levels of risk, and their safety and effectiveness can be ensured through routine safety checks.
- Class II medical devices are deemed to have medium levels of risk, and further control is required to ensure their safety and effectiveness.
- Class III medical devices have high levels of risk, and special measures must be taken to enforce strict control and administration of their safety and effectiveness.

Criteria for the classification of medical devices

The *Criteria for Classification of Medical Devices* are used as the basis of the *Medical Device Classification Catalogue*, and to identify the classification of new medical devices.[55] European SMEs can ascertain the administrative classification of their product according to these criteria, as shown in Table 8 and Table 9.

The notations "Ⅰ", "Ⅱ", and "Ⅲ" in Table 8 and Table 9 refer to Class I medical devices, Class II medical devices, and Class III medical devices, respectively; "－" indicates that no such condition exists.

[51] *http://www.gov.cn/zhengce/content/2021-03/18/content_5593739.htm (accessed: 29 June 2021).*

[52] *http://www.gov.cn/gongbao/content/2014/content_2758500.htm (accessed: 29 June 2021).*

[53] *http://www.gov.cn/gongbao/content/2014/content_2758501.htm (accessed: 29 June 2021).*

[54] *http://www.gov.cn/zhengce/content/2021-03/18/content_5593739.htm (accessed: 29 June 2021).*

[55] *https://www.nmpa.gov.cn/ylqx/ylqxfgwj/ylqxbmgzh/20150714120001554.html (accessed: 29 June 2021).*

Table 8: Criteria for Classification of Medical Devices with direct and/or indirect contact to the human body

①/②/③ under "Operating status" in Table 8 indicate the following:

① refers to skin/cavity (tract)

② refers to trauma/tissue

③ refers to blood circulation system/central nervous system

	Operating pattern \ Operating status		For temporary use			For short-term use			For long-term use		
			①	②	③	①	②	③	①	②	③
Not electricity-powered and/or energy-driven	1	Liquid delivery device	II	II	III	II	II	III	II	III	III
	2	Device for changing blood and body fluid	–	–	III	–	–	III	–	–	III
	3	Surgical dressing	I	II	II	I	II	II	–	III	III
	4	Invasive device	I	II	III	II	II	III	–	–	–
	5	Reused surgical instrument	I	I	II	–	–	–	–	–	–
	6	Implantable device	–	–	–	–	–	–	III	III	III
	7	Contraception and family planning device (excluding reused surgical instrument)	II	II	III	II	III	III	III	III	III
	8	Others	I	II	III	II	II	III	II	III	III

	Operating pattern \ Operating status		Mild impairment if out of control	Moderate impairment if out of control	Severe impairment if out of control
Electricity-powered and/or energy-driven	1	Energy healing device	II	II	III
	2	Diagnostic and monitoring device	II	II	III
	3	Liquid delivery device	II	II	III
	4	Ionizing radiation device	II	II	III
	5	Implantable device	III	III	III
	6	Others	II	II	III

Table 9: Criteria for Classification of Medical Devices without direct and/or indirect contact to the human body

	Operating pattern \ Operating status		No impact on medical effect	Mild impact on medical effect	Significant impact on medical effect
Not electricity-powered and/or energy-driven	1	Nursing device	I	II	–
	2	Cleaning and disinfection device for medical device	–	II	III
	3	Others	I	II	III

	Operating pattern \ Operating status		No impact on medical effect	Mild impact on medical effect	Significant impact on medical effect
Electricity-powered and/or energy-driven	1	Clinical examination device	I	II	III
	2	Stand-alone software	–	II	III
	3	Sterilization and disinfection device for medical device	–	II	III
	4	Others	I	II	III

An overview of the registration requirements and processes for medical devices, is provided in the Frequently Asked Questions at the end of this chapter 3.2.

In August 2015, the State Council issued the *Opinions on Reforming the Review and Approval System for Drugs and Medical Devices*,[56] which has been seen by the medical device industry as evidence of the Chinese government taking steps to simplify medical device approval. The NMPA has since issued multiple policies aiming to speed up approval procedures. For example, the *Priority Approval Procedure for Medical Devices*, issued by the NMPA in January 2017, states that certain types of Class II and III devices should be given approval priority.[57] Such devices include those capable of treating rare diseases and frequently occurring diseases that have no other effective treatment methods. Such policies and reforms regarding simplified medical device approval procedures are a good opportunity for European SMEs, as they will speed up market entry for some medical devices; nonetheless, it must be noted that, for most medical devices, the entire registration process will take more than a year to complete.

Similar to the pharmaceutical sector, the two-invoice system also significantly impacts the medical device market. By reducing the number of distribution layers, this system strives to reduce the retail prices of medical devices, resulting in medical device manufacturers having to manage multiple small-scale distributors. At present, it appears that the two-invoice system has had the greatest impact on the medical consumables market;[58] companies that manufacture medical consumables and reagents with high mark-ups must re-think their price structures in order to adjust to the new system. By the end of September 2019, 25 provinces had published policies regarding the implementation of the two-invoice system for high-value medical consumables.[59]

Key players

There are a growing number of important players in China's medical device industry, as the number of medical device manufacturers in China increased from 15,343 in 2016 to 18,000 in 2019. The vast majority of medical device manufacturers tend to be small-scale companies that are spread across the country, and these manufacturers usually do not have the capacity to conduct extensive R&D.

Table 10: Number of medical device manufacturers in China, 2016-2019[60]

Year	2016	2017	2018	2019
Number of Class I medical dvice manufacturers	4,979	6,096	7,513	8,232
Number of Class II medical device manufacturers	8,957	9,340	9,189	10,033
Number of Class III medical device manufacturers	2,366	2,189	1,997	1,977
Total	**15,343**	**16,000**	**17,000**	**18,000**

As shown in Table 10, Class I and II manufacturers outnumber Class III manufacturers, highlighting how China's medical device manufacturing market is dominated by Chinese companies producing lower-level medical instruments.

Distribution channels

In general, there are three distribution channels for medical devices in China:

- Retail;

[56] *http://www.gov.cn/zhengce/content/2015-08/18/content_10101.htm (accessed: 29 June 2021).*

[57] *http://www.gov.cn/xinwen/2016-10/26/content_5124635.htm (accessed: 29 June 2021).*

[58] *http://news.chinamedevice.cn/20200115/535410.html (accessed: 29 June 2021).*

[59] *https://www.sohu.com/a/344878379_100000405 (accessed: 29 June 2021).*

[60] *https://www.nmpa.gov.cn/zwgk/tjxx/tjnb/20200805110116109.html (accessed: 29 June 2021).*

- Hospital procurement;
- Government procurement (centralised procurement).

Specifically, the retail distribution channel includes sales via supermarkets, drug stores, and e-commerce platforms. The hospital procurement and government procurement channels often overlap, for instance in the case of a local government organising a bidding process for local hospitals. Hospital procurement often requires customised medical devices that are in high demand and dependent on different departments or doctors; while government procurements tend to include large purchases of similar products.

Due to the characteristics of these distribution channels, European SMEs that are new to the market often choose to work with distributors as a first step, as they often initially lack both the knowledge of the market and contacts within hospitals. Especially within the new two-invoice system, it is important for European SMEs to choose reliable partners that have experience in the market. Additionally, when first entering the market, European SMEs often choose to work with distributors rather than forming their own sales teams, as direct sales tend to be less effective and more costly for an European SME.

European SMEs should also be aware that a currently-popular topic of discussion in China is the government-initiated centralised procurement of medical devices, which affects the distribution strategy of medical device companies in China in different ways. On 19 July 2019, the State Council issued the *Reform Plan for the Control of High-value Medical Consumables*, aimed at resolving the problem of inflated prices and overuse of high-value consumables.[61] This reform plan brought forward the idea of volume-based and category-based centralised procurement for medical consumables. Following this, on 16 October 2020, the government issued the *State-Organized Centralized Procurement of Coronary Stents*, which started the centralised procurement of coronary stents at the national level; the procurement was completed on 5 November 2020: eight companies, including Medtronic and Boston Scientific, won at the bidding, and the unit price of the winning products ranged from RMB 469 (€61) to RMB 798 (€103), representing a 90% decrease compared to 2019.[62] On 1 April 2021, the government started collecting information on high-value medical consumables relating to artificial hip and knee joints, suggesting that the national centralised procurement will soon start to cover orthopaedic medical devices as well.[63]

The centralised procurement of medical devices has developed fast, largely exceeding industry expectations in terms of the expansion of product categories and the drastic decline in unit prices. As of July 2020, there have been approximately 40 centralised procurement projects announced in China, at both national and provincial levels.[64] It is expected that, in the future, the centralised procurement of medical devices will follow the path of the centralised procurement of drugs, to also become normalised in the future.

For products involved in the centralised procurement projects, the companies that win the procurement biddings will occupy major shares within those specific markets, while those failing will compete fiercely for the small share of the market remaining. According to the requirements, providers that win a bid should provide the required number of products within the procurement cycle; but while medical providers can arrange production accordingly and maintain a stable revenue, due to the relatively low price per unit, the revenue will remain within a limited range. Consequently, the revenues for those that failed in centralised procurement and do not own a large share of the procurement volume will be lower. Therefore, European SMEs that wish to enter the

[61] *http://www.gov.cn/zhengce/content/2019-07/31/content_5417518.htm (accessed: 29 June 2021).*

[62] *https://baijiahao.baidu.com/s?id=1684244539250546795&wfr=spider&for=pc (accessed: 29 June 2021).*

[63] *https://www.tjmpc.cn/website/home/infoPage?NEWSID=8e03890406b447d3939203e64b3977d0&NEWSCOLUMNID=1d597a6a11e546a2bc09e68e3a53bb85 (accessed: 29 June 2021).*

[64] *https://mp.weixin.qq.com/s/_lfWtTQsSxi9LIGZzhMC6g (accessed: 29 June 2021). For more information about the procurements, European SMEs can visit: http://www.smpaa.cn/.*

China market should pay close attention to what kind of products are involved in centralised procurement, in order to understand market trends in China and decide whether it is wise to compete in certain subsector markets.

Future outlook

Multiple policies issued by the State Council and the NMPA have demonstrated the government's intention to loosen policies within the medical device industry since 2015. Furthermore, the Chinese government is also promoting innovation among Chinese medical device manufacturers, providing them with policy facilitations and support.

The 14th FYP states that the government will promote the centralised procurement of medical consumables, and encourage the development of high-end medical equipment; it will also complete mechanisms for the quick evaluation and approval of medical devices, especially those facing urgent clinical need and new medical devices that have been approved to market in foreign countries.[65] European medical device manufacturers with advanced products could therefore benefit from this, but at the same time will face more competition from Chinese players, due to the strong support that the Chinese government is giving to the innovation in the medical device industry.

A further trend that the EU SME Centre has observed in the medical device market in China, is an increasing number of mergers and acquisitions (M&A).[66] In fact, by establishing higher quality and efficiency standards, the two-invoice system is driving small-scale and less innovative distributors and manufacturers out of the market; it is therefore likely that more small-scale medical device manufacturers will be purchased or invested in by larger manufacturers in China.[67]

Finally, many innovative and support policies for the development of the medical industry have been issued by the 21 Pilot Free Trade Zones currently existing in China. For example, in the Tianjin Pilot Free Trade Zone and Shanghai Pilot Free Trade Zone, both local governments are seeking to allow the importing of medical devices that are urgently clinically needed and that have no similar alternatives registered in China; moreover, the Tianjin Pilot Free Trade Zone specifies that it will optimise the customs clearing procedures for the importing of medical devices, by shortening the time span to 15 days. Many Pilot Free Trade Zones have also issued policies to offer fast-track and simplified review and approval processes for drugs and medical devices manufactured overseas. For example, the Boao Lecheng International Medical Tourism Pilot Zone – within the Hainan Free Trade Port – not only allows the importing of a small volume of urgently needed medical devices that have not been registered in China; it also allows the clinical data of these devices collected in the pilot zone to be used for registration.[68] Therefore, European SMEs can benefit from the many policies increasingly being issued in these Pilot Free Trade Zones, potentially finding a more efficient way to enter the China market.

Frequently asked questions [69]

1. *What are the administrative measures and regulatory bodies for Class I, Class II, and Class III medical devices seeking registration?*
    - Class I medical devices are required to be registered with medical products administrative authorities at the municipal level.

[65] *http://www.xinhuanet.com/2021-03/13/c_1127205564_14.htm (accessed: 29 June 2021).*

[66] *http://finance.sina.com.cn/roll/2018-01-24/doc-ifyquixe7153540.shtml (accessed: 29 June 2021).*

[67] *http://www.myzaker.com/article/5c9f25a777ac6433c24def42 (accessed: 29 June 2021).*

[68] *http://www.gov.cn/xinwen/2019-09/17/content_5430452.htm (accessed: 29 June 2021).*

[69] *Sources: https://www.nmpa.gov.cn/ylqx/ylqxfgwj/ylqxbmgzh/20140730120001346.html (accessed: 29 June 2021); https://www.nmpa.gov.cn/xxgk/fgwj/flxzhfg/20210319202057136.html (accessed: 29 June 2021).*

- Class II medical devices are required to be registered with medical products administrative authorities at the provincial level.
- Class III medical devices are required to be registered with the NMPA.

2. *Is the type test required for Class I, Class II, and Class III medical devices?*

- Type tests are not required on Class I medical devices. Self-test reports are accepted.
- Type tests are required on Class II and Class III medical devices.

3. *Are clinical trials required for Class I, Class II, and Class III medical devices?*

- Clinical trials are not required for Class I medical devices.
- Clinical trials are required for Class II medical devices.
- Clinical trials are required for Class III medical devices, as well as prior approval from the NMPA.

4. *What are the requirements for the registration of imported medical devices?*

- The regulatory agency for imported medical devices is the NMPA. Exporters should appoint a business entity registered in China as an agent to handle registration and associated issues.

5. *How is the administrative class of a newly-invented medical device defined when applying for registration?*

- For newly-invented products that have not been listed in the classification catalogue (Tables 8 and 9), products can be (i) directly registered as Class III, then re-classified by the NMPA; or (ii) self-classified by applicants according to the classification criteria, and submitted to the NMPA for confirmation. Once the class of the product has been confirmed, the product can be registered accordingly.

3.3. Healthcare service providers

Private healthcare institutions

By the end of 2020, there were 24,000 private hospitals in China.[70] Unlike public hospitals, private hospitals are usually not classified according to the three-tier system, and tend to provide a better patient environment, customer services, and longer one-on-one times with medical staff; as a consequence, they are more expensive than public hospitals.

The State Council has issued various notices and policies aimed at promoting private healthcare institutions since 2010. In the most recent policy issued in 2019, the *Opinion on Promoting the Sustainable and Healthy Development of Privately Funded Healthcare Institutions*,[71] the State Council urged local governments to simplify market access requirements and procedures for private healthcare institutions, by further lifting restrictions, providing more financial subsidies, allowing healthcare practitioners to work for both public and private institutions, and reducing taxes. The document also highlighted the need to put restrictions on the number of public hospitals, so as to encourage the development of private healthcare institutions. Although it would be too expensive to set up hospitals in China, with the opening up of private healthcare institutions, European SMEs could consider the possibilities of using their expertise to partner with Chinese small-scale general practice or dental clinics; selling medical products and devices to private hospitals and clinics in China will also be easier and more attractive compared to public hospitals.

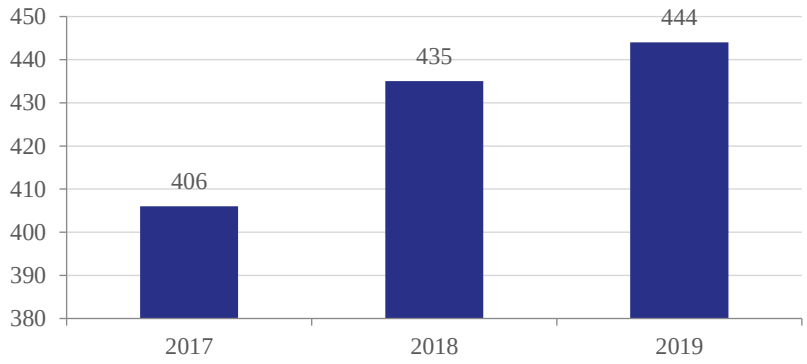
Independent laboratories

[70] *http://www.stats.gov.cn/tjsj/zxfb/202102/t20210227_1814154.html (accessed: 29 June 2021).*

[71] *http://www.gov.cn/gongbao/content/2019/content_5442285.htm (accessed: 29 June 2021).*

Following economic growth and the raising health awareness of Chinese consumers, the physical examination market in China has grown accordingly: its total size in 2019 increased to RMB 168.6 billion (€22 billion);[72] in the same year, 444 million health checks were offered, compared to 406 million in 2017 – a compound annual growth rate of 4.58%. In recent years, the percentage of healthcare expenditure within total consumption expenditure has grown steadily – reaching 8.7% in 2020, reflecting an overall increase of 1.5 percentage points since 2014.[73]

Figure 7: The number of health checks offered in China, 2017-2019, million



The growing physical examination industry provides good opportunities to independent laboratories in China. Unlike developed countries, where consumers are typically directed to independent laboratories for tests and examinations, in China, hospitals play an important role in carrying out physical examinations. However, with the healthcare sector opening up to private investment, the number of independent laboratories is growing significantly. European SMEs providing relevant services in the physical examination industry may benefit from this trend, and it is worth considering providing products or services to local independent laboratories.

Healthcare IT (HIT)

The Wise Information Technology of Med (WITMED) market provides digital solutions for medical systems and connects patients with medical staff, medical institutions, and medical equipment, by taking advantage of a wide range of technologies such as IoT, cloud computing, big data processing, and block chain. In recent years, this market has developed rapidly in China: in 2019, the WITMED market was valued at RMB 88.5 billion (€11.45 billion) in total, and in 2020, the market value had increased to over RMB 100 billion (€13 billion).[74]

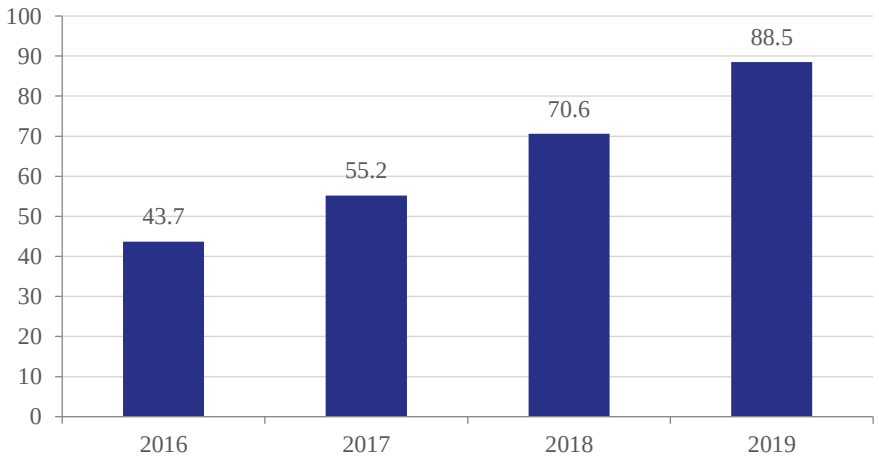
Figure 8: China's WITMED market size, 2016-2019, RMB billion [75]

[72] *http://www.ce.cn/xwzx/gnsz/gdxw/201906/19/t20190619_32402138.shtml (accessed: 29 June 2021).*

[73] *https://www.qianzhan.com/analyst/detail/220/210312-d419eefd.html (accessed: 29 June 2021).*

[74] *https://www.askci.com/news/chanye/20210310/1600451381498_3.shtml (accessed: 29 June 2021).*

[75] *https://www.askci.com/news/chanye/20201116/1020091283507_5.shtml (accessed: 29 June 2021).*



In 2018, the government issued three policies to regulate the telemedicine service, online hospital, and remote medicine service sectors. [76] According to these policies, doctors practicing on behalf of an internet hospital must first gain approval from the hospital where they are originally employed and can only provide further consultation service for patients with chronic diseases and certain common diseases if the patients do not pay an onsite visit to a physical hospital. All healthcare institutions offering online services must also clearly state their service scopes and practices accordingly. Online medical institutions are prohibited from providing telemedicine services for first-visit outpatients.

By 30 June 2020, the Chinese government had issued a total of 126 policies regarding online hospitals, covering guidance on setting up online hospitals, supervision over online hospitals, and payment methods.[77] In March 2021, there were over 1,000 online hospitals in total in China, which were joined by more than 7,700 Class 2 and Class 3 public hospitals providing telemedicine services for patients. Over 90% of Class 3 public hospitals have implemented internal information sharing. A remote medicine service network has been established among more than 24,000 medical institutions, and the online supervision platform for telemedicine services has been set up among 30 provinces.[78] With an increasing number of hospitals seeking to provide digital services to their patients, European SMEs in the HIT sector may consider taking advantage of this demand to play an integral part in the China market.

Rehabilitation service providers

Patients in rehabilitation hospitals and institutions in China tend to be:

- Elderly patients suffering from various diseases;
- Disabled;
- Patients suffering from chronic diseases;
- Women in need of postpartum recovery;
- Children in need of rehabilitation services;
- Patients in need of postoperative rehabilitation.

In 2019, the rehabilitation industry in China was valued at RMB 70.5 billion (€9 billion) in total, with a year-on-year growth of 21%. It is predicted that in 2025, the market value will increase to RMB 220 billion (€28 billion).[79] In 2011, there were 146 public rehabilitation hospitals and 155 private rehabilitation hospitals in

[76] *http://www.gov.cn/gongbao/content/2019/content_5358684.htm (accessed: 29 June 2021).*

[77] *Source: China Online Hospital Development Analysis Report (2020): http://med.china.com.cn/content/pid/195605/tid/1026 (accessed 30 June 2021).*

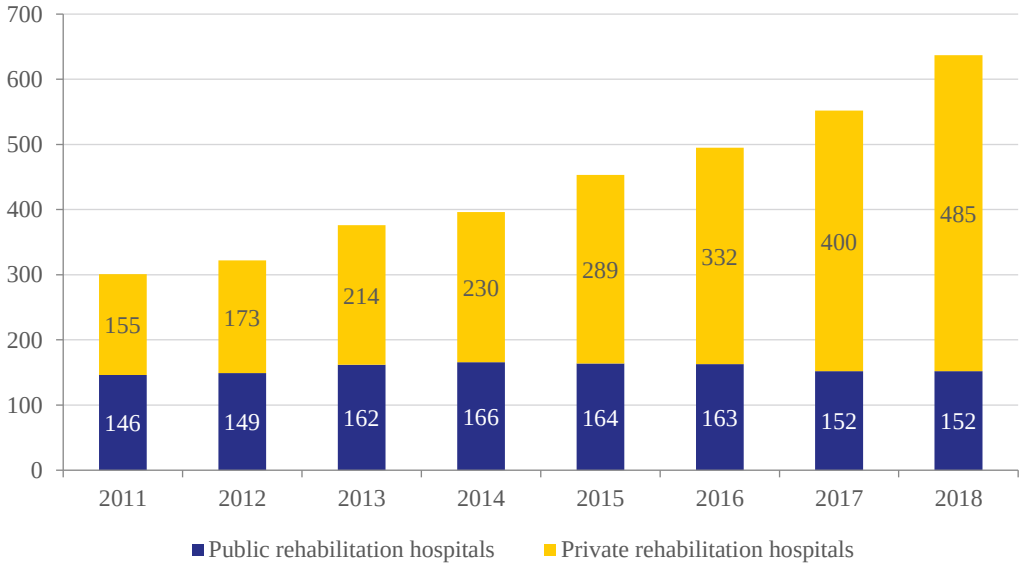
[78] *http://www.gov.cn/xinwen/2021-03/24/content_5595237.htm; http://www.gov.cn/xinwen/2021-03/26/content_5595808.htm (accessed: 29 June 2021).*

[79] *http://free.chinabaogao.com/yiyao/202008/0RK131F2020.html (accessed: 29 June 2021).*

China; in 2018, however, the gap widened drastically, as shown in Figure 9: private rehabilitation hospitals accounted for 76% of the market.

However, even though the number of rehabilitation hospitals increased rapidly, there remains a significant gap in meeting market demand. In 2019, there were a total of approximately 14,000 beds in hospital rehabilitation departments; in contrast to these figures, in the same year, there were 176 million people aged 65 and above, over 85 million disabled people, and approximately 300 million people with chronic diseases, with only 12.7% of disabled people gaining access to basic rehabilitation services. Thus, the rehabilitation industry in China is evidently underdeveloped, and with demand far exceeding current supply, this offers a potential opportunity for European SMEs in this sector effectively enter the market to help remedy this problem. [80]

Figure 9: The number of rehabilitation hospitals in China, 2011-2018



Elderly care providers

As shown in section 1.1., the ageing population in China is rising rapidly: in 2020, there were over 264 million people aged 60 and above, accounting for 18.7% of the total population. It is expected that by 2030, the percentage of the population aged 65 and above in China will reach 20%.[81]

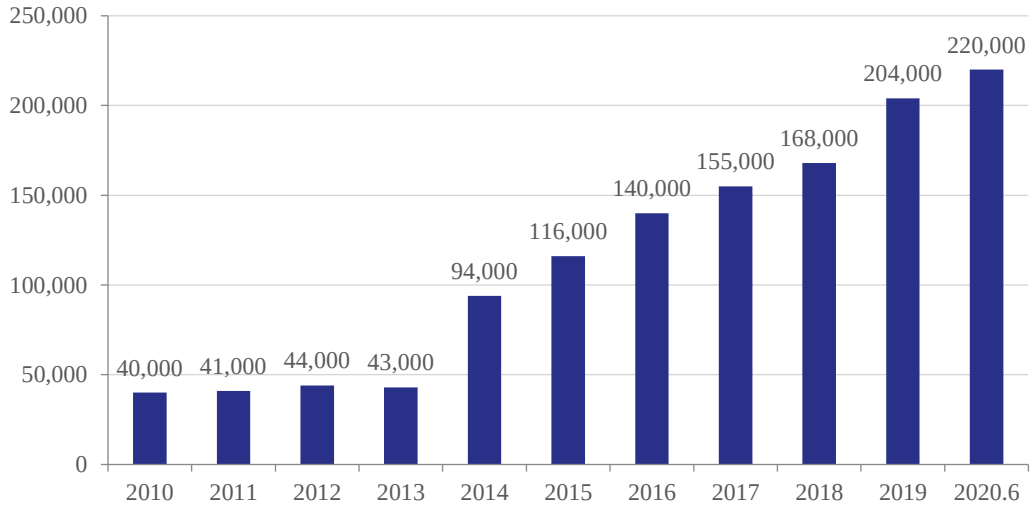
With an ageing population and increasing life expectancy, elderly care services will see growing demand in the coming decades. Since 2010, the number of institutions and facilities providing elderly care services has risen quickly in China: by June 2020, there were 220,000 elderly care institutions providing over 7.9 million beds. [82]

Figure 10: The number of institutions and facilities providing elderly care services, 2010-2020

[80] *https://baijiahao.baidu.com/s?id=1694624353458899727&wfr=spider&for=pc (accessed: 29 June 2021); http://free.chinabaogao.com/yiyao/202008/0RK131F2020.html (accessed: 29 June 2021); https://baijiahao.baidu.com/s?id=1668631375634006532&wfr=spider&for=pc (accessed: 29 June 2021).*

[81] *https://www.chyxx.com/industry/202004/854512.html (accessed: 29 June 2021).*

[82] *https://www.qianzhan.com/analyst/detail/220/210407-3c4e35d2.html (accessed: 29 June 2021).*



In December 2020, the State Council issued the *Opinions on Promoting the Sound Development of Pension Services*,[83] calling for more private capital investment for elderly care services, at the same time encouraging the full use of different kinds of houses and facilities to provide elderly care services. This policy also encourages service providers to develop different kinds of service lines to cover health consultation, first aid, chronic disease management, and nursing.

Fitness and medical aesthetics

There is an upward trend in the fitness industry and medical aesthetics industry in China. As of 2020, there are approximately 44,000 fitness centres in China; there are also 70 million people who have a gym membership, an increase of 3.2% compared to 2019, and 900,000 fitness coaches.[84] The large Chinese population base in the fitness sector provides opportunities for relevant market players, specifically in the following segments:

- Fitness equipment: In 2019, the fitness equipment market in China was worth RMB 46.1 billion (€6 billion), rising by 10.2% compared to 2018. It is estimated that, in 2021, the total market size will increase to RMB 51.85 billion (€6.7 billion).[85]
- Consumer healthcare products: In 2019, the consumer healthcare product market in China, which includes vitamins and dietary supplements, herbal and traditional products, sports nutrition, and weight management products, was worth RMB 396.5 billion (€51 billion), with a compound annual growth rate of 9.5% from 2009 to 2019.[86]
- Home-based fitness: Due to the outbreak of the COVID-19 pandemic, home-based fitness became a trend and fitness apps became popular. For example, Keep, a popular fitness app, reached approximately 3 million downloads in the pandemic period between 20 December 2019 to 17 March 2020.[87]

The medical aesthetics industry has also developed rapidly in recent years, increasing in value to RMB 176.9 billion (€23 billion) in 2019, with a compound annual growth rate of 28.9% since 2012.[88] There were approximately 18.73 million customers for medical aesthetics services in 2018. Still, compared with the US and

[83] *http://www.gov.cn/zhengce/content/2020-12/31/content_5575804.htm (accessed: 29 June 2021).*

[84] *https://www.sohu.com/na/457822586_120717030 (accessed: 29 June 2021).*

[85] *https://www.askci.com/news/chanye/20210426/0913211433492.shtml (accessed: 29 June 2021).*

[86] *https://bg.qianzhan.com/trends/detail/506/210412-5827d660.html (accessed: 29 June 2021).*

[87] *A detailed analysis of the sector and of the users, is available on: http://www.bigdata-research.cn/content/201910/1003.html (accessed: 29 June 2021).*

[88] *http://data.eastmoney.com/report/zw_industry.jshtml?infocode=AP202009251417334994 (accessed: 29 June 2021).*

South Korean markets, the medical aesthetics industry in China remains in its early stages. Moreover, the services provided by existing medical institutions with legal qualifications still cannot meet market demand, which has resulted in the emergence of illegal service providers. Therefore, since 2016, the government has issued numerous policies to regulate the industry and target these illegal institutions. With stricter market regulation and the rise of third-party medical aesthetics platforms, the pace of development within this industry will likely increase. For European SMEs seeking to sell medical aesthetics products or provide services in the China market, cooperating with a local distributor or service provider is recommended as they will have significantly more market knowledge and channels.

Market trends and pathway suggestions

Policy-level market trends

The development of the healthcare services sector is now backed by a growing number of government policies. In September 2020, the NHC replied to a proposal from the Chinese People's Political Consultative Conference,[89] providing details on healthcare services and indicating the following future development trends:

- The government seeks to promote the construction of healthcare information systems and the development of "internet + healthcare". In doing so, they will make full use of big data and cloud computing technology to analyse rehabilitation medical data.
- The government attaches great importance to the construction of disease prevention and rehabilitation systems, and will focus in particular on: (i) developing professional medical institutions specialising in disease prevention and control, as well as blood collecting and supplying; (ii) improving the capacity to monitor chronic diseases and their risk factors, including in early detection and intervention of chronic diseases; (iii) promoting the early detection, early reporting, and early treatment of major diseases in order to facilitate the transformation from disease treatment to health management; (iv) encouraging the transition of existing public hospitals into rehabilitation medical institutions and elderly care institutions.
- The government encourages private capital investment in rehabilitation services.
- The government encourages development of the rehabilitation assistive device industry.
- The government encourages technological innovation in the healthcare sector, and prioritises the development of remote medical systems, wearable physiological information monitoring devices, devices with cloud services and artificial intelligence functions for at-home elderly care and rehabilitation, as well as the development of new electrophysiological sensors, flexible display devices, high-performance batteries, and other common core components, which are all used for wearable medical devices.
- The government will strengthen the development of rehabilitation medicine disciplines in medical schools and promote the cultivation of talent in the rehabilitation sector.

In addition, policies issued in Pilot Free Trade Zones also indicate the future trends of the sector. For example, the Hainan Free Trade Port aims to become a key national hub for the medical tourism industry: nine policies have already been issued since 2013, [90] aimed at:

- Optimising registration and approval processes for the importing of medical devices and drugs;
- Relaxing restrictions on the practice time for foreign doctors;
- Allowing international capitals to invest in local medical institutions;
- Allowing frontier medical technology research projects such as the clinical research of stem cells to be conducted.

Furthermore, in 2019, the central government issued the *Implementation Plan for Supporting the Construction of Boao Lecheng International Medical Tourism Pilot Zone*.[91] This implementation plan further relaxes the restrictions for providing healthcare services in the Hainan Free Trade Port, and in particular in Boao. For example, clinical data collected from medical devices and drugs that have not been registered in China is allowed to be presented as real-world evidence.

[89] *http://www.nhc.gov.cn/wjw/tia/202009/eda128cab2d8462095b2698c8d72af8e.shtml (accessed: 29 June 2021).*

[90] *http://www.hkwb.net/news/content/2013-04/07/content_1141134.htm (accessed: 29 June 2021).*

[91] *http://www.gov.cn/xinwen/2019-09/17/content_5430452.htm (accessed: 29 June 2021).*

The policies issued in the Pilot Free Trade Zones indicate that the Chinese government will continue to ease restrictions on healthcare services in these areas, providing opportunities for foreign service providers in the China market.

Pathway suggestions

While directly and independently investing in the China healthcare services sector can be challenging for European SMEs due to the complicated market conditions, partnering with local Chinese healthcare service providers can help to alleviate many of these challenges. For EU private healthcare institutions, rehabilitation service providers, and elderly care service providers, partnering with local institutions, such as public and private hospitals, rehabilitation services, and elderly care service providers, is a good option for providing training services, engaging in daily operations including providing clinical services in local institutions, or even building new medical institutions in China.

With the development of the HIT sector in China, this market is now dominated by Chinese HIT providers. Cooperating with local HIT services providers in China can be an effective strategy for European SMEs as local companies have deeper knowledge and grasping of the market and the healthcare system in China. European SMEs can also explore the market on their own, but they should be aware that public medical institutions in China are the major service providers in the market and any procurement activities they carry out will have to be supervised by the relevant government bodies. It would not be efficient for international service providers, especially SMEs, to gain market share through government procurement, considering the very low purchasing prices. Therefore, European SMEs should target private medical institutions in China if choosing to explore the market independently.

4. Opportunities and challenges for SMEs

4.1. Opportunities

Since the implementation of economic reforms in the 1980s, China has experienced dramatic changes, including a fast-growing economy and improved life expectancy. However, China's population is also increasingly suffering from chronic diseases and so-called "lifestyle" diseases. According to the *Report on the Nutrition and Chronic Disease Status of Chinese Residents* published by the NHFPC in 2020,[92] the obesity rate for Chinese residents aged 18 and above was over 50% and approximately 20% for children aged 6 to 17. At the same time, China's population is becoming increasingly susceptible to chronic diseases and illnesses such as cardiovascular and cerebrovascular disease, cancer, chronic respiratory disease, and other non-communicable diseases. Another major trend in China is the country's ageing population, which increases the demand for elderly care and rehabilitation services.

European SMEs that specialise in these areas may find good opportunities to explore this market. Since the publication of the 14th FYP, the Chinese government has started a number of National Key R&D Projects covering a range of healthcare and life science areas, including medical equipment and biomedical materials, bio-safety, stem cell research, technical systems for epidemic prevention, health security for women and children, reproductive health, elderly care, and the integration of biotechnology and information technology – reflecting China's key priorities and development directions, and consequentially indicating the areas in which greater opportunities can be expected for European SMEs.[93]

Pharmaceuticals

In the 13th FYP, the Chinese government's priority in terms of pharmaceuticals was innovative and tumour-targeting drugs in both the biomedicine and chemical drugs areas. In October 2016, the Ministry of Industry and Information Technology (MIIT) issued the *Development Guide for the Medical and Pharmaceutical Industry*,[94] which provided a list of prioritised areas to be developed, including:

- Biomedicines: Prioritising the development of antibodies, recombinant protein drugs, vaccines, nucleic acid drugs and cell therapy products, and technology that could industrialise the production of the above drugs.
- Chemical drugs: Encouraging new chemical drugs that cure malignant tumours and various cardiovascular and nervous diseases. High-quality generic drugs and rare drugs are also encouraged.

The Chinese government also encourages the importing of foreign drugs. In certain free trade zones, such as Henan province and Beijing, some OTC drugs are allowed to be sold online via cross-border e-commerce.[95] In October 2017, the NMPA issued the *Decision Concerning the Adjustment of Imported Drug Registration* [96] to encourage the marketing of new drugs to meet clinical demands, the key points for which are as follows:

- For the implementation of international multi-centre clinical trials of imported drugs in China, phase I clinical trials can be conducted simultaneously in China and overseas, removing the requirement that

[92] *https://baijiahao.baidu.com/s?id=1686868730079847255&wfr=spider&for=pc (accessed: 29 June 2021).*

[93] *An overview of National Key R&D Projects launched for the 14th FYP is available at: https://www.sciping.com/35986.html (accessed: 29 June 2021).*

[94] *https://www.miit.gov.cn/ztzl/lszt/zgzz2025/wjfb/art/2020/art_9edb45b262da4fd291a3aceba97496cd.html (accessed: 29 June 2021). The EU SME Centre can assist to identify whether a certain product is on the list.*

[95] *http://www.gov.cn/zhengce/content/2021-05/12/content_5606009.htm (accessed: 29 June 2021).*

[96] *http://www.gov.cn/xinwen/2017-10/10/content_5230906.htm (accessed: 29 June 2021).*

the Investigational New Drug (IND) must have been first registered overseas or have entered phase II/phase III clinical trials (excluding biological products for preventive use).

- Upon completion of the international multi-centre clinical trial in China, the applicant can submit a New Drug Application (NDA) directly. The NDA shall comply with requirements of the Provisions for Drug Registration and relevant documents.
- For Clinical Trial Applications (CTA) for imported drugs, NDAs for imported new chemical drugs, and NDAs for imported innovative biological products for therapeutic use, the requirement that the product must have been approved in the country/region of the overseas manufacturer was removed.
- If an applicant had applied for clinical trial exemption for an imported product using data generated from multi-regional clinical trials (MRCT), and the application is accepted by the NMPA before October 2017 (i.e. the issuance of the *Decision*), the NMPA can directly grant approval if the application complies with the requirements of the Provisions for Drug Registration and relevant documents.

Additionally, the Chinese government will continue its efforts to develop traditional Chinese medicines (TCM). For European SMEs that have products that already have unique chemical structures or technology, China might be a market to consider exploring. European SMEs should consider partnering with a Chinese pharmaceutical company or a distributor to raise funding and explore the China market; however, in doing so, close attention must be paid to protecting their product patents prior to commencing any cooperation.

Medical devices

The Chinese government will grant priority and facilitate the registration of innovative medical devices and devices designed to treat rare diseases, and frequently occurring diseases that have no other effective treatment. Such medical devices include high-end medical imaging equipment, IVD equipment, surgical robots, Automated External Defibrillators (AEDs), portable ICUs, and wearable devices, amongst others. A detailed list of prioritised devices is included in the *Development Guide for the Medical and Pharmaceutical Industry*.[97]

When it comes to the high-end medical devices market, international brands have the upper hand as Chinese hospitals tend to favour international manufacturers regardless of their size, providing a natural advantage to European SMEs. European SMEs should also collaborate with experienced distributors that have experience in introducing international medical devices to China, however taking the two-invoice policy into consideration (see sections 3.2. and 4.2.).

Healthcare service providers

With the Chinese private healthcare sector further opening up, more opportunities can be identified for European SMEs. Although it is unlikely that European SMEs will set up wholly independently owned hospitals in China, there are still many options for European SMEs in China's healthcare sector. For example, as mentioned previously, the Hainan Boao Lecheng International Medical Tourism Pilot Zone aims to become a key national hub for the medical tourism industry. Various policies issued in this area highlight a series of priority sectors, including high-end physical examination, health management, third-party medical agencies, medical tourism and consultation platforms, and other medical service sectors.[98]

The high prevalence rate of chronic diseases may also provide opportunities for European SMEs that specialise in providing rehabilitation services. Currently, rehabilitation services are offered by either comprehensive hospitals or specialised rehabilitation hospitals, which tend to be publicly managed. However, European SMEs can focus on providing rehabilitation products that are currently not commonly used in China, such as

[97] *https://www.miit.gov.cn/ztzl/lszt/zgzz2025/wjfb/art/2020/art_9edb45b262da4fd291a3aceba97496cd.html (accessed: 29 June 2021). The EU SME Centre can assist to identify whether a certain product is on the list.*

[98] *http://www.gov.cn/xinwen/2019-09/17/content_5430452.htm (accessed: 29 June 2021).*

intermittent catheters. Intermittent catheters are much more commonly used in developed countries for patients who suffer from neurogenic bladder problems and wish to gradually restore their bladder function, as well as their quality of life. In China, however, doctors still prefer using suprapubic catheters and indwelling catheters despite the disadvantages compared to intermittent ones. European SMEs could therefore consider exploring the China market for similar opportunities in the rehabilitation sector.

Furthermore, China's population is ageing rapidly. The current number of beds offered by public and private homes for the elderly will soon fall behind the growth rate of China's elderly population. Traditionally, Chinese society has relied on individual families providing care for elderly members of their family. However, as a result of the One-Child Policy, the majority of children born during the late1970s and 1980s have to support up to four elderly relatives each, creating enormous difficulties when it comes to balancing their family life, work, and finances. The traditional family-orientated elderly care model continues to face difficulties due to China's rapid economic development. China is therefore urgently seeking new solutions for the elderly care sector. European SMEs that have experience in this sector will have advantages and should consider developing innovative elderly care solutions that would help solve existing problems in this sector.

Regarding HIT, this sector is relatively new compared to other healthcare sectors, though expanding steadily. The sector provides opportunities for European IT companies, such as software/applications, developers, and companies specialising in hospital IT system upgrading, especially as innovation and creativity are highly encouraged. Establishing 'internet hospitals' is not recommended for European SMEs as this requires an extensive hospital and doctor network in China. However, European SMEs can focus on providing software or apps that solve existing problems or improve efficiency: examples include software that helps hospitals manage and share patient information, apps that help private hospitals recruit international doctors, and apps that help doctors provide feedback to patients.

4.2. Challenges

There are a range of challenges that European SMEs should consider when contemplating and exploring China market entry.

Pricing pressures

The two-invoice policy may bring challenges to the distribution strategy of European SMEs that wish to sell their pharmaceutical or medical device products in China. Under the new system, European SMEs in the medical and healthcare sectors will have to work with more than one distributor to supply hospitals in different cities, thus increasing operating costs, as larger distributors tend not to directly maintain relationships with hospitals or doctors and have strict supplier filtering systems, while most small-scale distributors tend to only have capabilities to reach end users in their focus cities, provinces, or regions. There are, however, a number of cases of large general distributors (like Sinopharm) that can also reach end users, but being listed as a supplier for them is very difficult. When sales prices are fixed, increasing operation costs may also significantly reduce the profits of the manufacturer. Still, a positive aspect that European SMEs should be aware of, is that the two-invoice system does not apply when working with exclusive general distributors of imported drugs and medical devices, as they are effectively considered as the drug manufacturer.

While the two-invoice policy may bring increased operation costs, the centralised procurement of pharmaceuticals and medical devices impacts the profit of providers directly. In the long term, this may have negative impacts on generic drugs providers; once there are more than three companies with the same kind of generic drug passing the consistency evaluation, the competition will become extremely fierce, and the profit

margins decline. Generic drug manufacturers have the option of seeking to apply low-cost and multi-variety strategies, but the profit margins will likely remain low.[99]

Stricter unfair competition requirements

In 2016, the Supreme People's Procuratorate and the Supreme Court announced the *Interpretations of Several Issues Concerning the Application of Law in Handling Criminal Cases Related to Graft and Bribery*.[100] These interpretations clearly set out that any membership fees, accommodation, or transport fees paid to doctors would be considered acts of bribery. In the same year, the State Council also made new amendments to the *Chinese Anti-Unfair Competition Law* and further expanded the scope of bribery.[101]

For European SMEs that are conducting business in China, it is important to adhere to these regulations. When hiring a third-party agent or distributor, it is the responsibility of the European SME to ensure that an agent/distributor does not conduct any activity that may fall within the scope of bribery regulations in China. Traditionally, international enterprises in China have been aware of the important role of maintaining *guanxi* (a good relationship) when doing business, both with local governments and clients; while certainly still very important, European SMEs need to pay particular attention to not engage in monetary transactions or any other actions that may be construed as unlawful when building relationships. If such acts are conducted, the guilty enterprise may face severe punishment from both the Chinese and their home country's governments.

Local competition

With the Chinese government's focus and support to the development of the Chinese pharmaceutical and medical device industries, European SMEs in China are starting to face increasingly stronger competition from Chinese companies. Chinese manufacturers, especially state-owned enterprises, are usually given preference by local governments. For example, the Sichuan provincial government previously issued the *Notice of the Publishing of 2017 Provincial Government Imported Product Procurement List*,[102] explicitly indicating that local products should be given priority, and that healthcare institutions may only purchase imported products when local products cannot meet their requirements. In addition, if imported products are purchased, healthcare institutions must present a reasonable explanation as to why Chinese products could not meet their current needs. The *Consistency Evaluation of the Quality and Efficacy of Generic Drugs* introduced by the NMPA in 2016 will greatly enhance the quality of Chinese generic drug producers.[103] Although the process will eliminate a significant number of smaller companies, those that survive will pose a threat to European pharmaceutical producers that wish to enter the Chinese market by ensuring high quality products for lower prices.

Other issues – intellectual property

All European SMEs that wish to enter the China market take all the necessary steps to protect any patents and key technology. Although intellectual property (IP) protection has improved significantly in China, there still are frequent cases of IP rights infringements affecting foreign companies in China. The issue of patent trolls deliberately filing patent invalidation cases against foreign companies remains prominent in the pharmaceutical industry. Therefore, it is vital for all European SMEs in China to have solid IP protection strategies even before they enter the Chinese market. There are significant differences between the European and Chinese IP systems when it comes to the protection of trademarks and patents – most notably the first-to-file approach used by

[99] http://www.sdgdyf.com/news/43.html *(accessed: 29 June 2021).*

[100] https://www.spp.gov.cn/zdgz/201604/t20160418_116334.shtml *(accessed: 29 June 2021).*

[101] www.lawtime.cn/info/jingzheng/jzfg/201603033330143.html *(accessed: 29 June 2021).*

[102] www.ccgp.gov.cn/dfcg/dfdt/201702/t20170204_7900751.htm *(accessed: 29 June 2021).*

[103] http://www.gov.cn/zhengce/content/2016-03/05/content_5049364.htm *(accessed: 29 June 2021).*

China – but also trade secrets. Professional information and technical assistance on IP rights (IPR) issues can be obtained, free-of-charge, from the EU IPR SME helpdesk.[104]

4.3. Key success factors for SMEs

China represents one of the most promising markets in the global healthcare industry, yet it remains highly competitive. Large multinational companies in China have been active in China for decades and have established solid networks of partners and clients, while Chinese companies enjoy policy preferences from local governments in terms of subsidies, innovation, and preferential treatment, which leads to more competitive prices offered. It is therefore important for European SMEs to exercise their core competitive advantages in order to enter and prosper in the competitive China market: this section summarises key success factors to help European companies in doing so.

Stay up to date with the latest policies

Various policies covering pharmaceutical and medical device registration, classification, and distribution can change with short notice. European SMEs in these sectors should remain up to date with the latest policies and adjust their operation strategies accordingly; failure to do so in a timely manner will likely lead to loss of competitive advantage and market share. For example, the Ministry of Science and Technology has launched 52 National Key R&D Projects to advance research and innovation in the priority areas of the 14th FYP, some of which cover medical equipment and biomedical materials, biosafety, stem cell research, and others related to life sciences. Information on these projects, including the full texts of the grant applications and the expected deliverables, are available online,[105] and are useful to understand what products and technologies will receive stronger support by both the government and clients. To do so, European SMEs should closely monitor the Chinese government's various websites (a list of useful links is available at the end of this report). European SMEs should also consider visiting conferences in different industry sector areas held by trade associations, industrial alliances, pharmaceutical and medical device companies, as well as government agencies. Activities organised by different chambers of commerce are also a good platform for interaction and sharing information with different companies.

Be innovative and cautious

Innovation is a key quality of European SMEs. Typically, international enterprises cannot compete with Chinese companies on price, but with their creativity and expertise, European SMEs are often able to develop more innovative and higher-quality products. At the same time, products should be closely related to the needs of the Chinese government and market, and should provide solutions to existing issues. While promoting their products, European SMEs must remain extremely cautious and adopt all the necessary steps to protect their Intellectual Property (IP) rights in China even before they enter the Chinese market.

Identify and work with reliable partners

For European SMEs that are not familiar with the China market and China's social structure, it is often more efficient to cooperate with one or multiple reliable local partners. Potential partners can include distributors, investors, and R&D partners. Prior to signing a contract, to ensure that the Chinese partner(s) they intend to work with are reliable, European SMEs should undertake appropriate due diligence procedures, including doing a basic search of the company name, contact name, phone number, and email address from their partner's business card on the Chinese search engine Baidu. This simple check can potentially already reveal unexpected

[104] *https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/china-ipr-sme-helpdesk_en (accessed: 29 June 2021).*

[105] *On a dedicated platform: https://service.most.gov.cn/ (accessed 1 July 2021).*

information. European SMEs are also recommended to research their prospective partner's company name and its legal representative's name through the official website of the local Administration for Market Regulation (AMR). Almost all regional AMRs in China provide key registration information for all registered companies under its governance. Please note, however, that these are in Chinese and include only basic information. European SMEs should compare information obtained from this research with information provided by potential partners to make an informed decision on whether to partner with a company or not. European SMEs can contact the EU SME Centre for a free-of-charge preliminary due diligence service.

Hire effective agencies

It is necessary for European SMEs to hire agencies to conduct market research, and most importantly to help with pharmaceutical or medical device registration processes, as one single mistake in the process may result in significant delays and financial losses. Business license application and marketing are also two other aspects on which professional assistance is essential.

It is important for European SMEs to hire agencies that have proven track records in helping international companies in China. These agencies should be registered in China and understand relevant laws and regulations, as well as market conditions. European SMEs should also ensure that all the actions taken by agencies are compliant with laws both in China and in Europe. Agencies should not be engaging in acts of bribery when seeking business opportunities with hospitals, doctors, or government officials in any form. When necessary, European SMEs should hire lawyers to produce non-disclosure and anti-corruption agreements to be signed by partners; they can also approach the EU SME Centre for free-of-charge technical assistance and advice.

Seek opportunities in niche markets

Due to strong competition in popular sectors in the healthcare industry, European SMEs may find potential opportunities in niche markets. Furthermore, due to the gap existing between the healthcare sectors of developing countries and developed countries, European SMEs may explore opportunities to introduce products and services that are common in Europe but new or not popular in China – for instance intermittent catheters mentioned in section 4.1. To be successful in these niche markets, European SMEs need to have a good understanding of the local market, the size of opportunities identified, and act in a timely manner.

5. Other useful information

Key trade fairs

China International Medical Equipment Fair (twice annually)

International Component Manufacturing & Design Show (twice annually)

China International Medical Instruments and Equipment Exhibition (annually)

China International Pharmaceutical Machinery Exposition

Pharm China

China Beauty Expo

Industry associations

China Association for Medical Devices Industry

China Association of Pharmaceutical Commerce

Chinese Hospital Association

Shanghai Pharmaceutical Profession Association

China Association of Medical Equipment

China Association of Enterprises with Foreign Investment

R&D-based Pharmaceutical Association Committee

China Medicinal Biotech Association

Useful websites

National Medical Products Administration

National Health Commission

Centre for Drug Evaluation, NMPA

Centre for Medical Device Evaluation, NMPA

National S&T Service Platform (for information on China's national R&D projects and grant applications)

About the EU SME Centre

The EU SME Centre helps European SMEs get ready for China by providing them with a range of information, advice, training, and support services.

To find out more, visit: www.eusmecentre.org.cn.

Do you have a question about doing business in China?

Ask one of our in-house experts and receive practical and confidential advice within seven working days. We can provide information and advice relating to business development, market access, legal issues, and human resources.

To submit your enquiries directly to our experts go to *Ask-the-Expert* **www.eusmecentre.org.cn/expert**, or contact us at **info@eusmecentre.org.cn**

Further reading…

The EU SME Centre has nearly 200 reports, guidelines, and case studies in its Knowledge Centre, the following may be relevant to you:

- *The Medical Devices Market in China (2017)*: https://www.eusmecentre.org.cn/report/medical-devices-market-china-0
- *Impeto Medical – Exporting French Medical Devices to the Chinese Market (2017):* https://www.eusmecentre.org.cn/casestudy/impeto-medical-%E2%80%93-exporting-french-medical-diagnostic-devices-chinese-market

We have also available **recordings of previous webinars** on this field and other general topics:

- *Selling through livestreaming in China (June 2021), which includes a case study from an European beauty brand:* https://www.youtube.com/watch?v=d7k_IhcZjWQ
- *Knowing Your Chinese Partner (May 2021):* https://m.youtube.com/watch?v=5l0IOTTOrrU
- *China's Healthcare and Medical Devices Market (April 2021):* https://m.youtube.com/watch?v=sjpY4wfW-VA

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