

EXECUTIVE SUMMARY CHINA HEALTHCARE INDUSTRY REPORT



Ministero dello Sviluppo Economico

ITCA 
ITALIAN TRADE AGENCY

EXECUTIVE SUMMARY

Market Overview

- As China's healthcare reforms deepen, the central and local governments have managed to actuate the private investment in the healthcare sector especially in terms of new private hospitals and clinics established across the country, and reduce the purchasing prices for many essential drugs to lower burdens of individuals.
- Chinese expenditure on medical and healthcare increased at a CAGR of 13% from US \$534 billion to US \$779 billion between 2014 and 2017, among which social capital contributed 41%; the year 2018 and 2019 are estimated to continue growing to US \$843 billion and US \$894 billion but at a slower pace.
- The proliferation of aging population, increased prevalence of chronic diseases, historically low birth rate despite the government's newly implemented "Two-Child" policy, together with the progressively upgraded standards of living, have and will likely continue to drive the growth of the medical and healthcare sector in the coming years.
- Despite the sharp price cuts of pharmaceuticals in China due to the government's price control, domestic and international companies were able to benefit from the latest policies and regulations, in particular, the upgraded and expanded NRDL (National Reimbursement Drug List), expedited and simplified processes for drug approval and clinical trials, encouraging innovations and protection of innovators, tariff exemption on certain imported drugs, etc.
- Overinvestment and surplus production, the Central government's pressure for environmental protection, coupled with the continuously rising production costs, might have led to a consecutive drop to the fixed asset investment especially foreign investment in the medical and health sector in 2016 and 2017.
- On the other hand, the Chinese government has implemented drastic regulatory transformation in the past three years, which makes the medical and healthcare market more attractive for international players.
- Key changes include the expedited approval for innovative drugs and drugs treating rare diseases, expanding the NRDL (National Reimbursement Drug List), facilitating clinical trials, pilot of MAH (Marketing Authorization Holder) mechanism¹, China becoming an ICH² member, encouraging and protecting interests of drug (and medical device) innovation companies, two-invoice system³, elimination of import tariffs of certain imported drugs and medical products, etc.
- The 13th Five-Year Plan (FYP) in the Pharmaceutical Industry released on November 7, 2016 together with the 13th FYP in the Medical Device Sector released on May 26, 2017 and the 13th FYP of Biotech Innovation released on April 24, 2017 have identified key medical segments and technologies to develop and break through during the 13th FYP period (2016-2020), which will help private sectors navigate their R&D and investments.

¹ Marketing Authorization Holder mechanism means that pharmaceutical research and development institutions, technicians, manufacturers, etc. can be granted approval for marketing drugs; the pilot plan was valid from June 2016 to November 2018.

² ICH = The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

³ Two-invoice system refers to the procedure that sees pharmaceutical companies issue one invoice to distribution companies and the distribution companies issue another invoice to medical institutions; the purpose of the two-invoice system is to replace the previous long supply chain and reduce drug prices by eliminating multiple layers of distributors (e.g. tier-2, 3, 4...) in the healthcare systems.

- The *Healthy China 2030* promulgated in October 2016 serves as a national strategy for the Chinese government to build a healthy China focusing on the lifelong needs of all people and improving quality of medical services; the blueprint encourages private sectors to establish extensive facilities for medical care, healthcare, fitness, leisure and sports, etc. including internet-based health services.

Medical and Healthcare Ecosystem

- China's Central government plays a fundamental role in the entire ecosystem of the medical and healthcare sector, mainly through regulatory guidance and supervision and financial support.
 - The four key government bodies regulating the medical and healthcare ecosystem are State Administration for Market Regulation (SAMR), National Health Commission (NHC), China Banking and Insurance Regulatory Commission (CBIRC), and National Healthcare Security Administration (NHSA).
 - These government authorities are obliged to supervise and interact with pharmaceuticals and medical device suppliers, medical service providers, healthcare service providers, and medical expense payers in terms of license issuing, drug approval, bidding and procurement of drugs and medical facilities, etc.
 - 95% of the medical institutions in China are primary healthcare service providers including community health centers, village health clinics, etc.; public hospitals have encountered a steady decline due to government's policies on rectifying and eliminating public hospitals lacking in competitive advantages and having difficulties in operation.
 - Private hospitals have experienced the fastest growth among others, especially nursing homes, beauty, stomatological, ophthalmology hospitals, etc. due to high profitability.
 - However, foreign invested hospitals remained small, mainly due to the regulations limiting foreign ownership and the difficulty for them to participate in the Chinese social health insurance plan.
 - From 2014 to 2018, online medical diagnosis and treatment went through a rapid exploratory development in regulatory vacuum and entered the phase of licensing control; online hospitals must rely on the bricks-and-mortar hospitals and provide follow-up outpatient services.
 - Additionally, the Central government loosening online drug prescription and review is likely to benefit multiple groups including overcrowded public hospitals, patients, eCommerce pharmacies, etc.
 - Chinese patients still prefer to go to large public hospitals for outpatient, emergency and in-patient services, due to their perception of more qualified doctors and superior medical facilities in these large public hospitals.
 - The development of online medical service providers (e.g. online appointment, consultation, diagnosis, drug prescription and distribution, etc.) and private medical institutions have expanded more channels for Chinese patients to see doctors in China, shortened the waiting time, and made it more convenient for Chinese patients to obtain medical treatment.
 - Over 95% of the Chinese citizens are covered under some state insurances mainly through urban resident health insurance, urban employee health insurance, and new rural cooperative medical
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insurance, which provides different percentage ranges of reimbursements for medical expenses depending on hospital classification, outpatient or in-patient, amount of medical expenses, etc.

- The major channels of outpatient services for foreign patients who do not speak Chinese are still the foreign invested international hospitals and clinics or large 3A (Class III Grade A) public hospitals with international outpatient departments in China (mostly located in tier 1 cities and some tier 2 cities, e.g. Beijing, Shanghai, Guangzhou, Chengdu).
- Typically, foreign invested international hospitals provide more comfortable ambience, longer and more thorough treatment, and much less waiting time than public hospitals in China; increasing number of high-income Chinese patients choose to go to foreign invested private hospitals and some of them have purchased commercial insurance coverage that works with these hospitals.
- Foreign patients employed in China usually have social insurance through the employer with legal entity in China or have commercial insurance coverage which tend to work with many foreign invested international hospitals; otherwise, paying the outpatient fees out of pocket is an alternative.

Market Segment – Pharmaceuticals

- Many leading international pharmaceutical companies have experienced accelerated growth in China in the past two years, mainly due to the expedited drug approval and expanded NRDL together with the strong demand for innovative drugs and increasing purchasing power of the average Chinese population.
- China's pharmaceutical market size (based on domestic production, plus imports, less exports) increased at a CAGR of 8% from US \$376 billion to US \$474 billion between 2014 and 2017; however, it declined by 13% year-on-year in 2018; it is estimated to recover with a 5% year-on-year growth in 2019.
- The retail sales (e.g. pharmacies, supermarkets, etc.) of pharmaceuticals increased at a CAGR of 14% from US \$78 billion to US \$102 billion between 2014 and 2016, followed by a sharp drop of 21% year-on-year largely due to the implementation of "Two-invoice" system (replacing the traditional multiple layers of distributors who take large percentages of commission during the distribution process); the year 2018 saw a slight recovery by 4% year-on-year.
- Pharmaceutical production of by above-scale enterprises⁴ increased at a CAGR of 9% from US \$350 billion to US \$451 billion from 2014 to 2017, and decreased by 14% year-on-year to US \$390 in 2018.
- Domestic pharmaceutical production is mainly concentrated in the Eastern and Southern regions; Guangdong, Jiangsu, and Shanghai have the largest numbers of pharmaceutical companies and clinical trial institutions.
- In the past few years, many international pharmaceutical leaders such as *Pfizer*, *Roche*, *Novartis*, and *AstraZeneca* have established innovation centers or subsidiaries through WFOE⁵ or JV⁶ to accelerate the new drug development (particularly in oncology and lung diseases) in China.

⁴ Above-scale enterprises refer to industrial enterprises with annual revenue above US \$3 million.

⁵ WFOE = Wholly Foreign Owned Enterprise

⁶ JV = Joint venture

- The year 2017 and 2018 saw robust growths in VC/PE⁷ investment, M&As⁸ and IPOs⁹ in China's life science sector especially pharmaceutical segment.
- Hospitals and different levels of medical care organizations together with Chinese local governments (in particular the provincial/municipal Health Security Bureaus subject to the supervision of NHSA¹⁰) are still key purchasers of majority of pharmaceuticals; retail sales (e.g. chain pharmacies, hyper/supermarkets, etc.) accounted for 23% of the total.
- However, despite the centralized procurement of drugs, each province/ municipality currently still has the flexibility to adopt different procurement patterns – public tendering (e.g. Beijing, Anhui, Guangxi, etc.), third-party electronic trading pattern (e.g. Guangdong), third-party eCommerce medicine exchange (e.g. Chongqing), cross-region joint procurement (e.g. *Sanming Union* that consists of 21 cities in 15 provinces), group purchasing organization (e.g. Shenzhen), and procurement pattern combined with medical insurance (e.g. Fujian).
- Typically, each provincial/ municipal government has established their own procurement platform (e.g. <http://trd.udplat.org>) or work with a third-party procurement platform (e.g. <http://ggzy.gd.gov.cn>, <http://ucenter.yjsds.com>) for drug procurement, where they can publicize the tendering information, vet registered suppliers, organize the bid/ auction/ negotiation, and complete transactions.
- International pharmaceutical companies with legal entities or their distributors in China which intend to obtain tendering information and participate in the tendering process shall be registered with these provincial/ municipal government procurement platforms by submitting all of the required information.
- Due to the pressure from the central government on price control, international and domestic companies especially that provide low-price and competitive drugs will have to lower their prices to be able to win the bid.
- Moreover, the central government is looking to establish a nation-wide unified procurement and bidding platform for drugs and consumables; the launching of this platform is likely to further improve the centralized procurement process in the near future.
- The implementation of “two-invoice” system will likely provide more transparency in the procurement of pharmaceuticals in the healthcare system and eliminate a large number of small and medium sized distributors lacking competitive advantages.
- The experiment of “Procurement of drugs with target quantity” will presumably accelerate the replacement of innovative drugs by generics drugs in the near future, and pressure innovative drug companies to increase R&D to develop more new drugs and generics drug companies to pass conformance evaluation to obtain the qualification to compete in the procurement process.

Market Segment – MedTech

- China is the second largest MedTech market after the United States, contributing 19% of the global MedTech market value.
- From 2014 to 2018, the medical equipment market size maintained a CAGR of 20% from US \$39 billion to US \$80 billion, and it is estimated to reach US \$92 billion by 2019.

⁷ VC/PE = Venture capital / private equity

⁸ M&As = Merge and acquisitions

⁹ IPOs = Initial public offerings

¹⁰ NHSA = National Healthcare Security Administration

- Half of the domestic demand was fulfilled with imported medical devices; international brands such as *GE*, *Philips*, and *Siemens* still dominated the high-end MedTech market (e.g. 64-slice CT¹¹ and above, physical/ chemical analysis, surgical/ dental appliances, DR¹², MRI¹³, etc.) in China.
- China mainly manufactures mid-range and low-end medical equipment (e.g. stents, IVD, medical consumables, etc.), and over half of them were for exports; majority of the production clusters were located in the Pearl River Delta, Yangtze River Delta, and Bohai Bay areas.
- Similar to pharmaceuticals, China's MedTech market is highly fragmented, with 16,000+ manufacturers; the top ten medical equipment manufacturers held less than a 20% market share combined.
- Generally, Class III hospitals¹⁴ purchased the largest number of advanced imported medical devices, while the imported medical devices accounted for a much lower percentage in public Class II hospitals and private hospitals, and community hospitals (Class I) purchased the lowest number of imported medical devices.
- In the coming years, market growth will likely be driven by the replacement of outdated medical equipment especially from Class III hospitals, the upgrade of town and county hospitals to Class II hospitals, the expanding medical departments in Class II and III hospitals.
- Unlike the procurement of pharmaceuticals, there is generally no centralized procurement system for medical equipment except a few provinces such as Fujian which established centralized procurement platform for both drugs and medical devices (<http://trd.udplat.org>); medical equipment is usually purchased based on the needs of local medical and healthcare institutes and local government budget (for public hospitals).
- Public tendering is still the most common purchasing pattern for public hospitals, coupled with other patterns including invitation bid, competitive negotiation, etc., while inquiry is the most common procurement pattern for private hospitals.
- International companies with legal entities or their distributors in China shall be registered with provincial/ municipal government procurement websites (e.g. www.ccgp-beijing.gov.cn, www.ccgp-hunan.gov.cn) to be able to obtain tendering information and participate in public tendering process.
- However, there might not be public information about the procurement demand for other purchasing patterns; usually hospitals prefer working with qualified suppliers that have established long-term relationships with them.
- International medical equipment companies with legal entities or distributors in China shall become a qualified supplier in the supplier management system of private and certain public hospitals, and it is critical to maintain good relationship with these medical institutions to be able to keep up with the latest procurement demand.

¹¹ CT = Computed Tomography, CAT scan

¹² DR = Digital Radiography

¹³ MRI = Magnetic Resonance Imaging

¹⁴ Hospitals in China are organized according to a 3-tier system that recognizes a hospital's ability to provide medical care, medical education and conduct medical research. Based on this, hospitals are designated as Class I, II and III institutions. Class III hospitals round up the list as comprehensive hospitals at the city, provincial or national level with a bed capacity exceeding 500. They are responsible for providing specialist health services, perform a bigger role with regard to medical education and scientific research and serve as medical hubs providing care to multiple regions. Based on the level of service provision, size, medical technology, medical equipment, and management and medical quality, these three grades are further subdivided into 3 subsidiary levels – A, B, and C. In addition, one special level – 3AAA is reserved for the most specialized hospitals, which usually is very rare.

- Quality, price, and after-sales services are the key factors affecting the decision-making process; Class III hospitals tend to be less price sensitive compared with Class II and private hospitals which prefer medical devices with the highest quality-price ratio.
- However, there is a likelihood that medical equipment suppliers will be requested to lower their prices throughout China due to the central government's continuous implementation of price control, and some provinces such as Anhui have implemented such policies.

Import and Export Analysis

Pharmaceuticals

- The year 2016 was a turning point for China's imports and exports of pharmaceuticals; from 2016 to 2018, imports recovered with a CAGR of 20% to US \$117 billion, while exports saw a CAGR of 18% to US \$93 billion.
- Nearly half of imports were chemical formulations including cyclic hydrocarbons, cyclic alcohols and halogenated derivatives, acyclic hydrocarbons, etc.; the imports of these key chemical formulations experienced an upturn at a CAGR of 21% between 2016 and 2018.
- Imported pharmaceuticals products under HS Code 30 was one of the few segments that maintained double-digit growth from 2010 to 2018, with a CAGR of 19% from US \$-7 billion in 2010 to US \$-28 billion in 2018; accounting for 24% of the total imports.
- The top 5 countries exporting pharmaceuticals to China remained South Korea, Japan, United States, Germany, and Taiwan.
- After the 8% dip in 2015, China's imports of pharmaceuticals with *Italy* recovered in 2016 and 2017 with a double-digit CAGR of 12%; yet the growth trend ceased to continue in 2018 as imports went up only by 2% to US \$2.3 billion.
- *Italy* is strong in pharmaceutical ingredients especially medicaments, but relatively weak in chemical formulations such as acyclic alcohols and halogenated derivatives and acyclic hydrocarbons, and cyclic hydrocarbons.

MedTech

- After the slight dip (-3%) in 2015, China's imports of medical equipment recovered with a CAGR of 8% from US \$32 billion to US \$41 billion; exports of medical equipment picked up with a CAGR of 10% between 2016 and 2018 to US \$51 billion.
 - Imports of Instruments and apparatus for physical and chemical analysis and medical/ surgical/ dental/ veterinary instruments & appliances became the largest two import categories, accounting for 23% and 21% respectively of the total.
 - Orthopedic appliances remained the fastest growing segments among key medical equipment imported into China; from 2016 to 2018, imports of orthopedic appliances increased at a CAGR of 11% to US \$~4 billion, but the growing pace was much slower than the previous years.
 - The top 5 countries exporting medical equipment to China include the United States, Japan, Germany, South Korea, and Taiwan.
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- Similar to China's overall imports of medical equipment, the imports from *Italy* also experienced a slip in 2015 and a subsequent rebound at a CAGR of 7% from US \$657 million to US \$749 million; meanwhile, the exports to *Italy* picked up at a faster pace (a CAGR of 15%) over the same period of time.
- *Italy* is relatively strong in spectacles and protective glasses, nonelectric instantaneous / storage water heaters for hospital use, but weak in optical fibers and optical fiber bundles, electrical filament or discharge lamps, orthopedic appliances, and instruments and apparatus for physical or chemical analysis, and hydrometers, thermometers, hygrometers, psychrometers, etc.

Market dynamics and Trends

- China is still a fastest growing and attractive market for international medical players; the recent regulatory evolution such as expedited drug and medical device approval process has made it even more lucrative.
- A series of 13th FYPs in the medical industry have highlighted the market potentials for innovative and cutting-edge technologies in the next few years; areas that are encouraged for accelerated development include biopharma (e.g. new vaccines, antibody preparation, etc.), bio-tech, biomedical materials, advanced medical imaging, rehabilitation care, robotic therapy, etc.
- Biopharma has become the next fast-growing submarket, driven by the central government's stimulus policies, increasing VC/PE investment, M&A activities, and IPOs.
- Generics submarket is likely to experience polarized situations, with the implementation of conformance evaluation; large generics firms with strong capital and R&D capabilities will be able to obtain large stake of the market while small and medium sized generics firms might be gradually phased out.
- International and domestic pharma firms need to be adaptive to the market needs, as the Chinese market urges investment in R&D and innovation instead of marketing campaign and channel development.
- In the coming years, market concentration of retail pharmacies will be further improved, as a result of the government's endeavor to further rectify and regulate the chaotic retail drug market and outlaw disqualified drug stores.

Considerations for Italian Players


- Opportunities exist for *Italian* medical enterprises to access and expand in the China market, particularly with the growing middle class and steadily increasing purchasing power, improving standards of living and awareness of healthcare, rising aging population and prevailing chronic diseases, as well as the central and local governments' incentives for developing innovative and advanced medical technologies.
 - *Italian* pharmaceuticals and MedTech companies were generally not as known as their American, German and Japanese counterparts in the China market, but this might be an opportunity for *Italian* players to provide a fitting price strategy to tap into the high-end and medium-end markets specifically targeting at the demand from public Class III and Class II hospitals and private hospitals.
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- On the other hand, *Italian* players may have to face intensifying competition particularly in the mid and high-end market segments, as both international and domestic counterparts have stepped up investments in R&D and innovation in China and are seeking to grasp more market stake.
 - Moreover, with China's increasing pressure and efforts to improve air and water quality, *Italian* pharma companies looking to establish manufacturing base in China might encounter regulatory hurdles due to the limited quota of waste discharge in different regions.
 - Therefore, *Italian* players should direct concerted effort through partnership with reliable local partners to develop adaptive strategies, take advantage of the overall improving regulatory environment and local resources including talents, and increase penetration in China's medical and healthcare system.
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