



ITALIAN TRADE AGENCY

**ICE - Agenzia per la promozione all'estero e
l'internazionalizzazione delle imprese italiane**

意大利对外贸易委员会上海代表处



China Medical Industry Report

EXECUTIVE SUMMARY

April 11, 2016

EXECUTIVE SUMMARY

Market Overview

- Chinese expenditure on medical and healthcare was estimated to have increased at a CAGR of 15 percent from US \$234 billion in 2008 to US \$637 billion in 2015; from 2015 to 2018, it is expected to grow at a CAGR of ~12 percent to US \$890 billion by 2018.
- Key drivers include China's large population, the rapidly increasing aging population, consumers' increasing incomes, and the Chinese government's healthcare reforms initiated in 2009, which includes gradually expanding the national Essential Drug List¹ (EDL) and Reimbursement Drug List (RDL) covered under the national medical insurance plan.
- Through healthcare reforms, the Chinese government aims to build a more comprehensive and affordable national healthcare system by 2020, and ensure consumers' ability to pay for healthcare services.
- China's central and local governments play an important role in the medical industry as the majority of hospitals and medical institutes are state owned or affiliated.
- China's healthcare system has seen significant development in the past few decades especially in infrastructure establishment in both urban and rural areas; over 95 percent of the population is covered by some medical insurance (through national health insurance or a rural co-operative medical insurance system).
- Healthcare reforms and government policies have helped to drive the rapid growth of newly increased domestic fixed asset investment in the medical industry, which had a CAGR of 36 percent from 2008 to 2013 (US \$48 billion), much faster than the CAGR of 14 percent the industry grew from 2005 to 2008.
- Newly increased foreign fixed asset investment in the medical industry grew dramatically from 2009 to 2011, but went back to 2008 levels (US \$839 million) in 2014, accounting for less than 2 percent of total investment in the industry.
- In 2014, the State Council released guidelines and a timetable to reform public hospitals, and the central government is anticipated to increase expenditure on clinics, insurance, medical equipment, drugs, etc. in rural areas.

Market Segment – Pharmaceuticals

- China's pharmaceutical market size (based on domestic production, plus imports, less exports) increased at a CAGR of 19 percent from 2010 to 2014 to US \$442 billion; it is estimated to have reached US \$505 billion by the end of 2015.

¹ The national Essential Drug List (EDL): EDL contains various essential and affordable drugs for basic health needs. China issued its first EDL in 1984 and revises it every once 3 years.

- The retail sales (e.g. pharmacies, supermarkets, etc. excluding hospitals, clinics, and other non-retail channels) of pharmaceuticals increased at a CAGR of 24 percent from 2008 to 2014 to US \$73 billion; it is estimated to have reached US \$90 billion by 2015.
- Production of pharmaceuticals is concentrated in the Eastern and Southern areas; Zhejiang and Guangdong provinces account for over 20 percent of the total industry output, followed by Jiangsu and Shanghai.
- China's pharmaceutical industry is highly fragmented, with 5,800+ GMP certified manufacturers and 10,000+ distributors; the top domestic player, Sinopharm, only has ~6 percent market share.
- Around 1,000 foreign pharmaceutical firms have invested in China through multiple forms such as WFOE (Wholly Foreign Owned Enterprise), JV (Joint Venture), RO (Representative Office), etc.
- Domestic manufacturers dominate the generics market and heavily compete on pricing, which have caused many international companies to lose interest in the segment.
- Foreign firms have increased focus and investment on individual product segments in recent years; they hold ~20 percent of the OTC market, dominating sub-segments including vitamins and health supplements.
- Hospitals and different levels of medical care organizations supported by Chinese local governments are key purchasers of the majority of pharmaceuticals; retail sales (e.g. chain pharmacies, hyper/supermarkets, etc.) account for 17-18 percent of the total.
- Most drugs enter hospitals and medical institutes through multiple tiers of distributors or agents, and this complicated and long distribution chain has caused irrationally high drug price in China's medical and healthcare system.
- To tackle the issue of high drug price, the Chinese central government instituted healthcare reforms in 2009 and issued the *Guideline on Completing the Centralized Procurement of Drugs in Public Hospitals* in February 2015.
- Moreover, implementation of the new *Good Manufacturing Practice for Drugs* (GMP 2010) and *Good Supplying Practice for Drugs* (GSP 2013), together with more stringent drug registration and license approval and renewal process, is helping to restructure the industry and eliminate less qualified players at multiple stages of the healthcare and pharmaceutical value chain.

Market Segment – Medtec

- China is the fourth largest Medtec market after the U.S., Japan and Germany, but its medical equipment industry still lags behind many developed countries in terms of technology R&D, and market applications.

- However, China is the fastest growing medical equipment market and the market size was estimated to have grown at a CAGR of 27 percent from 2009 to 2015 reaching US \$56 billion, and it is estimated to reach US \$66 billion by 2016.
- The Pearl River Delta, Yangtze River Delta, and Bohai Bay are the three largest industrial clusters for Medtec in China and account for over 80 percent of the production and sales of medical equipment in China, especially Beijing, Shanghai, Jiangsu, and Guangdong.
- Similar to pharmaceuticals, China's medtec market is highly fragmented, with 16,000+ manufacturers; the top ten medical equipment manufacturers, including Wego and Mindray, have less than a 20 percent market share combined, and ~90 percent of the manufacturers are small and low-end with annual sales revenue less than US ~\$1.6 million.
- Domestic companies dominate the majority of the mid and low-end medical equipment market (e.g. stents), mainly attributed to their understanding of the local markets and competitive prices.
- Foreign companies account for ~70 percent of the high-end medical equipment market (e.g. physical / chemical analysis, surgical / dental appliances, digital radiography, etc.).
- Several large foreign players including Eli Lilly, Merck, General Electric (GE) and Siemens have adopted an "in China for China" strategy, establishing multiple R&D centers in China along with multiple manufacturing facilities designated for the development and production of mid-end products.
- Class III hospitals mostly located in urban areas mainly purchased imported medical equipment, while Class II hospitals or smaller scale medical and healthcare institutes tend to purchase domestic medical equipment; yet this will likely change since the central government has encouraged large and top hospitals to purchase domestic medical equipment, which will likely challenge foreign enterprises.
- Market growth is mainly driven by the replacement of outdated medical equipment and expanding coverage of advanced medical equipment in rural areas.
- Unlike the procurement of pharmaceuticals, there is no centralized procurement system for medical equipment; medical equipment is usually purchased based on the needs of local medical and healthcare institutes and local government budget.
- The actual tendering and procurement process for medical equipment might be different depending on different geographical locations; however, it usually involves the medical and healthcare institute (supported by the local government), tender agents, tendering companies, and experts evaluating the bidders.
- China has implemented the *Good Manufacturing Practice for Medical Devices* (the GMP) in January 2011 to tighten control over the production of medical equipment.
- Most medical equipment is subject to CCC (China Compulsory Certification) regulation, except for eight types of medical equipment and devices, which includes:

X-ray diagnostic equipment for medical use, hemodialysis device, hollow fiber dialyzer, artificial heart-lung machine, ECG (electrocardiogram), etc.

- Moreover, apart from the GMP, CCC, and stringent registration and approval processes, stricter clinical trial requirements for Class II and Class III² medical equipment since June 1, 2014; both domestic and foreign products need to complete trials before distribution and sales in China.

² Medical devices and consumables are also classified into 3 broad classes – I, II and III, dependent on the amount of risks and potential damages that the patient/end-user may be undertaking during use, from I with lowest risks to III at highest risks.

Import and Export Analysis

Pharmaceuticals

- In 2015, China's imports of pharmaceuticals reached US \$86 billion, a 12 percent drop from 2014; from 2010 to 2013, imports grew at a CAGR of 13 percent.
- In 2015, exports also experienced a 6 percent decrease from 2014 to US \$68 billion; from 2010 to 2014, exports grew at a CAGR of 11 percent from US \$47 billion in 2010 to US \$72 billion.
- Nearly half of imports were chemical formulations including cyclic hydrocarbons, cyclic alcohols and halogenated derivatives, acyclic hydrocarbons, etc.; however, the 37 percent decrease in imports of these key chemical formulations have led to the drop of imports of pharmaceuticals in 2015.
- Different from most other sub-segments, imported pharmaceuticals products under HS Code 30 have maintained growth at a CAGR of ~22 percent from US ~\$7 billion in 2010 to US ~\$19 billion in 2015; its percentage out of the total imports increased from ~11 percent in 2010 to ~22 percent in 2015.
- The top 5 countries exporting pharmaceuticals to China were South Korea, Japan, United States, Taiwan, and Germany.
- China's trades of pharmaceuticals with Italy discontinued the previous years' CAGR of over 20 percent in 2015; imports experienced a slight drop by 8 percent to US \$1.8 billion; exports to Italy merely maintained the level of 2014 at US ~\$1.3 billion.
- Italy is strong in pharmaceutical ingredients especially medicaments, but relatively weak in chemical formulations such as acyclic alcohols & halogenated derivatives and acyclic hydrocarbons, and cyclic hydrocarbons.

Medtec

- Imports of medical equipment ceased to continue the growth of previous years in 2015 and experienced a slight decrease (by 4 percent over 2014) to US \$32 billion; exports maintained the CAGR of 9 percent from 2010 to 2015 to US \$44 billion.
- Key reasons include that the Chinese government has been encouraging top-class and large hospitals to purchase domestically made medical equipment, and domestic companies have gradually absorbed and developed more advanced technologies and are able to provide competitive prices than their foreign counterparties.
- The largest imports of medical equipment remained optical fibers and optical fiber bundles which fluctuated between US \$7-8 billion over the past five years; however, its percentage out of the total imports decreased from 32 percent to 23 percent.
- Imports of Instruments and apparatus for physical and chemical analysis, and medical/ surgical/ dental/ veterinary instruments & appliances, and X-ray, alpha,

beta, gamma radiation machines in 2015 merely maintained the same level of imports as in 2014.

- Orthopedic appliances remained the fastest growing segments of medical equipment imported into China; from 2010 to 2015, imports of orthopedic appliances increased at a CAGR of 22 percent from US ~\$1 billion to US ~\$3 billion.
- The top 5 countries exporting medical equipment to China include the United States, Japan, Germany, South Korea, and China (e.g. export processing zones, etc.).
- China's imports of medical equipment from Italy also experienced a decrease by 10 percent from US \$727 million in 2014 to US \$657 million in 2015; similarly, exports to Italy had a slight decrease by 2 percent to US \$683 million in 2015.
- Italy is relatively strong in spectacles and protective glasses, nonelectric instantaneous / storage water heaters for hospital use, and weak in optical fibers and optical fiber bundles, electrical filament or discharge lamps, orthopedic appliances, and instruments and apparatus for physical or chemical analysis.

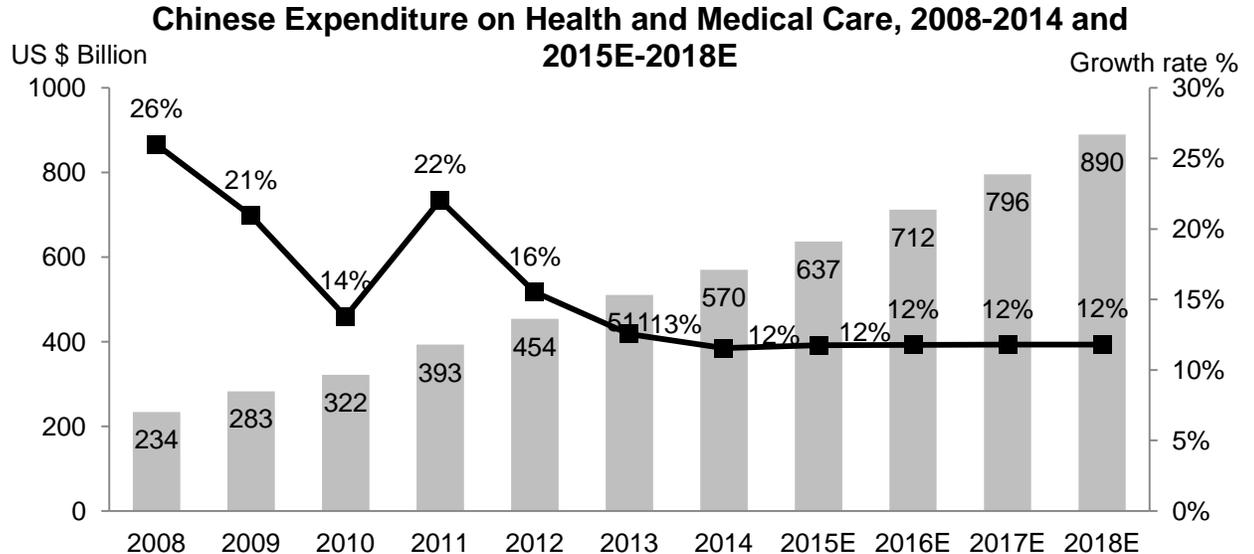
Market dynamics and Trends

- China's medical industry is highly complex, considering the complicated and prolonged market access process including product registration, license approval, distribution, and the involvement of various government bureaus.
- The market is fragmented, not only due to the large number of industry players, but the different business practice and regulation enforcement in different geographical locations.
- China is still a fastest growing and attractive market for international medical players; the market is driven by urbanization, increasing aging population, increasing household income and concerns for quality life and healthcare.
- With continuing healthcare reforms, significant improvements in terms of medical facilities, pharmaceuticals, and medical services in lower-tier markets are expected in the coming decade.
- However, the regulatory environment is becoming more stringent; new GMP and GSP certification, together with stricter clinical requirements, will likely make the market more difficult for new entrants.
- Moreover, central government's encouragement on using domestically manufactured medical equipment in top-class and large hospitals will likely continue impacting imports of medical equipment.
- The market is highly competitive, with tens of thousands of pharmaceutical and medtec companies; leading Chinese medical companies are gradually catching up with foreign counterparties on production process, technology, and durability.

- Yet innovative and cutting-edge medical products still have market potentials and will continue to be strongly encouraged by the Chinese government through preferential policies and government subsidies during the 13th Five-Year Plan period.

MARKET OVERVIEW

- With nearly 1.4 billion people, representing 20 percent of the world's population, China is the world's most populous country, which means a large demand for potential medical and healthcare services.
- The Chinese government's 'One Child Policy' initiated in 1979 aimed to control population growth has achieved its goal in the last three decades and resulted in a population growth of less than 5 percent by 2013; however, it has created other socio-economic challenges including a shrinking future workforce that will need to support a larger aging population.
- Although the central government has abolished the 'One Child Policy' from January 1, 2016 and allows each family to have two children, this will hardly change the issue of aging population in the coming two decades.
- In 2010, the aging population (people above 60 years old) accounted for 12.5 percent of the total population, and this rate is estimated to exceed 23 percent by 2030; this will drive increasing expenditure on medical and healthcare for the elderly.
- From 2008 to 2015, expenditure on medical and healthcare products and services was estimated to have increased at a CAGR of 15 percent from US \$234 billion to US \$637 billion; it is expected to continue growing at a CAGR of 12 percent from 2015 to 2018 reaching US \$890 billion by 2018, as illustrated in the following chart.

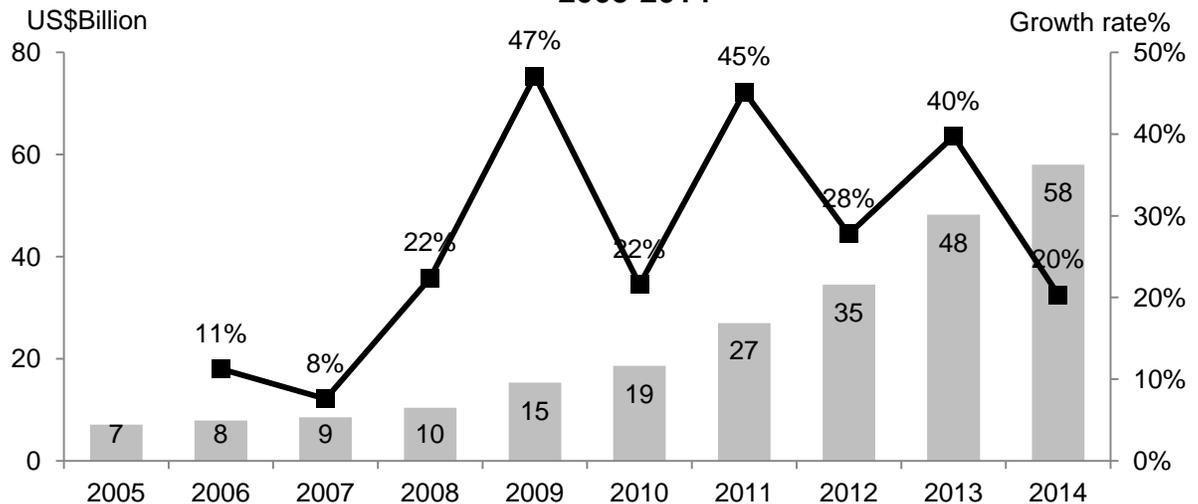


Source: Sovereign Analysis based on multiple sources including National Bureau of Statistics

- From 2010 to 2014, among the total expenditure on medical and healthcare, government expenditure increased fastest at a CAGR of 20 percent from US \$58 billion to US \$171 billion, compared with social expenditure (CAGR of 18 percent) and individual cash expenditure (CAGR of 12 percent).

- In 2014, the social expenditure on medical and healthcare realized an 18 percent year-on-year increase to US \$182 billion, accounting for 38 percent of the total expenditure.
- One important factor is the initiation and enforcement of healthcare reforms beginning in 2009, through which the Chinese government invested over US \$130 billion from 2009 to 2011, aiming to build a more affordable and comprehensive national healthcare system by 2020; by 2014, China's basic medical insurance covered more than 95 percent of the population.
- From 2008 to 2014, average urban individual expenditure on medical and healthcare increased at a CAGR of 12 percent from US \$300 to US \$584, while average rural individual expenditure increased at a CAGR of 23 percent from US \$73 to US \$249.
- China's healthcare system has seen tremendous development over the past few decades; during the past twenty years, the number of urban medical and health organizations in China increased from less than 200,000 to ~340,000, including ~100,000 hospitals, community health service centers and health centers as well as ~200,000 clinics and other healthcare institutes.
- Driven by healthcare reforms and government investment in the medical industry, newly increased fixed asset investment in the medical industry grew at a CAGR of 33 percent from US ~\$10 billion in 2008 to US ~\$58 billion in 2014, much faster than the growth from 2005 to 2008, with a CAGR of 14 percent, as illustrated in the following chart.

**Newly Increased Fixed Asset Investment in Medical Industry
2005-2014**



Source: Sovereign Analysis based on multiple sources including National Bureau of Statistics

- From 2005 to 2009, foreign fixed asset investment in China's medical industry increased at a CAGR of 24 percent from US \$436 million to US ~\$1 billion; from 2009 to 2014, this figure changed significantly and peaked at US \$1.1 billion in 2011;

however, by 2014 foreign fixed asset investment went back to 2008 levels (i.e. US \$839 million).

- The value of China's pharmaceutical industry was estimated to reach US \$416 billion in 2014, with a CAGR of 21 percent from 2008 to 2014; China is expected to become the second largest pharmaceutical market following the U.S. by 2020.
- China's medical equipment industry still lags behind many developed countries, but it is growing fast (at an estimated CAGR of 21 percent); in 2014, China's medical equipment market size reached US \$41 billion, accounting for ~8 percent of the total medical and healthcare sector, valued at US \$483 billion (i.e. pharmaceutical market size plus medical equipment market size).