



ITALIAN TRADE AGENCY

ICE - Italian Trade Commission - Shanghai Office
意大利对外贸易委员会 - 上海代表处



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China Medical Industry Report

May 6, 2015

EXECUTIVE SUMMARY

Market Overview

- Chinese expenditure on medical and healthcare grew at a 17 percent CAGR from 2008 to 2013 to US \$511 billion, and is expected to reach US \$700 billion by the end 2015.
- Key drivers include China's large population, the rapidly increasing aging population, 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 invested over US \$130 billion from 2009 to 2011, with the goal of building a more comprehensive and affordable national healthcare system by 2020.
- 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.
- 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 36 percent CAGR from 2008 to 2013 (US \$48 billion), much faster than the 14 percent CAGR the industry grew from 2005 to 2008.
- Newly increased foreign fixed asset investment in the medical industry grew dramatically from 2009 to 2013, but went back to 2008 levels (US \$758 million) in 2014, accounting for less than 2 percent of total investment in the industry.

Market Segment – Pharmaceuticals

- China's pharmaceutical market size (based on domestic production, plus imports, less exports) increased at a 21 percent CAGR from 2010 to 2013 to US \$393 billion; it is estimated to reach US \$547 billion by the end of 2015.
- Over the same period of time, the retail sales of pharmaceuticals increased at a 26 percent CAGR from US \$20 billion to US \$63 billion; retail sales are estimated to reach US \$97 billion by the end of 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 6,600+ manufacturers and 10,000+ distributors; the top domestic player, Sinopharm, only has ~6 percent market share.

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.

- 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 16-17 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 reform 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 and market applications.
- However, China is the fastest growing medical equipment market and the market size was estimated to have grown at a 27 percent CAGR from 2009 to 2013 reaching US \$34 billion, and it is expected to surpass US \$49 billion by 2015.
- The Pearl River Delta, Yangtze River Delta, and Bohai Economic Rim 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 13,000+ 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 3 hospitals mostly located in urban areas mainly purchased imported medical equipment, while Class 2 hospitals or smaller scale medical and healthcare institutes tend to purchase domestic medical equipment.
- 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.

Import and Export Analysis

Pharmaceuticals

- In 2014, China’s imports of pharmaceuticals reached US \$98 billion, a 1 percent drop from 2013; from 2010 to 2013, imports grew at a 13 percent CAGR.
- From 2010 to 2014, exports experienced an 11 percent CAGR from US \$47 billion in 2010 to US \$72 billion.
- Over half of imports were chemical formulations including cyclic hydrocarbons (HS Code 2902), cyclic alcohols and halogenated derivatives (HS Code 2905), acyclic hydrocarbons (HS Code 2901), etc.
- The majority of the import growth was attributed to pharmaceutical products classified under HS Code 30, which have increased at ~25 percent CAGR from US ~\$7 billion in 2010 to US ~\$18 billion in 2014.

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.

- The top 5 countries exporting pharmaceuticals to China were South Korea, Japan, Taiwan, United States, and Saudi Arabia.
- China's imports from Italy grew steadily at 23 percent CAGR from US \$857 million in 2010 to US ~\$2 billion in 2014; exports to Italy increased by 20 percent year-on-year from 2010 to 2011 to US ~\$1.3 billion, and remained at this level from 2011 to 2014.
- Italy is strong in pharmaceutical ingredients especially medicaments (HS Code 3004 and 3003), but relatively weak in chemical formulations such as acyclic alcohols & halogenated derivatives (HS Code 2905) and acyclic hydrocarbons (HS Code 2901), and cyclic hydrocarbons (HS Code 2902).

Medtec

- Imports and exports of medical equipment have shown continual growths from 2010 to 2014; imports increased at a 9 percent CAGR to US \$33 billion, and exports at a 10 percent CAGR to US \$43 billion.
- However, the growth rates of imports and exports both slowed to a 5-6 percent CAGR from 2012 to 2014 compared with double-digit growth rates from 2010 to 2012.
- The largest imports of medical equipment were optical fibers and optical fiber bundles (HS Code 9001), accounting for 24 percent of the total in 2014.
- Instruments and apparatus for physical and chemical analysis (HS Code 9027) and medical/ surgical/ dental/ veterinary instruments & appliances (HS Code 9018) were the fastest growing segments³ of medical equipment imported into China.
- 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 increased at a 16 percent CAGR from 2010 to 2014 to US \$727 million; exports to Italy have increased at a 5 percent CAGR to US \$698 million over the same period of time.
- Italy is relatively strong in nonelectric instantaneous / storage water heaters for hospital use (HS Code 8419), and weak in optical fibers and optical fiber bundles (HS Code 9001), electrical filament or discharge lamps (HS Code 8539), orthopedic appliances (HS Code 9021), and instruments and apparatus for physical or chemical analysis (HS Code 9027).

³ The imports increased at 16 percent and 18 percent CAGR from 2010 to 2014 to US \$6.5 billion (accounting for 20 percent of the total imports) and US \$6 billion respectively.

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 the 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 reform, 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.
- 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 are strongly encouraged by the Chinese government through preferential policies and government subsidies.