# China: Medical Devices Market and Healthcare Reform

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## Summary

China's large and aging population combined with its recently announced health care reforms, combine to make it one of the largest potential healthcare markets in the world. With rapid economic development and rising healthcare demands, China's healthcare and medical devices markets have witnessed strong growth over the past three decades. From 2001 through 2008, China's imports of medical devices recorded an average annual growth of 30 percent from $1.64 billion to $5.22 billion. By 2007, China produced over $28 billion worth of medical devices a year with almost 1/3 (equal to $8.4 billion) exported. There are approximately 11,000 domestic medical device manufacturers and a large number of foreign suppliers competing in the China market. Major buyers include 19,700 hospitals, 3,500 CDCs, and 63,000 urban and rural health centers. As a result of the New Healthcare Reform launched in April, 2009, China's medical devices market size is projected to expand at an annual rate of over 15 percent in the coming years. Such market expansion should generate opportunities for overseas suppliers of 1) advanced medical imaging equipment, 2) devices/consumables/implants for sophisticated surgical procedures and treatments, 3) rehabilitation and therapeutic equipment, 4) IVD products for disease prevention and early detection, 5) healthcare information systems and remote diagnostic technologies.

## Market Status and Development Trends

<u>China: The World's Largest Potential Healthcare Market</u>

China is the most populated country in the world with 1.3 billion people. Today, China has 160 million people over 60 years old. However, the number of people over 60 will likely increase to 170 million by 2010 and 240 million by 2020. Given the fast growth in population over age 60, combined with health problems associated with people in this age group, China should be recognized as a huge potential market for healthcare services as well as medical devices. Based on statistics from the Ministry of Health and press reports, China presently has 300 million overweight people, 300 million insomniacs, 300 million with rhinitis/pharyngitis, 200 million with intervertebral disc disorders, 170 million with hypertension, 120 million with hepatitis B, and 100 million with arthritis. Also, China reports 70 million patients suffering from oesteoporosis, 40 million from coronary heart disease (with an incidence rate of 2-6 million/year), 40 million with diabetes, 20 million with asthma, 16 million with mental disease, and 5 million with cataracts (with an incidence rate of 400 thousand per year). In addition, 1.2 million infants are born every year with birth defects, and 42 percent of married women have infections within their reproductive systems. Furthermore, China still faces serious challenges in disease control and regulating safety of foods, drug, and cosmetics. In 2007, China registered 3.5 million new cases of infectious diseases and 200,000- 400,000 food poisoning incidents. In order to meet these challenges and increasing healthcare demands, China began its first reform of the country's healthcare system in the mid-1980s.

Initial Market-Driven Healthcare Reforms led to both Fast Market Growth and Problems

China started its initial market-led healthcare reform in 1985. As a result of this market-oriented reform, between 1985 and 2005, China's healthcare and medical systems experienced a tremendous change. Such changes can be demonstrated through the following four examples: 1) From 1980 through 2007, China's total health spending rose by 80 times from $2 billion in 1980 to $161.3 billion; 2) From 1980 through 2007, the number of hospitals doubled from 9,902 to 19,852; 3) From 1991 through 2007, the value of annual domestic production of medical devices increased 57-fold from $475 million to $27 billion; 4) From 2001 through 2008, China's annual imports of medical equipment expanded roughly 3 times from $1.61 billion to $5.22 billion. Although this market-driven reform proved to be effective in upgrading healthcare infrastructure and in reducing government spending, the reform's profit-seeking nature and over-commercialization contributed to a series of severe "market disorders". Such disorders included commercial bribery, excessive drug prescription and redundant medical examinations, lack of government input, absence of medical insurance, uneven distribution of medical resources, skyrocketing medical costs, and healthcare services unaffordable to the general public. The following highlights reflect the market disorders resulting from this first reform:

- Of China's total health spending, the government's share dropped from 36 percent in 1980 to 18 percent in 2006, while individuals' share of such spending climbed from 21 percent to 50 percent during the same period.
- 80 percent of China's medical resources are currently allocated in urban regions for China's 500 million urban residents, while 20 percent of medical resources are allocated to rural regions for China's 850 million rural residents.
- By 2006, about 700 million of China's 1.3 billion people did not have any kind of medical insurance coverage.
- By 2006, rural residents paid for 80 percent of their medical expenses out-of-pocket due to the low level of subsidies from the government.
- In 2006, almost 50 percent of Chinese people with serious illnesses or health conditions did not consult doctors due to financial difficulties or other reasons.

New Healthcare Reform Measures Expected to Enlarge Market Demand

In order to rectify the aforesaid market failures and ensure that healthcare services are accessible and affordable to all Chinese citizens, China declared the initial reforms unsuccessful in 2005 and began working on the next round of reforms in 2006. After 3 years of research, opinion solicitation, and heated debate, China finally launched its new healthcare reform implementation plan in April, 2009. Based on this reform plan, the Chinese government will invest $122 billion to carry out five major aspects of reform that include: setting up a basic medical "safety net"; increasing the number of drugs for which the government provides some reimbursement to patients; improving the healthcare system at the grass-root levels; promoting gradual equalization in public health services; and pushing forward reforms on public hospitals. The following highlights, taken from the reform implementation plan, explain some of the key measures and goals for the period 2009 through 2011:

- Increase the reimbursement level of medical expenses. New levels of reimbursement will be approximately six times that of employees' annual average salary in urban areas, and more than six times per capita net income for rural residents.
- Increase the government's current annual subsidy of $11.- to $17.- for rural residents by 2010. The increase will be significant for China's 850 million rural residents, whose average annual income was approximately $700 in 2008.

- Improve rural healthcare infrastructure by building, rebuilding, or expanding 2,000 general county hospitals during 2009-2011, with similar investment in 29,000 township health centers over the same period.
- Improve urban healthcare infrastructure by building or renovating 3,700 urban community health centers and 110,000 community health service stations during 2009-2011.
- Begin work on a national database of health records beginning with citizens with the greatest need (seniors, disables, patients with chronic diseases, children, and pregnant women etc.) by 2011.
- Within the next 3 years, provide regular health checkup services to 110 million seniors over 65, and to infants and children under three.
- Proactively and steadily transform some public hospitals into non-public institutions.

Although some market players are concerned about a possible negative impact of the new reform, citing its intention to lower medical costs which may affect their high-end medical device businesses, most medical professionals interviewed by the U.S. Commercial Service, Guangzhou believe that the implementation measures are concrete and strong enough to expand China's medical device market size by more than 15 percent annually in the coming years. Ultimately, the new reform will provide more opportunities for overseas medical device suppliers.

## Best Sales Prospects

Generally speaking, technologically-advanced, high-performance medical devices, and training/consulting related to those devices, as listed below (but not limited to the list below), have good market potential in the Chinese market:

- Medical imaging equipment (digital X-ray machines, computed tomography, MRI, and ultrasonic scopes, etc.);
- Devices/consumables/implants for advanced and sophisticated surgical procedures, and for interventional, minimal invasive or non-invasive treatments;
- Rehabilitation and therapeutic equipment/devices for patients with chronic diseases;
- Atomic spectrophotometers and other devices for disease control testing;
- Point of care and other IVD products for rapid testing for disease prevention and early detection diagnostic purposes;
- Large scale fully automatic chemistry analyzers;
- Patient monitoring systems;
- Compact, portable diagnostic and emergency devices;
- Healthcare information systems and related equipment (e.g. regional network systems, information sharing and integration technologies, system software such as data security systems, and advanced application systems such as PACS, Electronic Medical Records, etc.)
- Remote diagnostic technologies and equipment;
- Health education expertise and related equipment;
- Hospital management consulting;
- Compact, portable monitoring and therapeutic devices for home care users.

## Key Suppliers

Overseas Suppliers

According to statistics from the China Chamber of Commerce for the Import and Export of Medicines and Health Products, of China's $5.22 billion in total imports of medical devices in 2008, the United States, Germany, and Japan were the top three overseas suppliers for the Chinese medical market. These three countries accounted for

64 percent of China's total imports of medical devices in 2008. Specific suppliers include such companies as 3M, Abbott, ABI, Ackermann, Agfa, Aloka, Baxter, BD, Beckman Coulter, Berthold, Canon, Carestream, Dade Behring, Drager, Esaote, GE Healthcare, Hitachi, Johnson & Johnson, Karl Storz, Medison, Medtronic, Olympus, Omron, Philips, Roche, Shimadzu, Siemens, Stryker, Toshiba, Tyco, Varian, Welch Allyn, and Wisap.

Local Suppliers

The following is a list of top 15 local medical device manufacturers (excluding foreign invested manufacturers) published by a local e-commerce service provider in 2007:

Shenzhen Mindray Bio-Medical Electronic Corporate Ltd. (www.mindray.com.cn)
Double-Dove Group Co., Ltd. (www.shuangge.com)
Shandong Zibo Shanchuan Medical Instrument Co., Ltd. (www.annamedical.com.cn)
Shandong Weigao Group (www.weigaogroup.com)
Shenyang Neusoft Digital Medical System Co., Ltd. (http://medical.neusoft.com)
Shinva Medical Instrument Co., Ltd. (www.shinva.com)
Jiangsu Yuyue Medical Equipment Inc. (www.yuyue.com.cn)
Beijing Wandong Medical Equipment Co., Ltd. (www.wdjf.com)
MicroPort Medical (Shanghai) Co.,Ltd. (www.microport.com)
Beijing Jingjing Medical Equipment Co., Ltd. (www.gmeditech.com)
Contec Medical Systems Co., Ltd. (www.contecmed.com.cn)
Shanghai Medical Equipment Works Co. Ltd. (http://www.smew.cn)
Kangdelai Zhejiang Medical Devices Co., Ltd (www.zjkdl.com)
Jiangxi Hongda Medical Equipment Group Ltd. (www.jxhd.cn)
Shaanxi Qinming Medical Instruments Co Ltd. (www.qinming.com)

Major Buyers

By 2008, China had a total of 19,712 hospitals (see table below). These hospitals will continue to serve as China's major buyers of medical equipment. It should be noted that under the new healthcare reform plan, China will invest in building, rebuilding, or expanding 2,000 rural county hospitals during 2009-2011. Furthermore, the plan calls for similar investment in 29,000 township health centers in 2009. As some rural hospitals have not been well-equipped and most township health centers are currently very ill-equipped, there should be sizeable demands for basic medical equipment/devices such as X-ray machines, ultrasonic scopes, patient monitors, chemistry analyzers, and sterilizers, etc. In addition, China also needs to build, rebuild, or expand about 200 hospitals/year in urban regions in the coming years. Although these additional urban hospitals are not part of the new reform plan, they will still serve to generate additional demand for medical devices.

Number of Hospitals by Beds **1990 – 2008**

| Year | 1990 | 2000 | 2004 | 2005 | 2006 | 2008 |
|---|---|---|---|---|---|---|
| Hospitals (total) | 13489 | 15446 | 18393 | 18703 | 19246 | 19712 |
| <100 Beds | 7787 | 7898 | 10867 | 11156 | 11516 | 11725 |
| 100-199 Beds | 2872 | 3976 | 3811 | 3746 | 3803 | 3572 |
| 200-499 Beds | 2389 | 2762 | 2757 | 2777 | 2832 | 3020 |
| 500-799 Beds | 441 | 661 | 715 | 740 | 764 | 907 |
| ≥800 Beds | --- | 149 | 243 | 284 | 331 | 488 |

Sources: 2009 Health Statistics Abstract

## Market Entry

Product Registration

In accordance with the "*Regulations for the Supervision and Administration of Medical Devices*" issued in 2000 by the State Food and Drug Administration (SFDA), all imported medical devices have to be registered with the SFDA in Beijing. The Department of Medical Devices under the SFDA is responsible for product registration. Overseas suppliers may choose to register their products in China through either authorized Chinese registration agents or distributors. For details of registration requirements for first time applicants, please visit the SFDA English website link:
http://eng.sfda.gov.cn/cmsweb/webportal/W45649090/A45714547.html

Product distribution

One of the most common methods for U.S. suppliers to distribute medical devices in China is to appoint local agents to handle distribution on their behalf. The U.S. Commercial Service provides a distributor search program known as the Gold Key Service. This program is designed to help U.S. companies find potential distributors through face-to-face matchmaking meetings. For more information about the Gold Key Service, please visit our website www.buyusa.gov/china/en.

Alternatively, based on the China's commitments as a WTO member-state, overseas suppliers are entitled to establish their own trading company in China to distribute their products directly. Or, they may choose to set up a China representative office to take care of product promotion, marketing, training, and to provide support to their designated distributors.

IPR Protection

As intellectual property rights (IPR) protection has become an important issue for businesses selling in China, U.S. suppliers should be aware how to protect their patents and trademarks in China. The Commercial Service strongly recommends U.S. producers of medical devices visit the Department of Commerce's IPR related website to learn more details:
http://www.stopfakes.gov

## Trade Events

1. China International Medical Equipment Fair (CMEF)
April, 2010
Shenzhen, China
Website: http://en.cmef.com.cn/
CMEF, the largest and most comprehensive medical equipment show in Asia, has been certified by the U.S. Department of Commerce. With the participation of approximately 2,000 exhibitors and over 50,000 visitors annually (distributors, hospital buyers and manufacturers) from both China and around the world, CMEF provides a good venue for overseas suppliers to screen and qualify potential distributors or agents.

2. Dental South China Expo and Conference
March, 2010
Guangzhou Chinese Export Commodities Fair Ground
Guangzhou, China
www.dentalexpo.cn

3. CHINAMED - International Medical Instruments and Equipment Exhibition
April, 2010
Beijing, China.
Website: www.chinamed.net.cn

4. The 14th China International Dental Equipment & Affiliated Facilities Exhibition (SINO-DENTAL)
June, 2010
China International Exhibition Centre

Beijing, China
www.sinodent.com.cn

5. MEDTEC CHINA
Date: September 8-10, 2009
Venue: Intex Center, Shanghai
Website: www.devicelink.com/expo/shanghai09/index_en.html

## Resources & Key Contacts

State Food and Drug Administration (SFDA)
The State Food and Drug Administration is directly under China's State Council, a legislative council of approximately 50 members similar to the president's Cabinet in the United States. It is responsible for comprehensive supervision of the safe management of drugs, medical devices, food, and cosmetics. Foreign medical devices must be registered with the SFDA before being distributed in China.
Website: http://eng.sfda.gov.cn/eng/

The Ministry of Health (MOH)
The MOH has overall responsibility for regulating China's healthcare system. It oversees public health, healthcare institutions, health system reform, and medical research. One of the MOH's specific functions is to examine and approve hospitals' procurement of large scale medical equipment such as CT. MRI, PET, and electron cyclotron Positioning System, etc.
http://www.gov.cn/english

The General Administration of Customs of the People's Republic of China (China Customs)
China Customs supervises and manages the arrival and departure of all cargo entering and departing China, ensuring all cargo complies with relevant Chinese laws and regulations. It is responsible for the examination of imported and exported cargo, the estimation of cargo value, and the collection of import and export duties. To learn more details about import duties and customs clearance problems, please visit their website: www.customs.gov.cn

China Association for the Medical Devices Industry (CAMDI)
CAMDI is a national association for the medical devices industry in China. Its mission is to represent the common interest of its members, safeguard the legal rights of its members, promote the safety and effectiveness of medical devices, and encourage the development of the Chinese medical device industry.
http://www.camdi.org/

Note: The dollar values indicated in this report are based on the following exchange rate: $1 = RMB7.-

## For More Information, please contact:

The U.S. Commercial Service in Guangzhou, China via e-mail at: shuquan.li@mail.doc.gov; Phone: 86-20-8667-4011 ext. 625; Fax: 86-20-8666-6409 or visit our website: www.buyusa.gov/china/en/guangzhou.html.

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