



Market Analysis Report: China's Medical Device and Healthcare IT Industries

Presented to:
Israel Ministry of Industry, Trade and Labor
and Israel Export & International
Cooperation Institute

APCO
worldwide®

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Table of Contents

1. EXECUTIVE SUMMARY	1
2. MARKET OVERVIEW	3
2.1 China's Healthcare Industry.....	3
2.1.1 Market Overview	3
2.1.2 Market Structure.....	4
2.1.3 Emerging Industry Trends.....	4
2.2 China's Medical Device Market	5
2.2.1 Market Overview	6
2.2.2 Market Structure.....	6
2.2.3 Emerging Industry Trends.....	7
2.3 China's Healthcare IT Market	8
2.3.1 Market Overview	8
2.3.2 Market Structure.....	8
2.3.3 Emerging Industry Trends.....	9
3. REGULATORY OVERVIEW	11
3.1 Regulatory Overview	11
3.2 China's Healthcare Industry.....	12
3.2.1 Implementation Plan of Deepening the Healthcare Reform.....	12
3.2.2 The 12 th Five Year Plan.....	12
3.2.3 Healthy China 2020.....	13
3.2.4 Catalogue for Guidance of Foreign Investment	13
3.3 China's Medical Device Market	14
3.4 China's Healthcare IT Market	14
4. MARKET OPPORTUNITIES	16
4.1 Existing Opportunities.....	16
4.2 Geographic Areas of Focus	18
4.3 Key Industry Parks	19
4.4 Key Industry Exhibitions/Events	21
4.5 Recommendations for Israel	23
APPENDIX I – TERMINOLOGIES	25
APPENDIX II – CHINA MAP	256

1. EXECUTIVE SUMMARY

Market Overview

Healthcare Industry—China's healthcare industry is growing at an unprecedented rate in response to both the unparalleled health concerns resulting from China's economic rise as well as from the government's prioritization of health concerns and access to treatment.

- Key subsectors include pharmaceuticals, biotechnology, medical devices, medical services, and health administration, with the first three subsectors constituting nearly 75% of the market.
- Factors driving growth include:
 - Increasing demand from Chinese citizens who are experiencing increased health concerns and have increased expectations for health care;
 - Government focus launching sweeping healthcare reforms aimed at increasing current coverage levels and distribution mechanisms; and
 - Favorable business environment attracting greater foreign investment and technology transfer to China.

Medical Devices—China ranks as the world's third largest medical device market and is expected to become the second largest market in the world within 5-7 years.

- Over 70% of medical device products fall into one of four categories: diagnostic imaging devices, medical supplies, orthopedics, and implanted medical devices and dental products.
- Foreign-made products occupy the majority of the middle and high end market, while Chinese companies have focused on low-end products (although they are seeking to upgrade).
- Substantial market opportunities are available as the government builds thousands of new healthcare facilities and upgrades existing facilities and equipment.

Healthcare IT—China's healthcare IT market is a rapidly emerging priority within the healthcare industry, as the government seeks to apply information technology to medical facilities and services.

- Healthcare IT products fall into one of three categories: hardware, software and digital services; to-date investment has focused on hardware, although a shift is occurring toward software and services.
- The market is highly fragmented with a few multinational players and numerous small, independent vendors.
- Opportunities are related to the rapid expansion of China's healthcare system, but also stem from incentive policies aimed specifically at enhancing the industry's IT systems.

Regulatory Landscape

- Oversight of China's healthcare industry involves numerous stakeholders with over-lapping authority, creating an incredibly complex and difficult to navigate landscape for companies operating in this sector.

- A number of broad policy pieces have been enacted guiding the development of China's healthcare industry:
 - **Implementation Plan of Deepening the Healthcare Reform (2009-2011):** reforming China's healthcare system to provide "safe, effective, convenient and affordable" health services to all urban and rural residents by 2020.
 - **12th Five Year Plan:** blueprint providing clear strategies for shaping social and economic growth and industrial planning in key sectors and regions.
 - **Healthy China 2020:** MOH's plan to reform the country's healthcare system and provide universal health care within 12 years.
 - **Catalogue for Guidance of Foreign Investment:** categorizing industry sectors into four groups (encouraged, permitted, restricted, and prohibited) and outlining the requirements for foreign investment in each category.
- Numerous sector-specific regulations which influence investment have also been adopted for both medical devices and healthcare IT.

Market Opportunities

Existing Opportunities — China's healthcare industry presents numerous opportunities for foreign firms:

- **New Facilities:** Numerous new healthcare facilities – including hospitals and community healthcare centers (CHCs) – are being built around the country creating demand for both medical devices and healthcare IT.
- **Facility Upgrade:** In addition to building thousands of new healthcare provision facilities, the government is also upgrading the medical devices of hospitals and purchasing essential medical equipment for rural hospitals.
- **Increasing Citizen Demand:** Citizen-driven demand for quality healthcare products is establishing a huge market for small and medium-size medical devices.
- **Evolving Business Climate:** Continued reforms will continue to present new opportunities and challenges for foreign firms within the industry.

Recommendations for Israeli Businesses — In order to take advantage of these opportunities, APCO has identified a number of core recommendations for Israeli companies considering entering China's healthcare industry:

- **Understand Demands:** APCO recommends that Israeli firms develop a strong understanding of the specific demands China's health facilities face.
- **Identify Unique Strengths:** Israeli firms should also identify the key healthcare areas and medical technologies where they lead in order to compete in this highly competitive market.
- **Leverage Government Influence:** In order to optimize Israeli firms' chances within this process, it would be very beneficial to leverage the full support of the Israeli Government.
- **Monitor Evolving Regulatory Environment:** In order to stay abreast of the latest developments, Israeli firms should continue to monitor the reform process and emerging regulations.

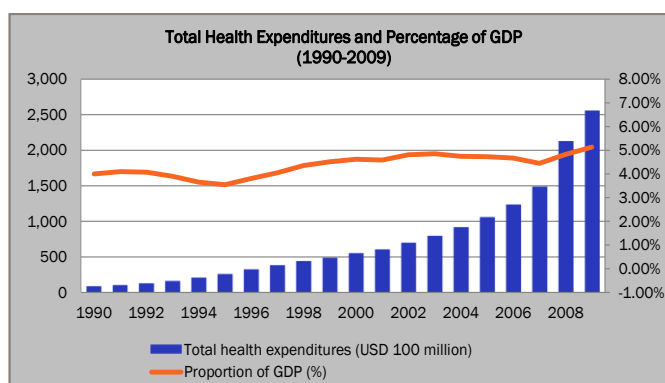
2. MARKET OVERVIEW

2.1 CHINA'S HEALTHCARE INDUSTRY

2.1.1 Market Overview

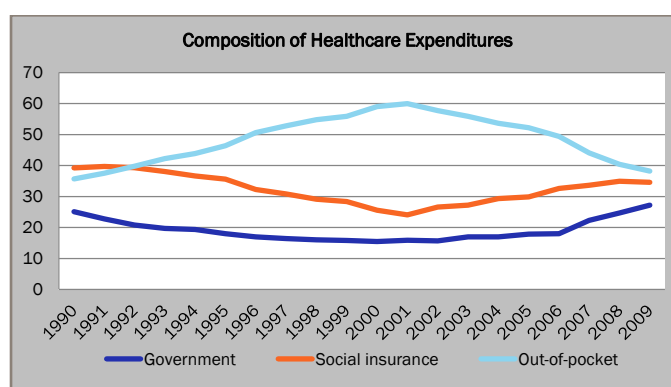
China's unprecedented economic rise over the last 30 years has resulted in similarly unparalleled health concerns. Urbanization, environmental pollution, and wealth disparities have led to widespread health problems including a significant rise in chronic diseases. More than 200 million Chinese citizens suffer from high blood pressure, and it has become the leading preventable cause of death in China resulting in 2.3 million deaths per year. China has more than 90 million diabetics and according to recent reports, nearly 150 million more are showing early symptoms. China is home to 350 million smokers, contributing to an estimated one million related deaths per year. Other serious health issues associated with China's rapid development include respiratory illnesses as well as growing incidences of cancer, cardiovascular disease and obesity problems.

In response to these rapidly emerging challenges, China has upgraded its healthcare services and expanded its health expenditures. In the last five years, total expenditures for healthcare have more than doubled, rising from RMB 759 billion (USD 110 billion) in 2004 to RMB 1.72 trillion (USD 256 billion) in 2009. Such rapid growth is expected to continue with total healthcare expenditures expected to reach USD 600 billion by 2015—a threefold increase from 2000.



Source: Chinese Health Statistical Digest 2010, Ministry of Health

China's leadership is well aware of the growing health concerns its citizens face and has invested heavily in healthcare for the past several decades. However, these investments have just kept pace with China's expanding GDP and thus government expenditures have accounted for less than 30% of total health expenditures.



Source: Chinese Health Statistical Digest 2010, Ministry of Health

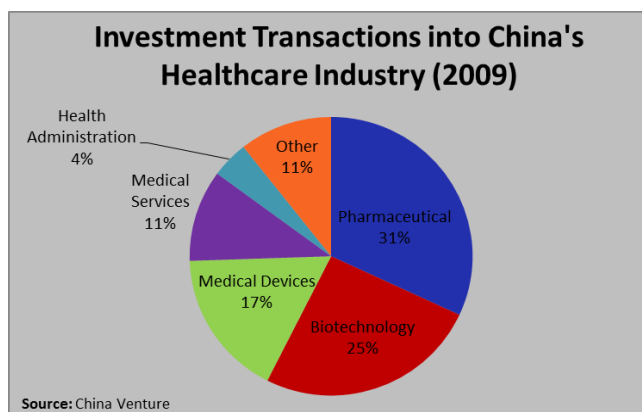
In the face of such rapidly increasing health expenditures, China's health insurance system has rapidly expanded and gradually increased its contributions to health expenditures. However, individuals still bear the greatest portion of healthcare costs. In 2009, individuals accounted for over 38% of expenditures, although this rate had been steadily falling since 2000, when out-of-pocket expenses reached nearly 60% of the total.

2.1.2 Market Structure

China's healthcare industry is generally sub-divided into five categories:

- Pharmaceuticals
- Biotechnology
- Medical devices
- Medical services
- Health Administration

Although healthcare IT is a top priority within China's healthcare sector and a rapidly growing sector, government statistics and other industry breakdowns place this sector not within the healthcare industry, but within China's IT industry. However, due to the overlapping priorities and regulatory structures found between China's healthcare sector and healthcare IT, APCO has included this sector within our analysis of China's healthcare industry.



Statistics summarizing investment inflows provide an indication of the relative size and priority of the various sub-sectors within China's healthcare industry. The table above summarizes the number of venture capital transactions conducted in 2009 within China's healthcare industry. The sector witnessed significant investment during 2009, including a total of 47 transactions valued at USD 415 million. As the graphic illustrates, the vast majority of the transactions fell within the five categories listed above, with pharmaceuticals, biotechnology and medical devices constituting nearly 75% of all investments.

Within this structure, the key influencing stakeholders and potential customers for Israeli technologies, equipment and services in the healthcare industry include:

- Ministry of Health and its local surrogates at the provincial and municipal level;
- State Food and Drug Administration and its local surrogates at the provincial and municipal level;
- Tier I, Tier II, and Tier III hospitals throughout China; and
- Community healthcare centers throughout China.

2.1.3 Emerging Industry Trends

Growth in China's healthcare industry has been driven by a combination of factors that include increasing public demand, strong government support, and a favorable business climate attracting foreign investment and technologies.

Increasing Demand: Public demand for healthcare has increased dramatically in China in recent years. China's rapid economic rise has resulted in a general increase in the incidences of chronic diseases—including heart disease, obesity and cancer—thereby creating greater demand for healthcare for China's citizens. In addition, China's economic growth has also resulted in increased expectations from patients. China's patients now demand higher-quality medicines, better conditions within medical facilities and highly-qualified medical professionals, and have the disposable income necessary to afford leading medical products and services.

China is also facing a rapidly aging population. China's one-child policy and the ensuing age distribution effects has resulted in one of the world's fastest ageing populations. This has in turn led to a greater prevalence of diseases as middle and old-aged citizens increase as a proportion of China's total population, once again increasing healthcare demands.

Government Focus: Healthcare reform is a major priority for China's current leadership and a central component of President Hu Jintao's 'Harmonious Society', as system-wide reforms are fundamental to improving the quality of life and building a fair society. In April 2009, the government launched sweeping healthcare reforms aimed at increasing current coverage levels and distribution mechanisms to greatly expand the country's healthcare service capabilities. The plan provided RMB 850 billion (USD 125 billion) over the next three years to develop the healthcare industry along five key pillars of reform, namely: expanding insurance coverage; building a national essential drug system; developing primary healthcare infrastructure; ensuring equitable access to public health services; and reforming China's public hospitals.



Hu Jintao

President of China and
General Secretary of the
Communist Party

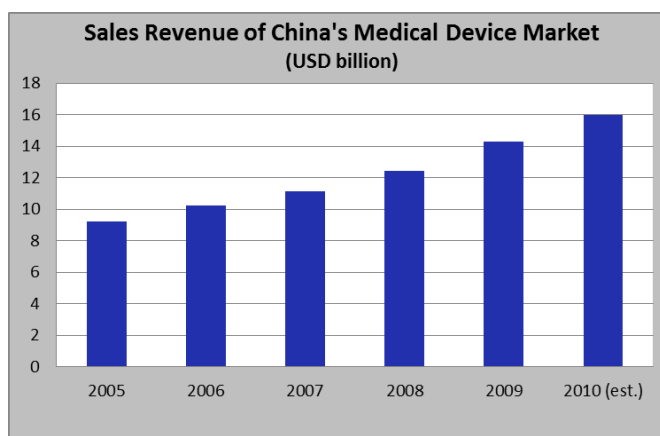
"We must do our best to ensure that all our people enjoy their rights to education, employment, *medical and old-age care*, and housing, so as to build a harmonious society."

– March 2009

Favorable Business Environment: A relatively favorable business climate has attracted greater foreign investment and technology transfer to China. A general reduction of tariff rates on foreign medical products and services came into effect following China's accession into the WTO. Moreover, a number of policies have been released facilitating foreign investment. Such reforms are expected to continue. A new version of the government's *Catalogue for Guidance of Foreign Investment* is due to be released soon, which is expected to encourage foreign investment in biopharmaceuticals and medicine and offers preferential treatment for companies investing in China's less-developed regions (for more information on the *Catalogue*, see section 3.2.2).

2.2 CHINA'S MEDICAL DEVICE MARKET

Based upon the composition of Israel's healthcare industry, including its extensive capabilities within the medical device sub-sector (more than half of Israeli healthcare companies operate in this sub-sector), this report includes a detailed analysis of China's medical device sub-sector.

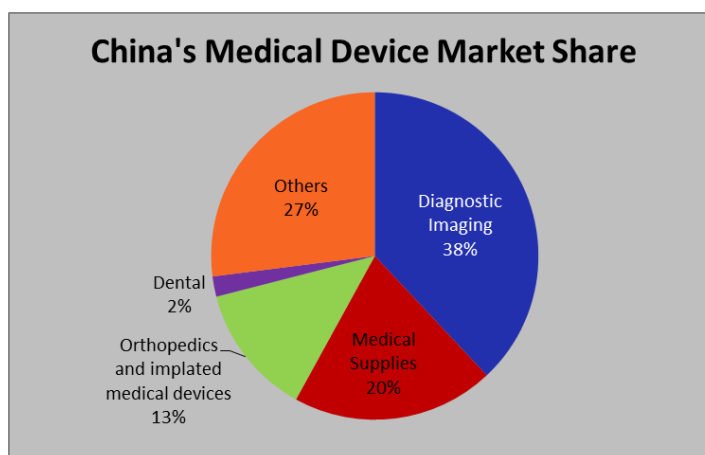


2.2.1 Market Overview

China currently ranks as the world's third largest medical device market following the United States and Japan, with sales revenue of medical equipment in China surpassing USD 14 billion in 2009. The sub-sector has continually experienced growth rates in the double digits and is forecasted to grow, reaching USD 16 billion by the end of 2010 and surpassing Japan to become the second largest market in the world within 5 to 7 years.

2.2.2 Market Structure

China's medical device market is fairly structured, with more than 70% of medical device products falling into one of four categories: diagnostic imaging devices, medical supplies, orthopedics and implanted medical devices and dental. All other products together comprise approximately 27% of China's medical device industry.



Each of these categories can be further divided, and is generally divided into high, mid and low-end products, based upon the sophistication and complexity of the products.

Medical Device Trade

China's medical device market relies largely on imports, with the United States as the major supplier, followed by Japan and Germany. The most in-demand imported products are those that utilize the most

China Medical Device Trade (2009)			
	Value	Products	Composition
Imports	USD 6.1 billion	CT, MRI, X-ray, Ultrasounds, Implants, Assistive devices	US: 30.66%
			Germany: 17.23%
			Japan: 16.78%
Exports	USD 12.2 billion	Medical patches, Massage devices, Catheter, Medical furniture	US: 26.26%
			Germany: 14.12%
			Japan: 6.21%
Source: China Chamber of Commerce for Import & Export of Medicine and Health Products			

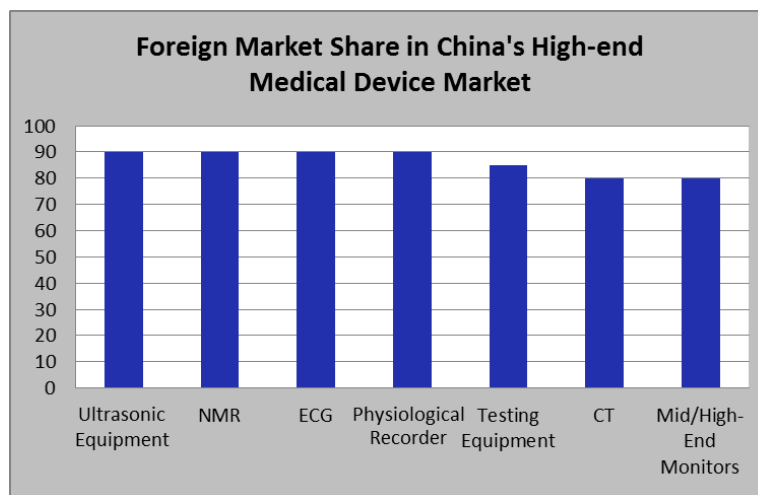
advanced technology. Indeed, 90% of value-added high-tech devices, which account for 70% of China's medical device market, are foreign-made. Many Tier-III, first class hospitals specifically require imports to serve wealthier clients who are willing to pay large sums to be treated with the best medical equipment, especially for cancer, cerebrovascular disease and cardiovascular disease.

Foreign Players

Most large medical device MNCs have already established a presence in China. In fact, among the industry's top ten manufacturers in this sector, seven are actually foreign invested firms or joint ventures. These companies have focused largely on China's high-end medical device sector and have established a dominant presence in many of the leading high-end product lines, currently constituting more than 80% of China's high-end medical device market. The middle to high-end market includes equipment that is moderately priced and utilizes reasonably advanced technologies. However, these

technologies are generally still two to three generations behind the cutting-edge in developed countries.

Foreign companies have seen increasing market share in the past several years. The foreign share of large, high-end medical equipment increased by 20% in 2008 and the annual increase in sales of this market was reportedly between 14-15%. The table to the right highlight several sectors where foreign companies control 80% or more of the market. Highlighted subsectors include: computed tomography (CT); clinical laboratory equipment, gynecological devices, pre-hospital medical equipment (including telecommunication systems), ambulances, emergency cardiac equipment and respiratory equipment and medical devices for care and rehabilitation.



Domestic Players

In contrast, China's low-end medical device market consists of small and medium-sized enterprises (SMEs) and is dominated by domestic companies. In addition, the domestic medical device industry is still highly fragmented. At present, China boasts some 3,000 medical device manufacturers. Most of these companies enjoy limited market share and function on a small scale. Furthermore, these companies tend to possess only a handful of profitable products, most of which are based on a low level of technology.

However, the domestic industry is consolidating and upgrading. Industry players have begun to compete on mid-level technologies, trying to take advantage of a cost basis on average 30% lower than that of foreign competitors.

2.2.3 Emerging Industry Trends

China's medical device market is expected to continue its rapid pace of growth, in large part driven by the government's aim to build and upgrade community healthcare centers in the rural regions of central and western China. As part of the greater healthcare reform initiative, the government allocated USD 250 million to subsidize medical equipment purchases in China's rural regions. This investment will likely focus on low and mid-range equipment as rural hospitals and clinics focus on these investment areas.

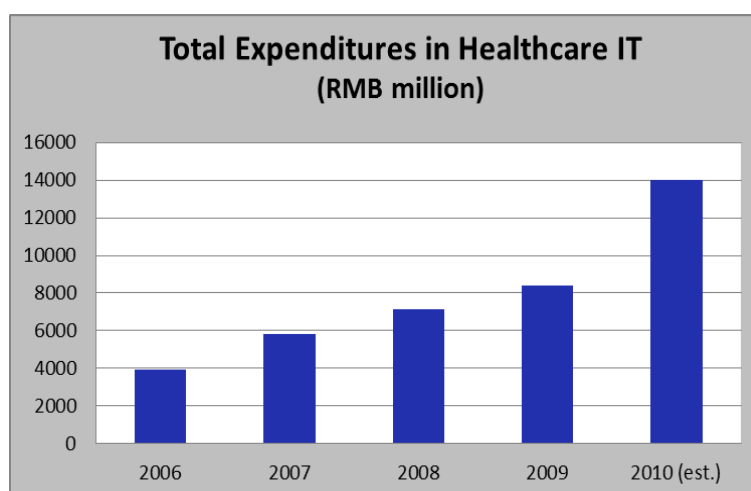
In addition to new investment, China's medical device industry will also benefit from the upgrade and improvement of existing equipment. Fifteen percent of the medical devices currently used in China are estimated to have been made in the 1970s and in need of replacement. The government has already announced its intention to replace these obsolete devices in order to elevate the quality of care available.

2.3 CHINA'S HEALTHCARE IT MARKET

Israeli firms also possess strong capabilities providing healthcare-specific information technology (healthcare IT) solutions. Based upon this competency, this report includes a detailed analysis of China's healthcare IT sub-sector.

2.3.1 Market Overview

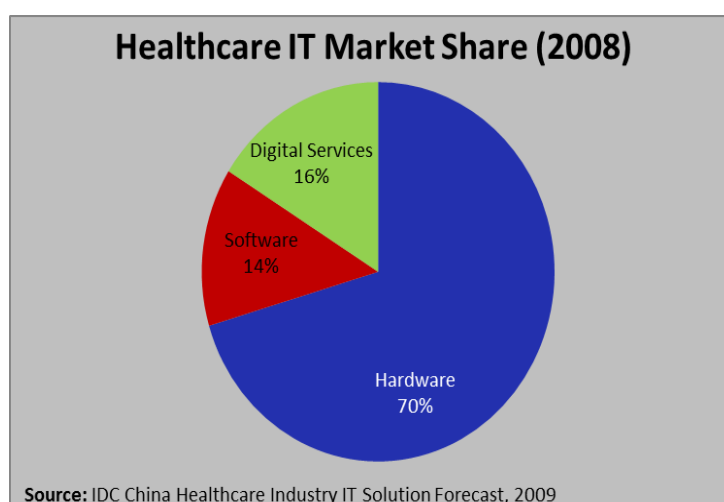
According to recent industry analysis, China's healthcare IT expenditures reached RMB 8.42 billion (USD 1.26 billion) in 2009, recording a 17.5% growth from 2008. The sector is expected to continue its rapid expansion, jumping to an estimated RMB 14 billion (USD 2 billion) for 2010. By 2015, the number will grow to RMB 40 billion (USD 6 billion), with an estimated compound annual growth rate (CAGR) of 25%.



A major driver of recent growth has been the inclusion of healthcare infrastructure investment as a key component of China's stimulus plan. China's 2009 healthcare reform plan included funds set aside to modernize healthcare services by providing for digital hospitalization, electronic medical records, and next-generation information networks. According to estimates, China will allocate 1.2-1.8% of the total RMB 850 billion (USD 124 billion) toward healthcare IT, or approximately USD 1.45 billion to 2.6 billion incremental spending for 2009-2011.

2.3.2 Market Structure

China's healthcare IT market is generally divided into three categories: hardware, software and digital services. To-date, most investments have focused on systems and hardware rather than software and applications. However, that investment trend is changing as investment strategies have begun to shift toward software and services. Long-distance healthcare and regional healthcare also present a growing market in China soliciting further investment.



China's hospitals account for the vast majority of healthcare IT spending and represent 73% of the total. On average, 2-5% of operating revenues are allocated into IT—a relatively low-level compared to the 12-15% found in developed markets such as the US. Capital spending is a highly decentralized process with each hospital making its own purchasing decisions. A lack of standardization has led to numerous unique or customized technical systems creating challenges regarding interoperability. Hospitals affiliated with the People's Liberation Army are the one notable exception to the otherwise pervasive trend of fragmentation. These hospitals have a unified technological approach for most IT platforms and services, creating an industry standard for their operations.

Unlike the IT sectors of industries such as telecom, finance and manufacturing – which enjoy well-established markets with strong international suppliers – China's healthcare IT market is far less established. Foreign players such as Microsoft, GE and IBM have a strong presence in China's healthcare IT market. However, China's domestic healthcare IT market is highly fragmented with the majority of industry players comprised of small, independent vendors. Fewer than 20 of the estimated Chinese independent software vendors have more than 100 staff and even the largest players maintain less than 8% market share.

2.3.3 Emerging Industry Trends

China's healthcare IT system in its final and completed form will sufficiently meet the basic demands of the healthcare industry. As the nation moves down this path, the short-term application of healthcare IT in the field is expected to focus on such areas as electronic medical records, electronic archiving of medical records, community healthcare and wider healthcare management. Many of these needs spring from a strong demand for cross-regional information and data sharing between medical institutions that have emerged from the rapid development of China's healthcare infrastructure.

Around 90% of China's hospitals are at some stage in the adoption of the standard Hospital Information

IPR Issues in China

While the protection of intellectual property rights (IPR) remains a contentious issue for companies in China, the country's laws and regulations have progressed considerably in recent years, with the large majority now being compliant with the requirements of the WTO's TRIPS agreement.

The main challenge surrounding IPR protection in China is the lack of effective enforcement of existing regulations. Enforcement issues arise from a range of root causes, including the relatively recent introduction of IPR legislation and concept of intellectual property in general, the absence of a fully independent judicial system, and provincial officials' often protective attitude towards local, job creating counterfeiting industries.

While most foreign companies considering business operations in China may have to accept an unavoidable degree of IPR infringement, there are nevertheless a number of actions that a company can take in order to limit their IPR-related risk:

- Ensure to register your patents, copyrights, or trademarks with the relevant bureaus
- Ensure that your trade or other business agreements include clauses to protect your IPR
- Sign contracts or confidentiality agreements with staff that has access to key technologies and make sure that your policies on trade secrets and other relevant issues are properly communicated
- Be aware of China's (often quickly changing) laws and regulations, and understand the different possible ways of redress, including administrative and judicial channels.

System (HIS)¹ platform, or more sophisticated alternatives. However, that still leaves an estimated 3,000 hospitals without a database system that is easily accessible or transferrable across a wider hospital and clinic community. In addition, China's hardware infrastructure is relatively basic. Thus the opportunity for IT players is significant, with each of the nation's 1,200 Tier-III hospitals requiring upwards of RMB 10 million in IT upgrades.

The fragmented nature of the required upgrades presents multiple contract opportunities, especially as the government wishes to consolidate the currently diverse IT resources – such as platforms, centralized servers and customized PC networks – used across China's various regions. Some areas where healthcare IT investment is likely needed include:

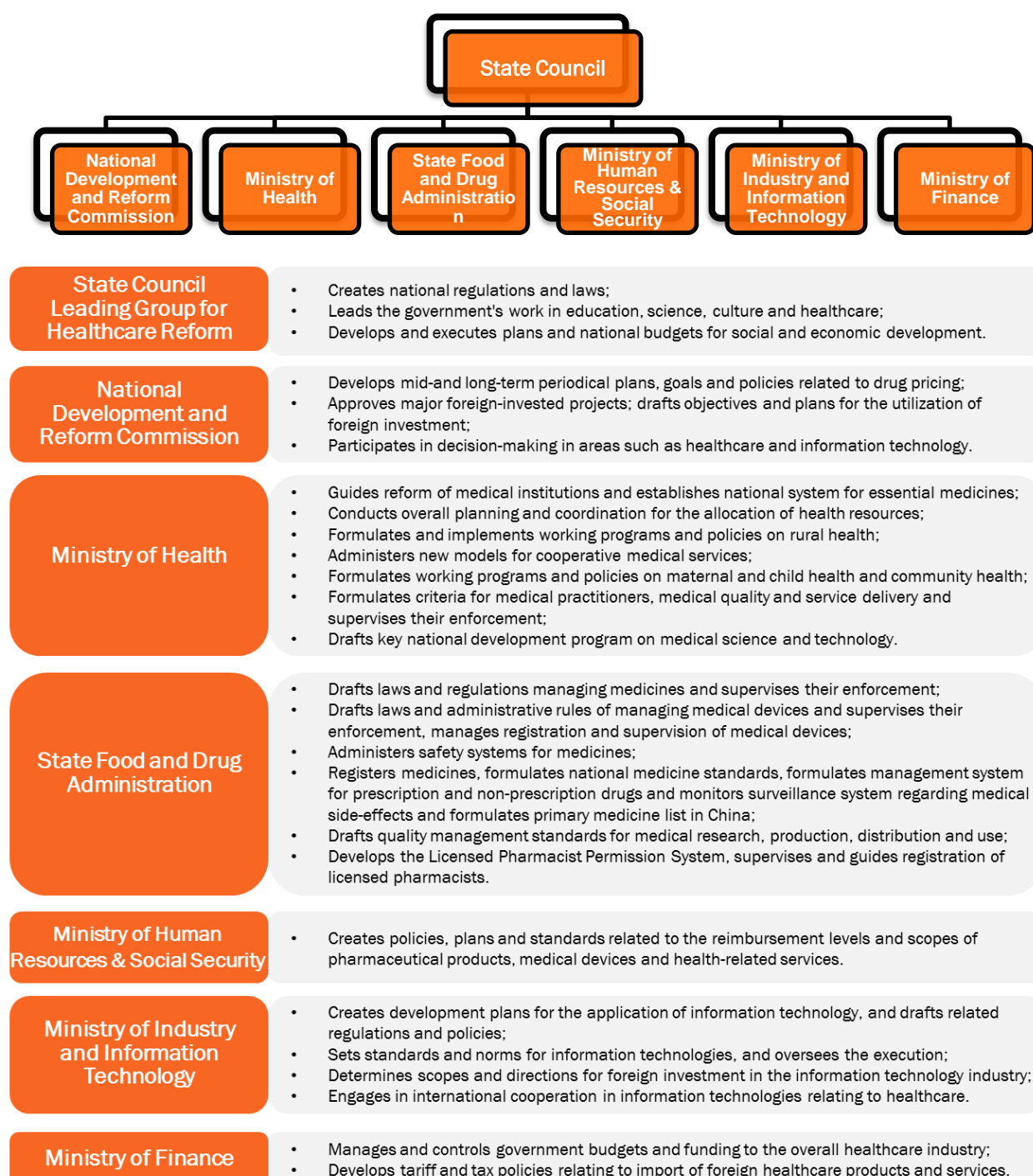
- Upgrade of healthcare IT to cover all medical systems in China;
- Expansion of healthcare information centers in big and medium-sized cities;
- Acceleration of the 'informatization' of medical centers in urban areas;
- Expansion of the use of EMR;
- Reform of health insurance management;
- Expansion of the market share of multinational IT providers; and
- Further development of mobile applications.

¹ Hospital Information System (HIS), also called clinical information system, is a comprehensive, integrated information system that is designed to manage hospitals' administrative, financial and clinical functions.

3. REGULATORY OVERVIEW

3.1 REGULATORY OVERVIEW

Oversight of China's healthcare industry involves numerous stakeholders with overlapping authority, creating an incredibly complex and difficult to navigate landscape for companies operating in this sector. Proposed healthcare reforms are expected to introduce additional actors into the arena, further complicating government supervision. Highlighted below are the key industry regulatory bodies and their primary responsibilities:



3.2 CHINA'S HEALTHCARE INDUSTRY

A number of broad policy pieces have been enacted guiding the development of China's healthcare industry. These regulations provide guidance regarding the industry's overall development path and areas of focus.

3.2.1 Implementation Plan of Deepening the Healthcare Reform (2009-2011)

In April 2009, the Chinese Government issued its *Implementation Plan of Deepening the Healthcare Reform (2009-2011)* providing RMB 850 billion (USD 125 billion) to deepen the nation's healthcare reform. According to this tone-setting document, China will have a basic healthcare system providing "safe, effective, convenient and affordable" health services to urban and rural residents by 2020.

The five major components of reform include:

- **Expand Insurance Coverage:** Increasing basic medical insurance enrollment rates to 90%, increasing basic government medical insurance subsidies and increasing maximum reimbursement payouts;
- **Build National Essential Drug System:** Creating a national essential drug list, setting production and supply security systems for essential drugs and setting retail pricing guidelines at the central level;
- **Develop Primary Healthcare Infrastructure:** Building 3,700 community healthcare centers (CHC)s and 11,000 community healthcare stations, investing in 2,000 county hospitals in rural areas, and developing 29,000 township medical stations;
- **Ensure Equitable Access to Public Health Services:** Raising public health expenditures and establishing a uniform national health record system;
- **Institute Trial Reform of Public Hospitals:** Initiating reform of state-owned hospitals, separating hospital services and drug sales and encouraging private sector, non-profit hospitals.

3.2.2 The 12th Five Year Plan

The soon to be approved *12th Five Year Plan for National Economic and Social Development (2011-2015)* (FYP) is a critically important document used by the government to outline its development goals, mapping out the country's future, guidelines, policy frameworks, and targets for policymakers in the five year period. The FYP serves as a blueprint providing clear strategies for shaping social and economic growth and industrial planning in key sectors and regions.

In the healthcare sector, the FYP focuses on creating a modern healthcare industry gaining efficiencies from increased use of IT in healthcare and consolidating the pharmaceutical distribution sector. Some of the major relevant priorities contained within the FYP include providing:

- **Broader basic healthcare coverage:** supporting the government's goal to provide basic medical coverage for over 90% of the population, including employed and unemployed urban residents, and insurance for all rural residents by 2011;
- **Expanded infrastructure for grassroots medical networks:** supporting government plans to build community healthcare centers, as well as to invest in county hospitals in rural areas and township medical stations;

- **National Health Action Plan:** building public awareness of disease prevention, particularly for high-risk groups in regard to diabetes, cancer, hypertension, and infectious diseases;
- **Improved healthcare administration:** improving overall hospital management, including upgrading hospital information systems, and hospital personnel training;
- **Established healthcare standards:** establishing national healthcare indicators that will serve as benchmarks for national health goals including indicators for healthcare, health resources, and health investments;
- **Healthcare IT:** investing heavily in healthcare IT, including systems integration and digital and remote provision of services to secure healthcare delivery efficiencies.

In addition, the FYP also identifies biotechnology as one of the nation's key "Strategic Emerging Industries" (SEIs), thereby positioning the sector to see high growth rates over the next five years.

3.2.3 Healthy China 2020

In early 2008, China's Ministry of Health (MOH) released its own plan to reform the country's healthcare system called *Healthy China 2020*. The reforms sought to provide universal healthcare and equal access for all of China's 1.3 billion people within 12 years. A core component of the initiative was improving and reforming the country's network of public hospitals.

3.2.4 Catalogue for Guidance of Foreign Investment

Another policy influencing foreign investment in China, including within the healthcare industry, is the *Catalogue for Guidance of Foreign Investment*. The catalogue categorizes industry sectors into four groups (encouraged, permitted, restricted, and prohibited) and outlines the requirements for foreign investment in each category.

According to the current catalogue, investments in China's healthcare industry fall into the following categories:

Industry	Encouraged Items	Forbidden Items
Healthcare Industry	<ul style="list-style-type: none"> • Foreign investment in medical institutions is encouraged but limited to joint ventures and cooperative partners 	<ul style="list-style-type: none"> • Medical institutions owned by Chinese • Major leading medical institutions
Medical Devices	<ul style="list-style-type: none"> • Medical imaging equipment (high field superconducting magnetic resonance MRI, CT, X-ray computed tomography, B- mode ultrasound), • Medical ultrasound transducer (3D) 	<ul style="list-style-type: none"> • Middle- and low-end B-mode ultrasound image screener • Disposable syringes, infusion sets, blood transfusion and blood bags • Manufacturing of X-ray computed tomography equipment (CT), magnetic resonance imaging sets (MRI) • Large-sized medical equipment such as accelerated synthesizers

The National Development and Reform Commission (NDRC) and the Ministry of Commerce (MOFCOM) have indicated that the catalogue will be updated soon, providing additional investment opportunities for foreign companies in China. The soon-to-be-

released document is said to encourage foreign investment in fields such as information technology, high-end manufacturing, biopharmaceuticals and medicine. In addition, the new catalogue will strongly encourage foreign investment in central and western China in an attempt to balance investment between those regions and the eastern regions.

3.3 CHINA'S MEDICAL DEVICE MARKET

In addition to the policy documents listed above which guide the entire industry, numerous regulations have been enacted providing specific requirements within China's medical device sector. In compliance with World Trade Organization (WTO) regulations, China has allowed foreign companies to import medical device products and to be involved in distribution services. However, significant regulatory requirements exist within the industry including:

- ***Draft Regulations for Supervision and Administration of Medical Devices*** (2007): The regulations categorize different medical devices and equipment (Class A, B and C) and outlines detailed requirements for the production, management, use and advertising for medical devices within each category, and punishments for violations. It also calls for a licensing system to be introduced into medical device manufacturing based upon these classifications. A revised version is expected to be released in the near future. Relevant documents include *Catalogue of Medical Device and Equipment* and *Catalogue Description*.
- ***Notice on Improving Import and Utilization of Drugs and Medical Devices*** (2010): This short notice emphasizes the regulatory responsibilities of government bodies such as the SFDA and its regional branches regarding the marketing and the utilization of imported medical devices and drugs.
- ***Notice by Ministry of Health on Management Standards (Trial) for Medical Devices and Equipment for Clinical Use*** (2010): The notice sets criteria to supervise the management and utilization of medical devices for clinical use.
- ***Provision for Medical Device Registration (Draft Regulations)*** (2009): The draft regulation details the registration process as well as the management and utilization procedures for both domestic and foreign-made medical devices/equipment. The document was released for comment, and the formal revised version is expected in the near future.
- ***Provisions for Medical Device Classification***: The provisions standardize classification of medical devices. They direct formulation of The Category of Medical Device Classification and determine the classes of newly registered products.
- ***Provisions for Clinical Trials of Medical Devices***: The provisions detail requirements for implementation and supervision of the clinical trials. They include conditions for trials, rights of trial subjects, trial plans, responsibilities of trial implementers, trial reports, and appropriate archiving and keeping of trial materials.

3.4 CHINA'S HEALTHCARE IT MARKET

In order to foster the development of the China's healthcare IT industry, the Ministry of Health in cooperation with the Chinese Health Information Association has recently

issued multiple key regulations and standards focused on standardizing the healthcare IT market, electronic medical records, and information platforms for regional healthcare. These regulations and standards lay the foundation for the growth of areas such as electronic health records and regional medical care. Some key regulations within the sector include:

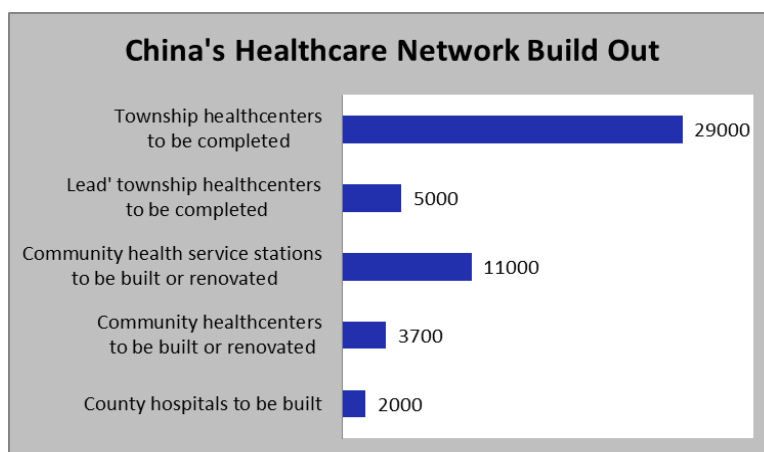
- ***Notice by Ministry of Health on Pilot Program for Electronic Medical Records*** (2010): This notice outlines the requirements for the establishment and management of electronic medical records in China. The document also identifies 22 provinces and municipal cities as targets for the trial.
- ***Notice by Ministry of Health on Implementing Pilot Action Plan of Electronic Medical Records*** (2010): The notice aims to establish a nation-wide medical record system by October 2010. Details include the timeline for various stages from preparation and implementation to evaluation and apply to qualified hospitals in 22 provinces and municipal cities.
- ***Notice by Ministry of Industry and Information Technology on Bidding Catalogue for Development Fund of Electronic and Information Industry in 2010*** (2010): The notice concerns the research and development of operating and supporting healthcare IT as part of the government's tender target in 2010-2011.
- ***Notice by General Offices of NDRC and MIIT on Improving Electronic Information Technology Industry and Technology Transformation*** (2009): The notice emphasizes healthcare IT will be one of China's investment focuses in upcoming years.

4. MARKET OPPORTUNITIES

4.1 EXISTING OPPORTUNITIES

The combination of factors contributing to growth in China's healthcare industry – identified earlier in section 2.1.3 – is creating significant opportunities for foreign firms looking to participate in China's growing medical device and healthcare IT markets.

New Facilities: Due largely to strong government support of healthcare reform in China, numerous new healthcare facilities – including hospitals and community healthcare centers (CHCs) – are being built around the country. These new facilities, which are aimed at addressing imbalances in access to healthcare that currently exist between developed urban



centers and less-developed rural areas, will drive demand for both medical devices and healthcare IT solutions. According to the healthcare reform plan, by the end of 2011, China will build 29,000 township health centers, 5,000 'lead' township health centers, 11,000 community healthcare stations, 3,700 community health service stations and invest in 2,000 county hospitals in rural areas.

These new facilities represent significant opportunities for both medical device and healthcare IT providers to supply their products and services. However, challenges exist for winning a share of these bids. China's healthcare industry is a highly competitive market with foreign players dominating the high-end market and Chinese firms competing for the low cost market. In addition, new policy initiatives seek to expand domestic capacity, creating substantial challenges to firms seeking to enter the market. Successful firms will have a deep understanding of the unique needs China's new healthcare centers face—especially within rural healthcare markets—and provide tailored and packaged solutions.

Upgrade of Existing Facilities: In addition to building thousands of new healthcare provision facilities, the government has also embarked on an ambitious plan to upgrade the medical devices of hospitals in both first and second-tier cities and purchase essential medical equipment for rural hospitals. A sustained drive from government to develop the country's healthcare IT market is also underway, particularly in areas such as establishing and managing electronic medical records and improving healthcare IT application. Huge opportunities therefore exist for foreign firms to be involved in this process. However, once again, attention should be paid to how firms can tailor solutions to the specific healthcare challenges of different healthcare facilities in China. For example, the government requires that hospitals first consider qualified local domestic devices before buying foreign-made devices.

Furthermore, foreign-made equipment tends to be more expensive, and therefore more likely to be affected by the government's tight controls, especially over the purchase of A-type medical devices (defined as devices costing over RMB five million or roughly USD 710,000) for Class B and C hospitals. In favor of foreign firms, hospitals tend to prefer foreign-made medical products, and urban hospitals can increasingly afford the very latest advanced technology. At the same time, rural areas are being encouraged to increase expenditures on medical devices such as X-ray, patient monitoring and ultrasonic testing equipment. To cater to these differing needs, foreign firms should provide medical devices and IT solutions that are not only advanced but also competitively priced, and be able to offer strong post-sales services, such as training and maintenance.

Increasing Citizen Demand: Citizen-driven demand for quality healthcare products is establishing a huge market for small and medium-size medical devices. As discussed in section 2.1.3, expectations surrounding healthcare services continue to increase as do Chinese citizens' ability to afford leading medical products and services. Combined with an increase in the incidence of chronic diseases and a rapidly-aging population, many citizens seek to improve their health and well-being by acquiring relatively easy-to-operate medical equipment for domestic use. While Chinese citizens remain cost-conscious, most consumers perceive foreign-made devices to be more advanced and reliable. The challenge for foreign firms will be to understand the emerging needs of Chinese patients and effectively demonstrate how their medical devices might meet these specific needs in the Chinese market.

Evolving Business Climate: The evolving policy and business climate for the healthcare industry is also driving both opportunities and challenges for foreign firms. New policies and regulations on healthcare reform continue to be developed and released. The 12th FYP is certainly a center-piece, but a new healthcare reform plan is expected by the end of 2011, as well as other core policy initiatives. These new policies will likely create new opportunities for foreign firms to participate in China's medical device and healthcare IT markets; however foreign firms must keep abreast of new developments in China's ongoing healthcare reform and closely monitor the regulatory landscape in this area in order to take advantage of these opportunities.

Leading Players in the Medical Device Market

Mindray Medical International Limited

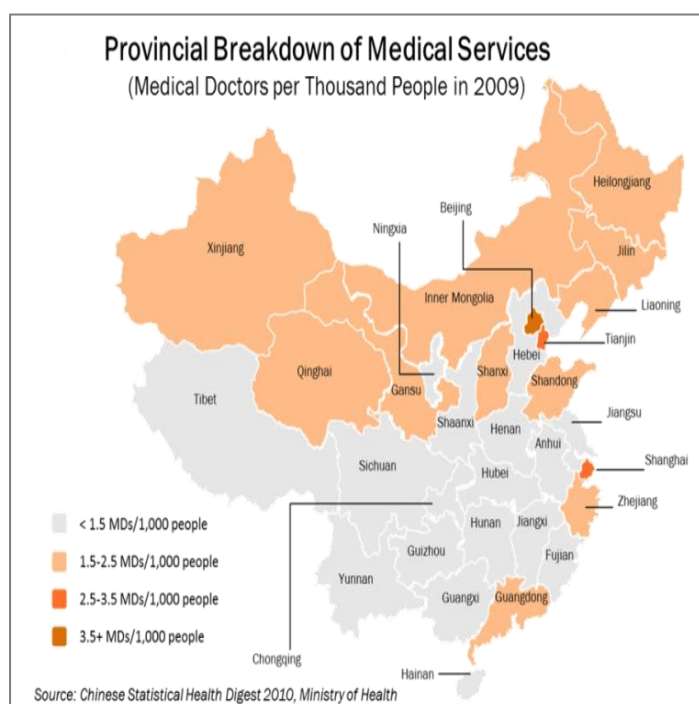
Founded in Shenzhen in 1991, Mindray is a leading developer, manufacturer and marketer of medical devices in China with a rapidly growing international presence.

- Aims to deliver high-quality, competitively-priced medical devices to make healthcare more accessible and affordable around the world.
- Fiscal 2007 worldwide sales were USD 109 million.
- 29 local sales and service offices in China, as well as sales and service subsidiaries in Amsterdam, Istanbul, London, Mexico City, Moscow, Mumbai, Sao Paulo, Seattle, Toronto and Vancouver.
- Good reputation in Tier 3 hospitals (the highest ranking in China) and medical institutions due to its high quality products and services.
- Mindray's products have won several awards including in blood cell analysis and digital ultrasonic diagnostic systems.

China's regulatory regime also creates significant barriers for foreign players in China's healthcare industry. Companies face challenges such as a difficult and often drawn-out registration process and a complex and non-unified bidding process (each province has its own procedures and bid requirements). These challenges present hurdles to be overcome by foreign players seeking entry into China's market.

4.2 GEOGRAPHIC AREAS OF FOCUS

Due to the current distribution of China's healthcare services, the market opportunities for both medical devices and healthcare IT have strong regional considerations. Significant disparity exists in China's healthcare capabilities, with certain provinces possessing world-class capabilities and other regions lacking even basic care for much of its inhabitants. The graphic below showcases this disparity by showing the relative availability of medical doctors. As the map demonstrates, city centers such as Beijing, Shanghai and Tianjin have relatively high doctor to patient ratios. However, once one leaves the city centers and travels to rural China, particularly southwestern China, the ratios become much lower, dropping to a low of 0.81 doctors per thousand patients in Guizhou.



Leading Players in the Medical Device Market

Beijing Wandong Medical Equipment Co., Ltd.

Established in 1997, it is one of China's leading suppliers of medical imaging equipment.

- Headquartered in Beijing, the company's business network covers over 50 countries and regions including second-tier cities such as Nanjing, Chongqing, Hangzhou, Xi'an, Nanchang, Fuzhou and Jinan.
- With over 1,100 employees, the company's medical imaging products were awarded as Beijing's famous brand.
- Its products enjoy over 50% share in the domestic market.

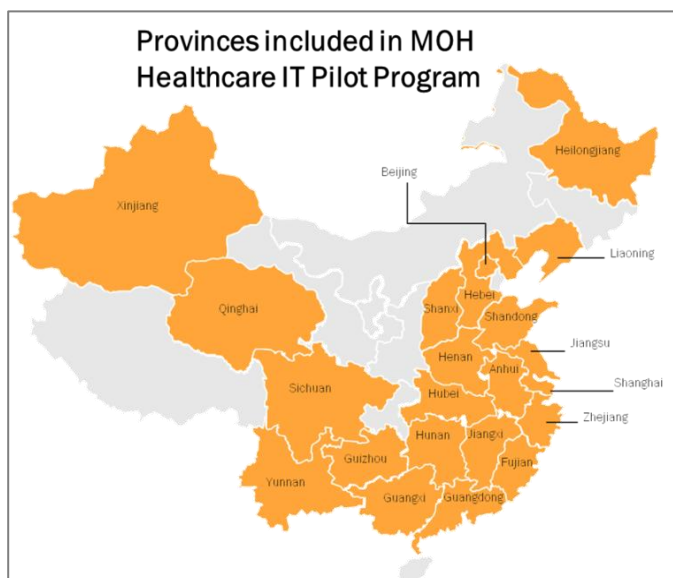
GE Healthcare (Shanghai)

GE Healthcare has been commercially active in China since 1991, and in 2009, was ranked a "top 20 company" in China in the medical device and healthcare product industry.

- Specializes in medical imaging and information technologies, medical diagnostics, patient monitoring and life support systems and biopharmaceutical manufacturing technologies.
- Products and services designed to help physicians: detect diseases earlier and to tailor personalized treatments for patients enhancing patient care.
- With over 3,000 employees, its business in China covers 29 regions including Beijing, Shanghai, Wuxi (Jiangsu Province) and Guangzhou.
- Owns factories in Beijing producing CT scanning, magnetic resonance imaging and X-ray imaging systems; has a base for life science in Shanghai; and runs a factory that manufactures ultrasound and monitoring equipment in Wuxi.

China's plan to construct new facilities will be focused in the regions currently facing low doctor to patient ratios and therefore many market opportunities for medical device and healthcare IT companies will be located in these regions.

In response to the government's call for wider utilization of IT in the healthcare industry, the developed coastal regions have kicked off a series of healthcare IT trials. Beijing and Shanghai, together with other developed cities in the east and south coast, are taking the lead in establishing a unified healthcare IT system in China. Significant investment is therefore already underway in these developed markets. However, China is seeking to encourage IT investments in rural regions by selecting 22 provinces and municipalities for a pilot program to trial a system that can better use and manage electronic medical records. The program includes the following



provinces: Hebei, Liaoning, Heilongjiang, Jiangsu, Zhejiang, Anhui, Fujian, Jiangxi, Shandong, Henan, Hubei, Hunan, Guangdong, Guangxi, Sichuan, Guizhou, Yunnan, Shanxi, Qinghai and Xinjiang. The two municipal cities are Beijing and Shanghai

4.3 KEY INDUSTRY PARKS

In order to facilitate the continued development of China's healthcare industry, China's central, regional and local governments have developed industrial parks focused on fostering and growing domestic capacity in this prioritized industry. Shanghai has led the way in developing these parks with four key development zones located within the city limits:

- Shanghai Zhangjiang Hi-Tech Park** is a newly-established industrial zone in Shanghai that focuses on bi-pharmaceutical and medical products. Founded in 2010, the Zhangjiang Park aims to consolidate healthcare resources and strengthen innovation, development and international cooperation for Shanghai's medical device and equipment market.



- **Zizhu Science-Based Industrial Park** is one of the country's oldest and most well-established medical industrial parks. The park was founded in 2002 and named a Municipal High-Tech Industrial Development Zone in 2003. It is currently applying for National High-Tech Industrial Development Zone status.
- **Shanghai International Medical Zone (SIMZ)** is China's only "medical valley." It is a relatively new park with construction initiated in 2005. However despite its relative youth, SIMZ has aggressive development plans, seeking to become Asia's most comprehensive medical zone when construction ends in 2020.
- **Caohejing Pujiang Hi-Tech Park** is a national-level development zone medical park focused on the development of bio-pharmaceutical and medical products. Established in 2003, the park was recently approved as a national biopharmaceutical & medical industrial base.

Although Shanghai has led this process, a number of new medical and healthcare-focused parks have recently been created outside of Shanghai seeking to challenge the cities dominance in this area:

- **China National Engineering Research Center for Ultrasound Equipment** was established in Chongqing in 2009. This center is considered as the only one of its kind for digital medical device and equipment, seeking to position Chongqing as a base for innovation in ultrasound medical equipment.
- **National Medical Device & Technology Industrial Base** is the first pilot industrial base for the medical device and equipment industry. The facility was approved by the Ministry of Science and Technology (MOST) in 2009 and located in Chongqing. The base will support ongoing healthcare reform and seek to attract capital, technology and expertise in the near future.
- **China Medical Device Industrial Base** is the first national-level industrial base for medical devices and equipment. Approved by the China Association for Medical Device Industry (CAMDI) in 2006, this Guangdong-based facility aims establish itself as a leader role in the medical device market both domestically and internationally.

Leading Players in the Healthcare IT Market

Xian Huahai Medical Info-Tech Co., Ltd.

A high-tech enterprise specializing in digitalized healthcare, R&D of healthcare IT as well as related manufacturing, sales and services.

- Huahai has served many well-known hospitals in China and was the first to offer 24-hour customer service via 800 toll free phone calls.
- It has branch offices in over 20 cities in China including Beijing, Shanghai, Guangzhou, Urumqi, Jinan, Kunming, Chengdu and Nanjing.
- It has developed software products with "indigenous innovations" such as MedPACS, the first of its kind approved by MoH and a pilot product by NDRC.
- Its partners include HP, IBM, EMC, Oracle, BARCO, Planar and WIDE, and the company aims to further strengthen its international cooperation.

4.4 KEY INDUSTRY EXHIBITIONS/EVENTS

The 23rd International Medical Instruments and Equipment Exhibition (China Med)

(第 23 届国际医疗器械设备展览会)

China National Convention Center, Beijing

March 25-27, 2011

Co-organized by the Chinese People's Liberation Army's Health Department within the General Logistics Department, China Med is regarded as one of the most influential exhibitions in the Chinese medical devices and equipment sector, attracting participants from all over the world. In 2010, the latest medical products and technologies from 20 countries were exhibited at the event, and participants included well-known foreign companies such as GE, Siemens, Philips and Toshiba. Due to its co-organizer's background, China Med places a focus on medical devices for military medical uses.

Website: <http://www.chinamed.net.cn/download/e-newsletters/e-newsletter19/en.htm>

MEDTEC China

INTEX Shanghai

September 7-8, 2011

MEDTEC China is a leading trade show in China for the medical manufacturing industry. The event goes beyond a pure exhibition including conferences and seminars on relevant industry topics. The first MEDTEC China was held in 2005 and attracted attention from market leaders and practitioners in the medical manufacturing industry as well as key government officials.

Website: http://www.canontradeshows.com/expo/shanghai10/index_en.html

65th CMEF Spring 2011 & 12th ICMD (第 65 届中国国际医疗器械博览会 & 第 12 届中国国际医疗器械设计与制造技术展览会)

Shenzhen Convention & Exhibition Center, Shenzhen, China

16-19 April, 2011

CMEF has become the largest exhibition of its kind in the Asia-Pacific since it was first held in 1979. Currently, it is considered as the largest platform for medical device trading and technology/academic exchange in China. It is also a medium for companies to gather medical-related news and to elevate their profile. It is held in the spring and fall of every year.

Website: <http://en.cmef.com.cn/>

Leading Players in the Healthcare IT Market

Microsoft Corporation (China) Limited Co.

Microsoft China was founded in 1995. The company has a long-term development strategy for China, and also has a number of investments in the Mainland.

- Microsoft has representative offices in many Chinese cities, including Shanghai, Guangzhou, Chengdu, Nanjing, Shenyang, Wuhan, Shenzhen, Fuzhou, Qingdao, Hangzhou, Chongqing and Xi'an.
- With its wide network, Microsoft is able to run a nation-wide business with a focus on primary research, product development, sales, technological support, and education and training.
- After years of expansion, Microsoft has established a Microsoft China R&D Group, Microsoft Hardware Technology Center in Asia, and a number of other R&D centers and technology support units (in Beijing, Shanghai and Shenzhen).
- The company collaborates with Chinese government bodies such as MoH, medical institutions and other partners to develop solutions in the following fields: digitalized hospital; informatization of community clinics; regional healthcare IT systems; and application of healthcare IT in rural areas.

2010 China Innovative Healthcare IT and Management Conference

Beijing, China

March 2011 (tentative)

The event was organized by the China Information Association. Participants include high-ranking officials from the Ministry of Health, Ministry of Industry and Information, and Ministry of Science and Technology, and the event is also attended by healthcare practitioners and scholars. Key discussions include unified standards for healthcare IT, medical information sharing, reforms of public hospitals, and better application of healthcare IT to foster healthcare development in general.

Website:

<http://cj.39.net/ylhy/xwdt/lthy/103/30/1204646.html>

2010 Chinese Exhibition of Medical IT and Low-carbon Medical Device

Beijing, China

August 2011 (tentative)

As a response to the Chinese Government's healthcare reform agenda – in particular the promotion of healthcare IT and electronic medical records – the China Medical Informatics Association (CMIA) held the Chinese Exhibition of Medical IT and Low-carbon Medical Device in Beijing from August 18-20, 2010. The event highlighted digital technologies such as EMR, PACS, HIS, CIS, LIS and RIS, and low-carbon medical devices such as magnetic resonance imaging, digital radiography, and B ultrasonic wave. The first exhibition of Electronic Medical Records and Digital Technology was held in 2006.

Website http://www.ccnf.com/fair/20100624/index_201006240009_0.shtml (in Chinese)

Leading Players in the Healthcare IT Market

Tianjian Technology Group

Founded in 1993, Tianjian is one of the first companies in Mainland China to engage in medical information technology R&D.

- Tianjian provides software products that support digitalized hospitals and regional systems, and provides solutions to integrate healthcare IT and other related operations.
- Tianjian's headquarters are in Beijing, and the company's business spans China.
- In terms of market share, sales growth, technology and standards, the company has taken a leading role in China and Tianjian is regarded as the top Chinese company providing comprehensive medical solutions.
- The company was appointed to support the healthcare IT system of the People's Liberation Army.

4.5 RECOMMENDATIONS FOR ISRAEL

In light of this report's central findings, APCO Worldwide has identified a number of core recommendations for Israeli companies considering entering China's healthcare industry.

Understand the Specific Demands Created by China's Healthcare Reform

The Chinese Government's healthcare reform agenda provides significant investment to increase China's basic medical service provision and improve rural and urban healthcare infrastructure, as well as to greatly expand access to healthcare resources for the country's citizens. However, the healthcare demands of leading urban hospitals will be very different to those of rural hospitals, which will in turn be different to the needs of community healthcare centers (CHCs). As a first step, APCO recommends that Israeli companies investigate and understand the specific demands generated by China's healthcare reform and market opportunities. For example, hospitals and CHCs in rural areas will have much more basic healthcare needs than large urban hospitals, and are therefore focused on acquiring basic medical devices and healthcare IT solutions; these facilities will also be very price conscious. In contrast, China's top-tier hospitals are in search of world-class technology and will have significantly larger budgets available. In addition, foreign firms should understand the need for post-sale services and training needs for operation and maintenance support as part of any purchasing agreement.

Identify the Unique Strengths of Israeli Healthcare Firms

In order for Israeli firms to participate in the rapid growth and numerous opportunities presented by China's healthcare reform, they must first demonstrate to the Chinese Government their core strengths through rounds of competitive bidding. It is therefore of crucial importance that Israeli firms identify the key healthcare areas and medical technologies where they lead. Once a number of targeted areas of strength are identified, Israeli firms should endeavor to build awareness of their leadership position among key Chinese government stakeholders. Without this awareness, it will be very difficult for even leading Israeli firms to win through China's competitive bidding process.

Leverage the Influence and Support of the Israeli Government

Major procurement and purchasing decisions in the Chinese healthcare industry are made by stakeholders in the central and regional governments. In order to optimize Israeli firms' chances within this process, it would be very beneficial to leverage the full support of the Israeli Government. This can be done in a number of ways, including organizing a high-level Israeli Government delegation to China accompanied by the CEOs of major healthcare firms, providing high-profile opportunities to sign trade deals and opening the door for Israeli firms to compete for major healthcare projects. Similarly, ministerial-level leaders of key Chinese Government stakeholders could be invited to pay an official visit to Israel. This will create another platform to build awareness and discuss the leading technologies of Israeli healthcare firms.

Pay Close Attention to Stakeholders and Evolving Regulations

Proposed healthcare reforms in the 12th FYP are expected to introduce additional stakeholders into the healthcare arena. Israeli firms should continue to update their understanding of relevant stakeholders emerging as a result of the 12th FYP, development of the SEI, and wider healthcare reform. It is also possible that certain regulations may be significantly altered as the healthcare reform process continues to

move forward. A clear understanding of the ongoing evolution of China's healthcare regulatory environment coupled with robust relationships with key institutions and actors will enable Israeli firms to better monitor potential issues and effectively inject their views into the policy process. Finally, since the Chinese Government intends to strengthen cooperation between domestic and foreign companies in healthcare-related areas, many domestic companies will be seeking partners. This presents potential opportunities for Israeli companies.

APPENDIX I – TERMINOLOGIES

CAGR	Compound Annual Growth Rate
CAMDI	China Association for Medical Device Industry
CHC	Community Healthcare Center
CIS	Clinical Information System
CMEF	China International Medical Equipment Fair
CMIA	China Medical Informatics Association
CT	Computed Tomography
ECG	Electrocardiography
EMR	Electronic Medical Record
FYP	Five Year Plan
HIS	Hospital Information System
LIS	Laboratory Information System
MIIT	Ministry of Industry and Information Technology
MOF	Ministry of Finance
MOFCOM	Ministry of Commerce
MOH	Ministry of Health
MOHRSS	Ministry of Human Resources and Social Security
MOST	Ministry of Science and Technology
MRI	Magnetic Resonance Imaging
NDRC	National Development and Reform Commission
NMR	Nuclear Magnetic Resonance
PACS	Picture Archiving and Communication System
RIS	Radiography Information System
SEI	Strategic Emerging Industry
SFDA	State Food and Drug Administration
SIMZ	Shanghai International Medical Zone
SMEs	Small and Medium-sized Enterprises
WTO	World Trade Organization

APPENDIX II – MAP OF CHINA



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