Sector Report

The Medical Devices Market in China
The sales of medical devices in China have increased rapidly over the last decade, reaching a total value of CNY 255.6 billion (EUR 36 billion) at the end of 2014.

On account of an ageing population, increased awareness of diseases and growing expenditure on healthcare, the sector is expected to continue to expand in the coming years. Competition in the market is strong, with foreign companies concentrated in the high-end segment and Chinese companies occupying the mid-to-low end section.

Regulation-wise, even though China’s healthcare system and medical device regulations can often be challenging to understand, the PRC’s government has recently implemented a set of new measures aimed at increasing the standardisation of the market and promoting its development. Such trends will provide EU SMEs with a new set of opportunities, provided that the right preparation is made to face existing challenges.

This report aims to provide an overview of China’s medical device industry with an introduction to relevant government bodies, China’s medical device classifications system, current market situation, as well as presenting potential opportunities and challenges for EU SMEs.
# Table of Contents

1. Regulatory Bodies, Policies, Regulations, Definitions and Classifications ........................................ 4  
   1.1. Regulatory Bodies .................................................................................................................. 4  
   1.2. Policy and Regulations ......................................................................................................... 4  
   1.3. Definitions & Classifications ............................................................................................... 4  
   1.4. Medical Device Registration Numbers ............................................................................... 6  

2. Market Overview .......................................................................................................................... 8  
   2.1. Market Size and Performance ............................................................................................... 8  
   2.2. Import & Export .................................................................................................................... 8  
   2.3. Key Growth Drivers ............................................................................................................. 10  
   2.4. Market Structure .................................................................................................................. 12  
   2.5. Buyer Segmentation & Consumption Trends ....................................................................... 15  
   2.6. Supply Chain Structure ....................................................................................................... 17  
   2.7. Market Outlook & Forecasts ............................................................................................... 18  

3. Case Study .................................................................................................................................. 20  
   3.1. Case Study I: Timesco UK .................................................................................................... 20  
   3.2. Case Study II: Beijing Yes Medical Devices Co Ltd ............................................................. 21  
   3.3. Case Study III: Beijing Kinghawk Pharmaceutical ................................................................. 22  

4. Opportunities and Challenges ..................................................................................................... 25  
   4.1. Opportunities ....................................................................................................................... 25  
   4.2. Challenges ........................................................................................................................... 28  
   4.3. Hospital Operations & Procurement Processes for Medical Devices .................................. 29  
   4.4. Supply Chain Structure for Medical Devices ..................................................................... 29  

5. Practical Advice on How to Access the Market .......................................................................... 30  
   5.1. Understand the Market ........................................................................................................ 30  
   5.2. Find a Local Partner ............................................................................................................. 30  
   5.3. Distribution and Pricing ...................................................................................................... 30  
   5.4. Branding & Pricing .............................................................................................................. 30  
   5.5. Intellectual Property (IP) Protection & Due Diligence ......................................................... 31  

6. Report Summary ........................................................................................................................ 32  
7. Exhibitions .................................................................................................................................. 33  
8. Relevant Associations .................................................................................................................. 35  
9. Useful Websites .......................................................................................................................... 35  
10. Annex .......................................................................................................................................... 36  
   10.1. Annex I: Terminology ......................................................................................................... 36  
   10.2. Annex II: Provisions and Regulations for Medical Devices in China .................................. 37  
   10.3. Annex III: Key Chinese Players ........................................................................................ 38  
   10.4. Annex IV: PET/CT Equipment Purchase approved by NHFPC in 2015 ............................ 41  
   10.5. Annex V: Medical Device Classification .......................................................................... 43  

© 2015 EU SME Centre
1. Regulatory Bodies, Policies, Regulations, Definitions and Classifications

1.1. Regulatory Bodies

The China Food and Drug Administration (CFDA), previously known as the State Food and Drug Administration (SFDA), is the administrative and supervisory authority for medical devices in China. CFDA oversees the administration of food, drugs and cosmetics.

The CFDA drafts regulations for medical devices, draws up standards, classifies medical devices, and inspects the manufacturing, sales and distribution of medical devices in China. In addition to this, the CFDA also manages the import of medical devices.

There are a number of departments under the CFDA, including the Department of Medical Device Registration and the Department of Medical Device Supervision. Other organisations that are involved in the technical evaluation of medical device standards include the Centre for Medical Device Evaluation and the National Institute of Food and Drug Control.

1.2. Policy and Regulations

There are a number of regulations concerning medical devices in China, but the Regulations for the Supervision and Administration of Medical Devices are the only regulations officially endorsed and approved by the State Council. After the latest version of the regulations was published on 7th March 2014, the CFDA released a series of specific provisions and regulations for medical devices in China. Please see Annex II for detailed information regarding policies and regulations.

1.3. Definitions & Classifications

1.3.1. Definition of Medical Devices

Medical devices are defined by the CFDA as:

Any instrument, apparatus, appliance, material, or other article – whether used alone or in combination, including the software necessary for its proper application – that does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means.

Medical devices are used to achieve the following intended objectives:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disabled patients;
- Investigation, replacement or modification for anatomy or a physiological process
- Control of conception;
- Support or maintenance of life;

1 http://www.sfda.gov.cn/
2 http://www.cmde.org.cn/
3 http://www.nicpbp.org.cn/.
4 http://www.cmde.org.cn/CL0001/.
8 http://www.sda.gov.cn/WS01/CL0784/97814.html. (English is only available for the last version of the regulations, but not the latest version http://eng.sfda.gov.cn/WS03/CL0767/61641.html).
• Investigation of samples taken from humans to provide information for medical treatment or diagnostic purposes.

1.3.2. Classification of Medical Devices

Medical devices are organised into three classes in China – Classes I, II and III – based on the risk level of the device (determined by the purpose, structural features, whether it comes into direct contact with the body, methods and status of use) from low to high. Classifications are used predominantly for risk management; therefore different classes of medical devices are governed by different rules. For example:

• **Class I** medical devices are deemed to have low levels of risk, for which safety and effectiveness can be ensured through routine administration;
• **Class II** medical devices are deemed to be of medium level of risk, for which further control is required to ensure their safety and effectiveness;
• **Class III** medical devices have high levels of risk, where special measures must be taken to enforce strict control and administration regarding safety and effectiveness.

According to the Regulations for the Supervision and Administration of Medical Devices, (March 2014), the CDFA implemented product filing management for Class I medical devices before they can be distributed in China. For Class II and Class III medical devices, manufacturers require approval from the CFDA.

A medical device can be divided into four categories according to its structural characteristics (powered/active or non-powered/passive) and whether it touches the human body. These categories are as follows:

• Passive human body contacting medical devices;
• Passive non-human body contacting medical devices;
• Active human body contacting medical devices;
• Active non-human body contacting medical devices.

Please see examples for these four categories and sub-categories below.

<table>
<thead>
<tr>
<th>Categories</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Passive human body contacting medical devices</strong></td>
<td>Devices used to transport pharmaceutical liquids, devices for the alteration of blood and body fluids, medical dressings, invasive devices, reusable medical devices, implantable medical devices, contraception and family planning devices.</td>
</tr>
<tr>
<td><strong>Passive non-human body contacting medical devices</strong></td>
<td>Nursing devices, passive disinfection and cleaning equipment for medical devices.</td>
</tr>
<tr>
<td><strong>Active human body contacting medical devices</strong></td>
<td>Energy treatment equipment, diagnostic and monitoring equipment, liquid conveying equipment, ionising radiation instruments and, active implantable medical devices.</td>
</tr>
<tr>
<td><strong>Active non-human body contacting medical devices</strong></td>
<td>Checking/testing equipment; stand-alone software, active disinfection and cleaning equipment for medical devices.</td>
</tr>
</tbody>
</table>

---

9 As the rule of classification is in the process of being updating, the revised draft was used for this report. [http://www.sda.gov.cn/WS01/CL0779/110264.html](http://www.sda.gov.cn/WS01/CL0779/110264.html)

Based on the above classifications, the four categories can be further divided into sub-categories, according to different classification standards. Different terms of use apply to each type of medical device, please see the examples below:

Table 2: Medical Sub-categories

<table>
<thead>
<tr>
<th>Categories</th>
<th>Sub-categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive human body contacting medical devices (in terms of use for time limit)</td>
<td>Temporary use, short-term use, long-term use.</td>
</tr>
<tr>
<td>Passive human body contacting medical devices (regarding specific body part contacted)</td>
<td>Skin or cavity (apertures), wound or tissues, blood circulation system or central nervous system.</td>
</tr>
<tr>
<td>Passive non-human body contacting medical devices (influence of medical effects)</td>
<td>Insignificant influence, indirect influence, indirect significant influence.</td>
</tr>
<tr>
<td>Active human body contacting medical devices (possible harm when not controlled)</td>
<td>Slight injury, medium injury, heavy injury.</td>
</tr>
<tr>
<td>Active non-human body contacting medical devices (the influence of medical effects)</td>
<td>Insignificant influence, indirect influence, indirect significant influence.</td>
</tr>
</tbody>
</table>

If a medical device can be categorised into two or more sub-categories, a higher level classification shall be applied. If a medical device package contains several devices or types of device, the highest level is applied. Sterile medical devices are not permitted to be classified lower than Class II. Please find the Medical Device Classification Determination in Annex V.

It must also be noted that some medical devices may be required to gain China Compulsory Certification (the EU SME Centre Guideline on China Compulsory Certification (CCC) can be found at: http://www.eusmecentre.org.cn/guideline/china-compulsory-certification-ccc)

1.4. Medical Device Registration Numbers

As of the end of December 2013, of the 15,698 medical device manufacturing companies with licensed certificates, 35 companies were listed either in China or overseas. A total of 93,592 types of medical devices were licensed as well as 34,655 types of imported medical devices.

Table 3 shows that the number of registered Class I medical devices in China has grown significantly from 3,452 in 2007 to 7,990 in 2013. The number of Class II medical devices registered in China grew by around 7,000 from 2009 to 2012, while in 2013 the number of registered and re-registered devices in China reached 10,192. For Class III medical devices, there was huge growth in 2012; this growth began to stabilise from 2013. Table 3 shows the medical devices registered and re-registered from 2007-2013.11

11 http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml
Table 3: Number of Registered Medical Devices in China

| Year | Class I | | Class II | | Class III | | Imported from Foreign Countries |
|------|--------|------|----------|------|----------|------|
|      | Registration | Re- | Registration | Re- | Registration | Re- | Registration | Reregistration |
|      |          | registration |          | registration |          | registration |          |          |
| 2007 | 3,452 | =\(^{12}\) | 3,883 | - | 1,366 | - | 2,221 | - |
| 2008 | 2,117 | 1,583 | 2,172 | 2,234 | 1,485 | - | 3,683 | - |
| 2009 | 3,156 | 2,294 | 2,646 | 4,473 | 345 | 711 | 1,441 | 1,701 |
| 2010 | 3,526 | 2,493 | 3,251 | 4,181 | 374 | 890 | 1,626 | 1,746 |
| 2011 | 3,583 | 2,095 | 3,350 | 3,441 | 388 | 701 | 1,654 | 1,336 |
| 2012 | 4,331 | 2,739 | 3,637 | 3,300 | 913 | 1,628 | 3,517 | 4,181 |
| 2013 | 4,252 | 3,738 | 4,391 | 5,801 | 1,030 | 1,852 | 3,916 | 3,798 |

\(^{12}\) Not clear whether company re-registered.

Click the following link to download the EU SME Centre Guideline on the Medical Device Registration in China:
http://www.eusmecentre.org.cn/guideline/medical-device-registration
2. Market Overview

2.1. Market Size and Performance

In 2014, medical device sales in China totalled CNY 255.6 billion (EUR 36 billion); a year on year increase of 20%, according to the China Medical Pharmaceutical Materials Association.\textsuperscript{13, 14} In recent years, China’s medical device industry has seen significant sales increases. Sales doubled in the period 2010-2014 alone as shown in Figure 1 below.

Figure 1: 2001-2014 Medical Device Sales in China \textsuperscript{15}

Sales of medical devices totalled CNY 17.3 billion (EUR 2.4 billion) in 2001, and by 2014 had reached CNY 255.6 billion (EUR 36 billion); more than a 14-fold increase. The largest increase in sales occurred between 2013 and 2014, when total value rose by CNY 43.6 billion (EUR 6.1 billion).

2.2. Import & Export

According to customs data, in 2014, the import and export value of medical devices was approximately USD 35.7 billion (EUR 31.2 billion),\textsuperscript{16} a 4% year on year increase. In 2014, China’s medical device total import value was USD 15.7 billion (EUR 13.7 billion), a 5% increase from 2013, but a growth rate 15% slower than in 2013.\textsuperscript{17, 18}

Joint Ventures (JV) And Wholly Foreign-Owned Enterprises (WFOE) were the main importers of medical devices, making up almost 40% of China’s total import value of medical devices in 2014. Diagnostic medical devices totalled approximately 70% of the medical devices import value; the highest amongst all imported medical devices.

\textsuperscript{13} RMB100.00 = EUR 14.08 (Yahoo Finance, accessed on 18\textsuperscript{th} May 2015)
\textsuperscript{14} http://www.cmpma.cn/.
\textsuperscript{15} http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml.
\textsuperscript{16} USD 100 = EUR 87.42 (Yahoo Finance, accessed on 18\textsuperscript{th} May 2015)
\textsuperscript{17} http://www.askci.com/chanye/2015/03/21/842566a0.shtml.
\textsuperscript{18} In 2014, the growth rate of imported medical devices entering China was the lowest in three years.
2.2.1. Europe: China’s largest Exporter

Out of 200 countries/regions, Europe was the largest medical device exporter to China in 2014, accounting for 39% of China’s total import value of such products. In comparison, North America accounted for 32%, and Asia for 25%. The top six EU countries exporting medical devices to China in 2014 were Germany, Ireland, Switzerland, the UK, the Netherlands and Italy. The top five exporters of medical devices to China in 2014 were the US, Germany, Japan, Ireland and Switzerland; these five countries provided 68% of China’s total import value for medical devices.  

2.2.2. Imported Products

In 2014, 35 types of medical devices imported to China exceeded the value of CNY 620 million (EUR 87.3 million). These 35 types of medical devices included:

- General diagnostic equipment;
- Ultrasound diagnostic apparatus;
- Rehabilitation appliances;
- X-ray tomography instruments;
- Endoscopes artificial joints;
- Orthopedic equipment;
- Fracture equipment;
- Medical accelerators;
- Medical catheters and Magnetic Resonance Imaging (MRI) equipment.

Among these, diagnostics and treatment equipment were valued at USD 11.3 billion (EUR 9.8 billion), a year on year increase of over 6% and accounting for 72% of the total import value.

2.2.3. Major Importers

Importers of medical devices were mainly from private companies; JVs (52%), WFOEs (39%), and State Owned Enterprises (SOE), (9%) of China’s medical device import value.

Major Import Company Type, 2014

![Pie chart showing major import company types: Joint Venture (9%), Wholly Foreign Owned Enterprise (52%), State Owned Enterprise (39%)]

19 [http://www.askci.com/chanye/2015/03/21/842566a0.shtml](http://www.askci.com/chanye/2015/03/21/842566a0.shtml)
20 [http://www.askci.com/chanye/2015/03/21/842566a0.shtml](http://www.askci.com/chanye/2015/03/21/842566a0.shtml)
Major importers include Johnson & Johnson Medical Companies, Medtronic, Shanghai Dong Song International Trading Co Ltd and Olympus Trade (Shanghai) Co Ltd.

2.2.4. Import Regions

Shanghai, Beijing and Guangdong were the top three importing municipalities/provinces in 2014.

- Shanghai imported over USD 6.3 billion (EUR 6.5 billion) a year on year increase of over 10% or 40% of all medical device imports to China in 2014;
- Beijing imported over USD 3.7 billion (EUR 3.2 billion) or 24% of the total value of medical device imports;
- Guangdong imported over USD 1.6 billion (EUR 1.3 billion) or 11% the total value of imported medical devices in 2014.

Other provinces/municipalities with considerable import values are: Jiangsu, Zhejiang, Shandong, Liaoning, Tianjin, Fujian and Hubei.

2.2.5. Exports

The total export value of China’s medical devices was CNY 124.1 billion (approx. EUR 17.8 billion) in 2014.

Low-end devices, such as medical tubing, medical cotton, gauze, bandages, disposable apparel, medical nonwoven material, X-ray examination contrast agent, hearing aids and syringes, exceeded an export value of CNY 620 million (approx. EUR 89 million). Major exporters of these medical devices included Terumo, Allmed, Winner Medical and Mindray.

2.3. Key Growth Drivers

By the end of 2013, there were 15,698 medical device companies in China, with a total output of CNY 212 billion (approx. EUR 29.94 billion).

Local medical device manufacturers have grown over the past decade. In 2014, the leading Chinese enterprises producing medical devices included:

- Mindray Medical
- Yuwell Medical
- Well Tech
- Andon Health
- Neusoft Medical
- Lepu Medical
- Weigao Medical
- Microport Medical

21 http://www.jjmc.com.cn/
22 http://www.medtronic.com/
23 http://www.dongsong-cn.com/
25 http://www.askci.com/chanye/2015/03/21/842566a0.shtml
26 http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml
28 http://www.terumo.com.cn/
29 http://www.allmed-china.com/
30 http://www.winnermedical.com/
31 http://www.mindray.com/
32 http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml
Several key drivers are pushing forward the growth of China’s medical device industry growth. These are highlighted below.

### 2.3.1. Ageing Population

China is regarded as an ageing society and the demand for related medical devices is expected to increase in the future. It is estimated that by 2030 there will be over 230 million people living in China aged 65 or over. Chronic diseases are increasingly becoming more prevalent; heart disease, high blood pressure and diabetes diagnosis are increasing.

### 2.3.2. Increasing Middle-Class

As China’s economy has expanded, so too has the country’s middle class. China’s growing middle class is typically found in larger cities and has access to hospitals that use high quality medical devices. China’s middle class tend to prefer better quality products and therefore is expected to be a driver of China’s medical device sector.

The middle-class is also fuelling China’s cosmetic surgery industry, which is growing rapidly. According to a survey conducted by the International Society of Aesthetic Plastic Surgery (ISAPS) in 2011, China accounted for 12.7% of all cosmetic surgeries in the world, making it the third largest market for cosmetic surgery. In 2014, it was estimated that China’s cosmetic surgery market was worth CNY 510 billion (EUR 75 billion) and more than 7.4 million people underwent cosmetic surgery. Several issues surround China’s plastic surgery market; such as staff shortages, low entry barriers and disputes, resulting in some patients travelling overseas to receive surgery; for instance in 2014, 56,000 Chinese residents visited South Korea to undergo cosmetic surgery.

### 2.3.3. China Health Reform

State funded medical institutions dominate China’s healthcare system. The government introduced its Healthcare Reform in 2009 to tackle serious issues such as imbalances in the allocation of healthcare resources, over pricing of medicines and reducing the cost of treatment for patients.

The government’s reforms aim to have universal health insurance coverage by 2020. This will signify heavy investment from the government on infrastructure, especially on primary clinic and community centre construction. The basic medical equipment market is therefore expected to grow in the coming years. The market for such products, however, is dominated already by Chinese companies (e.g. the Shandong Pharmaceutical Glass Co., Ltd providing basic glass bottles and the Shandong Wei Gao Group producing consumables such as infusion sets, syringes, medical needles, and blood sampling equipment).

On the other side, the high-end section of the medical equipment market for products such as image diagnostic equipment, X-ray machines and ultrasounds are is dominated by foreign

---

35 Click on the following link to download the EU SME Centre report on the Healthcare sector in China: http://www.eusmecentre.org.cn/report/healthcare-sector-china.
brands. In the coming years it is expected that international brands will control the market share of high-end medical equipment. However, Chinese brands such as Neusoft Medical, China Resources Wandong, and Mindray are gradually entering this market\[^{16}\].

**2.3.4. China Two Children Policy**

In late 2013, China’s Central government introduced reforms to the country’s one child policy. Reforms came into effect in early 2014 and allow couples to have two children if either parent is an only child.\[^{37}\] Although the long-term effects in this policy change will not be known for years to come\[^{38}\], an increasing birth rate may bring opportunities for companies that provide products relating to pregnancy and child birth. Recent reports have claimed that less than one million of the 11 million eligible couples applied to have a second child; this is less than expected.\[^{39}\]

**2.3.5. Increasing Competition**

Chinese brands occupy the mid-low-end market, while foreign brands have potential opportunities in the high-end market; however competition is strong among domestic brands and they are improving the quality of their products. Nevertheless, imported products are often deemed to be more advanced due to the R&D capabilities of foreign players.

Annex III of this report provides an introduction to leading Chinese medical device companies and introduces their product categories.

**2.4. Market Structure**

**2.4.1. Domestic Manufacturers-Low Concentration and Mid-Low-End Market**

China’s domestic medical device industry is characterised by a high number of medical device manufacturers scattered around the country. Chinese medical device companies tend to be small in size, produce similar products and often lack core competences such as R&D capabilities.

As of the end of 2013, there were 15,698 medical device manufacturers in China. With a total generated revenue of CNY 212 billion (EUR 29.8 billion) in 2013, the average revenue for each company was CNY 14 million (EUR 1.9 million), a year on year increase of CNY 1.5 million (EUR 0.21 million).

According to the CFDA, the number of trading companies of medical devices has increased from 160,952 to 183,809 in the period 2007-2013. The number of medical device manufacturers grew from 12,601-15,698 a 24% increase.\[^{40}\]

\[^{38}\] Recent reports have claimed that less than one million of the 11 million eligible couples applied to have a second child; this is less than expected.
\[^{39}\] China’s National Health and Family Planning Commission.
\[^{40}\] http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml
Table 4: Number of Medical Device Manufacturers and Trading Companies in China, 2007-2013

<table>
<thead>
<tr>
<th>Year</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Total</th>
<th>(distributor/retailer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>3,245</td>
<td>7,233</td>
<td>2,123</td>
<td>12,601</td>
<td>160,952</td>
</tr>
<tr>
<td>2008</td>
<td>3,368</td>
<td>7,533</td>
<td>2,240</td>
<td>13,141</td>
<td>157,364</td>
</tr>
<tr>
<td>2009</td>
<td>3,696</td>
<td>7,869</td>
<td>2,311</td>
<td>13,876</td>
<td>155,765</td>
</tr>
<tr>
<td>2010</td>
<td>4,015</td>
<td>7,906</td>
<td>2,416</td>
<td>14,337</td>
<td>165,203</td>
</tr>
<tr>
<td>2011</td>
<td>4,051</td>
<td>8,174</td>
<td>2,405</td>
<td>14,603</td>
<td>168,596</td>
</tr>
<tr>
<td>2012</td>
<td>4,095</td>
<td>8,247</td>
<td>2,586</td>
<td>14,928</td>
<td>177,788</td>
</tr>
<tr>
<td>2013</td>
<td>4,218</td>
<td>8,804</td>
<td>2,676</td>
<td>15,698</td>
<td>183,809</td>
</tr>
</tbody>
</table>

Of the 15,698 medical device manufacturers in China in 2013:

- 17% engaged in Class III medical devices;
- 56% engages in Class II medical devices;
- 27% engages in Class I medical devices.

The data shows that the number of medical device manufacturers engaged in Class III medical devices is relatively small, and innovation capability needs to be improved.

China’s medical device industry is concentrated in eastern and southern coastal regions. Many foreign companies have established manufacturing bases in the Yangtze River Delta (Shanghai, and Jiangsu province) and Bohai Rim (Beijing and Tianjin). In terms of medical device products, the Yangtze River Delta has a cluster of companies that produce disposable syringes and infusion sets. Computerized Tomography (CT) machines are mainly manufactured in Beijing by companies such as GE. Philips established a JV with Neusoft Medical System, Philips Neusoft Medical Equipment System in 2004. This JV mainly manufactures CT, MRI, X-Ray and ultrasonic machines. In 2013, it was announced that Neusoft would purchase 25% of Philips equity in the JV. Shenzhen has become an important city for high-end medical devices over the last decade, with rapid developments of devices in medical imaging, blood analysers, and patient monitors.

2.4.2. Foreign Branded Medical Devices

Foreign branded medical devices account for the majority of the mid-high-end medical devices sold in China. The value of imported mid-high-end medical devices accounts for 40% of the total import value. It is estimated that 80% of the CT market in China, 90% of the ultrasound equipment market, 85% of diagnostic equipment market, 90% of magnetic resonance equipment, 90% of Electrocardiogram (ECG) market, 80% of high-end monitor market, 90% of high-grade recordings instrument market and 60% of Polysomnogram (PSG) market are dominated by foreign brands.

41 http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml
42 http://www.jobcn.com/cozone/38/20/382007/page
The Enterprise Observer, a Chinese newspaper, reported that over 70% of the high-end medical device market has been dominated by GE, Philips and Siemens in recent decades.\(^{45}\)

2.4.3. Sales Channels of China’s Medical Device Market in 2014

There are three major traditional channels for selling medical devices in China - hospitals, pharmacies and medical device shops. The online sales of medical devices in China is regarded as innovative and is becoming an increasingly popular channel for distribution. According to CFDA’s website, there are 296 online pharmacies registered, which are eligible to sell medical devices.\(^{46}\) China’s traditional brick-and-mortar retail stores are facing increasing competition from online stores, not only for Fast Moving Consumer Goods (FMCGs) but also for medical devices.

The medical device market was worth CNY 255.6 billion in 2014 (EUR 36 billion), hospitals accounted for CNY 194.4 billion (approx. EUR 27.3 billion) or 76% of sales, and retail sales channel accounted for CNY 61.2 billion (approx. EUR 8.6 billion) or 24%. In the retail sales channel, physical stores accounted for CNY 45.4 billion (EUR 6.3 billion) or 74% of total sales in the channel. E-commerce sales accounted for CNY 15.8 billion (EUR 2.2 billion) or 26% of total sales in the retail sales channels.\(^{47}\)

According to statistics released by the Medical Mall of T-mall\(^{48}\), on the 11th November 2014 (‘Single’s Day’ or Chinese E-consumers’ day),\(^{49}\) the top 10 medical E-shops achieved sales of over CNY 130 million (approx. EUR 18.3 million).\(^{50}\)

According to a survey by Taobao, one of China’s largest business to consumer e-commerce platforms, in 2014 its annual revenue in the medical device market was CNY 7.5-8 billion (approx. EUR 1.0-1.1 billion), which accounted for half of the e-commerce market of medical devices in China.\(^{51}\)

Yu Yue (‘Yuwell’) achieved an online sales revenue of CNY 200 million (EUR 28.1 million) in 2014, while its online sales revenue was CNY 30 million (EUR 4.2 million) in 2013, showing rapid growth. Other medical device brands such as Omron, Johnson & Johnson and Roche have set up independent e-commerce departments and established sales channels in the e-commerce market.

According to Beijing Business Today, an industry and commerce newspaper, the number of hearing aids sold online reached 200,000 in 2014, accounting for 20% of total hearing aid sales in China.\(^{52}\) The Aviation Industry Corporation of China (AVIC) /Jiangsu Jianghang Medical Instrument sold 160,000 oxygen machines online in 2014, accounting for 40% of all of its oxygen machine sales.

---


\(^{47}\) http://yao.tmall.com/.

\(^{48}\) http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml.

\(^{49}\) Singles day is the largest online shopping day in China. E-commerce platforms offer discounts to customers.

\(^{50}\) http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml.

\(^{51}\) http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml.

2.5. Buyer Segmentation & Consumption Trends

According to the National Health and Family Planning Commission (NHFPC), as of the end of November 2014, there were 984,926 medical and health organisations in China including:

- 25,509 hospitals;
- 36,937 township health centres;
- 34,339 community health service centres;
- 189,590 clinics;
- 649,121 village clinics;
- 3,491 centres for disease control and prevention;
- 3,089 health monitoring institutions.\(^{53}\)

There are approximately 7 million healthcare workers in China, including almost 3 million practising doctors and assistant doctors, and almost 3 million registered nurses.\(^ {54}\)

Medical and health institutions in China have over 6 million inpatients beds, of which 4.5 beds are located in hospitals and 1.1 million are located in township health centres.\(^ {55}\)

By the end of 2014, there were 38,000 healthcare institutions with over 5.9 million beds. 34,000 of these were elderly-care organisations with 5.5 million beds, accommodating 3 million people. It must be noted that some regions in China suffer a shortage of beds.\(^ {56}\)

At the end of 2014, a minimum living allowance was granted to over 19 million urban residents and 52 million rural residents; roughly 5 million rural residents received support from the ‘Five-Guarantees’ programme, which include medical care along with proper food, clothing, housing and funeral expenses for residents.\(^ {57}\)

2.5.1. Hospital Classification

Hospitals in China are categorised according to a three-tier system that distinguishes hospitals due to their ability to provide medical care, medical education, and conduct medical research. Hospitals are therefore categorised into:

- First-grade hospitals (Class 1)
- Second-grade hospitals (Class 2)
- Third-grade hospitals (Class 3)

Class 3 hospitals are regarded the best whilst Class 1 are regarded as having the lowest capabilities. According to the National Health & Family Planning Commission (NHFPC), there were 1,898 Class 3 hospitals as of the end of November 2014, 6,807 Class 2 hospitals and 6,853 Class 1 hospitals. There were also 9,951 Chinese hospitals that were not graded.

When Class 3 hospitals purchase medical devices (especially large medical devices), they typically consider quality to be the most important factor – price and customer service are secondary considerations. Class 3 hospitals tend to have the best equipment/medical devices while clinics and community care medical institutions tend to have the most basic equipment/medical devices.

\(^{53}\) http://www.nhfpc.gov.cn/mohwsbwstjxzzx/s7967/201501/1e39cfd2159d426c8e46e29280dbd7f9.shtml

\(^{54}\) http://www.stats.gov.cn/tjsj/zxfb/201502/t20150226_685799.html

\(^{55}\) http://www.stats.gov.cn/tjsj/zxfb/201502/t20150226_685799.html

\(^{56}\) http://www.stats.gov.cn/tjsj/zxfb/201502/t20150226_685799.html

\(^{57}\) http://www.stats.gov.cn/tjsj/zxfb/201502
Table 5: Medical and Health Organisations by November 2013 and November 2014

<table>
<thead>
<tr>
<th>Healthcare Institutions in Total</th>
<th>End of November 2013</th>
<th>End of November 2014</th>
<th>Difference (+/-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>961,958</td>
<td>984,926</td>
<td>22,968</td>
</tr>
<tr>
<td>Hospitals by type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public Hospitals</td>
<td>24,470</td>
<td>25,509</td>
<td>+1,039</td>
</tr>
<tr>
<td>Private Hospitals</td>
<td>11,029</td>
<td>12,166</td>
<td>+1,137</td>
</tr>
<tr>
<td>By the hospital grade:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Third-grade Hospitals</td>
<td>13,441</td>
<td>13,343</td>
<td>-98</td>
</tr>
<tr>
<td>Second-grade Hospitals</td>
<td>11,029</td>
<td>12,166</td>
<td>+1,137</td>
</tr>
<tr>
<td>First-grade Hospitals</td>
<td>6,385</td>
<td>6,853</td>
<td>+468</td>
</tr>
<tr>
<td>Hospitals without grades</td>
<td>9,655</td>
<td>9,951</td>
<td>+296</td>
</tr>
<tr>
<td>Healthcare Institutions at Grass-root Level, by type:</td>
<td>922,630</td>
<td>92,2257</td>
<td>-373</td>
</tr>
<tr>
<td>Community Health Service Centres</td>
<td>34,007</td>
<td>34,339</td>
<td>+332</td>
</tr>
<tr>
<td>Government-run</td>
<td>19,746</td>
<td>18,579</td>
<td>-1,167</td>
</tr>
<tr>
<td>Township Health Centres</td>
<td>6,692</td>
<td>6,807</td>
<td>+115</td>
</tr>
<tr>
<td>Government-run</td>
<td>6,385</td>
<td>6,853</td>
<td>+468</td>
</tr>
<tr>
<td>Clinics</td>
<td>6,655</td>
<td>9,951</td>
<td>+296</td>
</tr>
<tr>
<td>Village Clinics</td>
<td>9,655</td>
<td>9,951</td>
<td>+296</td>
</tr>
<tr>
<td>Specialised Public Health Institutions, by type:</td>
<td>12,456</td>
<td>33,997</td>
<td>21,541</td>
</tr>
<tr>
<td>Centres for Disease Control and Prevention</td>
<td>3,523</td>
<td>3,491</td>
<td>-32</td>
</tr>
<tr>
<td>Maternity and Child Care Institutions</td>
<td>3,060</td>
<td>3,131</td>
<td>+71</td>
</tr>
<tr>
<td>Specialised Prevention &amp; Treatment Centres</td>
<td>1,278</td>
<td>1,257</td>
<td>-21</td>
</tr>
<tr>
<td>Health Monitoring Centres</td>
<td>3,227</td>
<td>3,089</td>
<td>-138</td>
</tr>
<tr>
<td>Other Institutions</td>
<td>2,402</td>
<td>3,163</td>
<td>+761</td>
</tr>
</tbody>
</table>

Furthermore, Class 3 hospitals primarily consider whether the medical device is able to:

- Meet the surgical needs of the hospital;
- Provide reliable data;
- Deliver accurate diagnostic results and provide precise treatments.

Foreign branded medical devices have proved reliable and brands are often well-known in the medical device and healthcare industry. The public image of a hospital is often enhanced when it owns imported medical devices. In addition, feedback from doctors suggests that foreign branded medical devices are more user-friendly. 58

Some doctors are also under the impression that foreign branded medical devices are better than domestically produced brands. Since public hospitals are funded by the Chinese government, they are often able to invest in equipment that some new private hospitals might not be able to afford.

Figure 2: Demand and Supply in Hospitals

Figure 2 above shows that most medical resources (doctors and high end equipment) were located in major hospitals while primary hospitals lacked medical resources where they needed it most.59

Please see the Annex IV for detailed information on the NHFPC approved purchase of large scale medical equipment.

For Class 2 and Class 1 hospitals, government funding may not be as high as for Class 3 hospitals; therefore they are more practical when choosing medical devices. For medical devices that are not available by a Chinese brand, yet vital for the hospital, they often have no choice but to purchase imported medical devices. For medical devices that are available from Chinese companies, in most cases Class 2 and 1 hospitals will choose this option as it is cheaper than imported medical devices. Gradually perceptions are changing and for some Chinese made medical devices are seen as good as imported ones, so hospitals are becoming rational in their choices.

Clinics and community level or county level medical institutions provide a basic level of medical care, and hence use basic medical devices, which are primarily manufactured by local companies.

2.6. Supply Chain Structure

The following chart illustrates how medical devices are distributed from manufacturers/suppliers to consumers. The supply chain of medical devices generally follows the four steps as shown below. Most Chinese manufacturers and larger foreign players have

their own sales department for the distribution of their products or they have direct sales online shops. They also license provincial level or regional level agents.

Of the three traditional sales channels (hospitals, pharmacies and medical device shops), hospitals take the largest share, especially for large and high-value medical devices. While online medical shops have become a popular and important channel for low-value and home use medical devices.

In addition to online medical device shops, a number physical shops and pharmacies (especially those located to well-known/large hospitals) are also important channels for small and mid-low value medical devices.

Figure 3: Distribution Structure

2.7. Market Outlook & Forecasts

According to the China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE), it is estimated that in 2015, the market size of China’s medical device sector will reach CNY 300 billion (EUR 42.2 billion). According to research conducted by Espicom Business Intelligence, a publisher of reports associated to the pharmaceutical and medical device industry, China is expected to see its medical device industry grow on average by over 15% per annum in CNY terms and in terms of USD it will see a Compound Annual growth Rate (CAGR) of over 15%, until 2018.

2.7.1. Maintain High Growth

The medical device industry is connected to several other sectors such as ICT, and is expanding and absorbing other areas of the medical sector. With China’s health reforms, a growing ageing population, and improving living standards, consumer habits are changing and are forecasted

---

61 http://www.researchandmarkets.com/research/r4rr64/the_medical.
to drive further growth in the medical device industry. Compared with developed countries, the space for growth in China’s medical device sector is significant.

2.7.2. Increased Competition

With an increasingly concentrated medical device sector, the market is becoming more competitive – especially between imported foreign brands and domestic brands. New regulations are also being enforced to oversee the conduct and central bidding practices associated with medical devices.

2.7.3. Higher Market Share of Domestic Medical Devices

The Chinese government has issued a number of preferential policies to improve the share of Chinese domestically made medical devices in the market. It has set up funds for improving R&D capabilities of Chinese medical device manufacturers, approved channels for innovative medical device registration, given priority to Chinese branded medical devices during hospital bidding processes, and legislated that public hospitals should prioritise domestic brands (the government has provided a recommended list of domestic medical device suppliers for this purpose). The term ‘domestically made’ does not refer exclusively to products that are manufactured in China, but also to products whose raw materials were sourced from China and JV products where the higher proportion of shares is owned by a Chinese investor(s). These measures are being used to stimulate demand for domestically made medical devices.

2.7.4. Price Reductions for High-Value Consumables

10 provinces and municipalities conduct central bidding for high value consumables. Thus, the government has confirmed that it aims to reduce the price of costly medical devices and other related consumables. 62

2.7.5. Online Sales

For many medical devices that are used at home, online sales have increased rapidly and further sales growth through e-commerce platforms are expected in 2015. E-commerce platforms such as T-mall, JD.com and Kang Fu Zhi Jia are some of the most important sales channels for Chinese home use medical device consumers.

2.7.6. Rise of Chinese Manufacturers

Historically, Chinese medical device manufacturers have been at the bottom of the value chain. This has been the case for several reasons, including low R&D capabilities and the absence of medical device start-ups.

However, in recent years, a number of Chinese medical device companies have moved up the value chain. For mid-low-end medical devices, domestically-made equipment such as monitors and low-end ultrasound and diagnostic devices are not substandard to imported counterparts. Furthermore, the prices of locally produced medical devices are often far more competitive than imported devices (sometimes up to half the price) increasing their competitiveness.63

62 http://www.askci.com/chanye/2015/01/31/111749rsn6_all.shtml
63 http://finance.ifeng.com/a/20140624/12598926_0.shtml
3. Case Study

3.1. Case Study I: Timesco UK

Timesco\textsuperscript{64} specialises in producing laryngoscopic products in the UK, and has over 50 years’ experience within the UK market. Timesco has supplied several products to the UK National Health Service (NHS) system. Timesco entered the Chinese market and has experienced high growth rates.

<table>
<thead>
<tr>
<th>Type of business</th>
<th>Manufacturing and supplying medical products in the UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation History in China</td>
<td>Operating in Chinese market over 8 years</td>
</tr>
<tr>
<td>Company Size</td>
<td>30 employees</td>
</tr>
<tr>
<td>Target Market</td>
<td>China market; specialists in anaesthesia equipment, podiatry equipment and primary care equipment</td>
</tr>
</tbody>
</table>

Developing Business in China

Timesco is a leading surgical and medical company in the UK; its laryngoscopic products have been sold in the Chinese market for over eight years. Timesco has good working relationships with local partners. In 2014, the CFDA registration certificate for Timesco’s laryngoscopic products expired. Timesco needs to renew this certificate; however, CFDA’s provisions and regulations for medical devices changed in 2014 (Timesco are required to submit additional supplementary information regarding their medical devices).

Obstacles and Difficulties

Mr Ismail Fayyaz, CEO of Timesco, described some of Timesco’s concerns with the new CFDA regulations for medical devices in China during his interview. According to Mr Fayyaz

1. Costs have increased: It is now more expensive to renew CFDA certificates and Timesco is required to spend much more than it did when it originally applied for medical device certification. Timesco is worried that it might not be able to afford this application fee, if its sales in China are low.

2. Longer registration processing times: Renewing registration now takes longer due to the new regulations. Without this approval, however, Timesco’s products are illegal to sell in China. Timesco is concerned that this lengthy registration process might stall its sales in China; this is risky for an SME.

3. Accuracy of information: Mr Fayyaz is concerned that Timesco may not have received completely accurate information, which might affect how accurately the company is able to apply for its new registration. It is common to receive two or three different responses from local partners and government departments on the same issue; this makes rules and regulations appear very opaque and difficult to navigate.

Solutions

Mr Fayyaz is still optimistic about Timesco’s opportunities in China. It is normal to encounter changing regulations as the central government attempts to ‘standardise’ the market. Timesco has decided to come to China regularly to attend trade fairs, to meet market insiders and to

\textsuperscript{64} http://www.timesco-uk.co.uk/.

© 2015 EU SME Centre
discuss market developments with its local partners. According to Mr Fayyaz, this enables Timesco to keep up to date with regulation changes and market updates.

3.2. Case Study II: Beijing Yes Medical Devices Co Ltd

Beijing Yes Medical Devices Co Ltd\(^6\) (henceforth referred to as ‘Beijing Yes’) is a medical device company that specialises in the development of biomedical, gynaecological and obstetrics equipment. It focuses on developing high quality medical devices to sell to the Chinese market.

Mr Zhang Song, CEO of Beijing Yes, an Associate Professor at the College of Bioscience and Biomedical Engineering at Beijing University of Technology, has been engaged in developing biomedical technology for over 30 years.

<table>
<thead>
<tr>
<th>Type of Business</th>
<th>Distributing and manufacturing medical devices in China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation History in China</td>
<td>Operating in the Chinese market over 20 years</td>
</tr>
<tr>
<td>Company Size</td>
<td>50 + employees</td>
</tr>
<tr>
<td>Target Market</td>
<td>China market; specialises in maternity and child medical care</td>
</tr>
</tbody>
</table>

Developing Business in China

Beijing Yes currently focuses on distributing and manufacturing medical devices for use on maternity and prenatal wards. Beijing Yes cooperates with several well-known UK universities, which develop medical technologies for the commercial market.

Business Opportunities in China

When interviewed on potential business opportunities in China, Mr Zhang said that opportunities are huge for foreign enterprises that have products that are new to the Chinese market. For companies selling products/technology already on sale in China, Mr Zhang noted that China tends to look abroad for leading technology. Thus, high quality products tend to attract more attention from China than lower quality products that they can easily source in the domestic market, according to Mr Zhang.

Finding a good JV partner is the best way to access the Chinese market believes Mr Zhang. It is therefore advisable to attend local trade fairs and seminars that aim to provide foreign companies with information about Chinese registration and market rules.

Difficulties Entering the Chinese Market

Mr Zhang described his experience with foreign companies entering China. He noted one issue that foreign companies often face is a poor understanding of the Chinese health system and regulations. As such, many companies tend to formulate their business strategies in China according to their previous experiences in other countries. This regularly results in over-estimation or under-estimation of sales figures and a poor market entry experience, according to Mr Zhang.

The Chinese medical device market (as with the majority of Chinese markets) is ‘stamped’ with Chinese characteristics, such as government regulations, intricate market rules, and cultural nuances. As such, many strategies that work in Europe or the US do not succeed in China.

Moreover, many firms underestimate the time required for investment in China, according to Mr Zhang. Many companies believe that when investing in China they are likely to see high profits within three to five years. Investing in the Chinese market requires a significant amount of time says Mr Zhang; it takes a lot of preparation to be able to take advantage of Chinese opportunities successfully, and a significant period of time to establish lucrative working partnerships.

When interviewed, Mr Zhang shared an example of a European company setting up a business in China. He explained he was approached by an agent representing the product of a European company, Beijing Yes agreed to partner with the European company and to treat the product as its own. However, Mr Zhang advised the European company that it should invest more time in understanding Chinese culture and the Chinese business environment. He also suggested that the European company should establish strong brand awareness in China from the outset, so that its product gained popularity and recognition. However, because the European company was a small firm and the product it was promoting was new, the company needed to recover its cost quickly. As a result, the company did not heed Mr Zhang’s advice, and the product was not as successful in China as the company had hoped.

**Obstacles to Operating in China’s Business Environment**

Mr Zhang believes it is very important to seek local partners; a reliable local partner can assist companies entering China navigate through the local business environment. A good local partner should have well-established distribution channels, industrial connections and a good relationship with market insiders and the CFDA. He further emphasises that before cooperating, either JV or partner companies should clarify all relevant details and come to a mutually beneficial agreement.

Some foreign companies simply regard their Chinese partner as a useful sales channel, and rarely communicate with them when business is going well in China. This becomes problematic, according to Mr Zhang, when regulations change and revenues decrease for reasons that the foreign partner is not aware of. As a result, frequent communication with Chinese partners is strongly advised.

**Recommendations**

Mr Zhang recommends that:

- Foreign firms coming to China should talk regularly with their local partner;
- Foreign companies entering China should attend professional trade fairs, forums and understand the health care and medical environment in China in more depth;
- If an organisation creates a device and files the appropriate paperwork for IP registration, it could sell the IP; he therefore stated IP protection is strongly advised.

Mr Zhang further stated that Chinese medical device manufacturing companies are willing to spend money on purchasing imported technologies and manufacturing innovative devices in China.

**3.3. Case Study III: Beijing Kinghawk Pharmaceutical**

Beijing Kinghawk Pharmaceutical (henceforth referred to as ‘Kinghawk’)\(^6\) was founded in 1993 and is located in the state level development zone - Beijing Economic and Technological

Kinghawk focuses on bio-technology and product development. Its product lines are divided into six categories: elisa, blood grouping, fluorescence quantitative polymerase chain reaction, colloidal gold rapid rest, reference material/controls and biochemical diagnostic reagent. It has developed 150 In Vitro Diagnostic (IVD) products covering all six of their product lines.

<table>
<thead>
<tr>
<th>Type of Business</th>
<th>Chinese manufacturers of IVD products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation History in China</td>
<td>22 years</td>
</tr>
<tr>
<td>Company Size</td>
<td>N/A</td>
</tr>
<tr>
<td>Target Market</td>
<td>IVD China market, especially in elisa, blood grouping, fluorescence quantitative polymerase chain reaction, colloidal and clinical chemistry.</td>
</tr>
</tbody>
</table>

**Opportunities**

Mr Zhang Chao, Marketing Manager from Kinghawk maintains that China’s health reform, especially for grass roots level medical institutions, mainly in rural areas, will boost the medical device industry in China. More growth space in rural areas will contribute to the rapid growth of the industry, especially for middle to low end medical devices.

Mr Zhang also thinks that for foreign SMEs that have strong R&D capabilities, there are opportunities to collaborate with local medical device companies that want to upgrade their technology, and expand their share in the market.

**Obstacles and Difficulties**

Competition from Chinese medical device manufacturers will be an important obstacle. As some Chinese manufacturers are paying greater attention to R&D, they are moving up the value chain in providing high-quality and cost effective medical devices. Imported medical devices are not as competitive as domestically made devices, considering Chinese made medical devices have a lower price, often the same quality, and provide more convenient after sales services.

Another potential obstacle, according to Mr Zhang, is that the Chinese government has been promoting Chinese branded medical devices in hospitals and medical institutions. This is to encourage the use of Chinese branded medical devices, especially for high-end medical devices. Although the policy is not compulsory, it is a meaningful policy of guidance and will have an effect on buying decisions.

**Advice**

Mr Zhang advises newcomers to the market to be prepared. He emphasises the importance to research the latest regulations on medical devices, understand the criteria and procedures for medical device registration, clinical trials or other processes that are required.

Visiting the market regularly, attending industry expos and events, and talking to industry experts before trying to conduct any business is advisable.
Mr Zhang suggests to prepare a Chinese language version of the company’s profile, product catalogue and other marketing materials. Minimising the language barrier is an important and efficient way to communicate with potential clients or partners and show respect and knowledge of China’s business culture.

Forming partnerships with Chinese partners is an effective way to minimise risks, which include identifying distributors for products as well as in the long-term to form partnerships and JVs. According to Mr Zhang, some Chinese medical device companies are in need of the latest technologies, EU SMEs could consider forming partnerships with them. He further noted that before considering partnering with them, it is important to conduct due diligence checks on potential partners, and research the latest Chinese regulations on medical devices and policies.

Forming a JV in China, and making the product locally ultimately results in the product becoming domestically made, which greatly reduces the barriers and difficulties that imported products face.
4. Opportunities and Challenges

4.1. Opportunities

China’s GDP growth rate reached 7.4% in 2014.\(^68\) Although this signified a slow-down on the previous year’s growth rate, China still presents opportunities for EU SMEs. Pharmalive Consulting Company\(^69\) predicts that in 2050, China will possess a 25% share of the world’s medical market. Like many markets in China, healthcare products and services sectors have seen explosive growth in recent years; this is expected to increase as the Chinese government increases expenditure in the sector and as awareness of healthcare issues increases.

Underlying market growth is typically attributed to China’s Healthcare reform, an ageing population, increasing rates of chronic diseases and increases in wealth.

4.1.1. China’s Healthcare Reform and Its Relevance

In 2009, the Chinese government announced an investment of CNY 850 billion (EUR 119.7 billion) in healthcare reforms. These reforms aimed to extend basic healthcare insurance coverage to 90% of the population by 2012, and to achieve universal coverage by 2020.\(^70\)

By the end of 2014, 341 million people participated in urban basic pension programmes for staff and workers – an increase of almost 19 million from 2013 – and just over 597 million people participated in basic health insurance programmes – an increase of around 27 million.\(^71\)

In 2010, the central government unveiled a long-awaited policy to allow private investment in hospitals, which was previously forbidden. This signified the dawning of investment opportunities in hospitals and services, and the opening-up of a lucrative, yet largely untouched segment of the Chinese healthcare industry.\(^72\)

Caixin news agency recently reported that China will provide policy support to encourage private health insurance investment, which will relieve its overburdened healthcare sector. While official policy guidelines for the accelerated development of private health insurance were developed in late 2014, these guidelines were officially confirmed only in April 2015.\(^73\)-\(^74\)

4.1.2. Hospital Equipment Procurement and Primary Hospital Construction

According to some programmes from new healthcare reforms, the Ministry of Health in conjunction with the National Development and Reform Commission (NDRC) will invest CNY 100 billion (EUR 14 billion) to support the construction of 2,000 county hospitals, 5,000 health centres and 2,400 community health centres. Basic medical services are to play a vital role in the diagnosis and treatment of common diseases.\(^75\)

China’s healthcare industry presents numerous opportunities for foreign firms:

\(^68\) http://www.stats.gov.cn/tjsj/zxfb/201504/t20150416_713042.html
\(^70\) http://www.gov.cn/zwgk/2009-04/07/content_1279256.htm
\(^71\) http://www.stats.gov.cn/tjsj/zxfb/201502/t20150226_685799.html
\(^72\) http://www.gov.cn/zwgk/2010-05/13/content_1605218.htm
\(^73\) http://www.gov.cn/zhenge/content/2014-11/17/content_9210.htm
\(^74\) http://www.zhb.gov.cn/zblj/rddl/gwy/wj/201505/20150511_301364.htm
- **New Facilities:** Numerous new health care facilities, including hospitals and community health centres are being built across the country, which is stimulating demand for medical devices.

- **Facility Upgrade:** In addition to building new healthcare facilities, the government is also upgrading medical devices in urban hospitals and purchasing essential medical equipment for rural hospitals.

- **Evolving Business Climate:** Continued reforms will present new opportunities and challenges for foreign firms within the industry.

- **An Ageing Population:** In the 1980s 5% of China’s population were aged 65 and over; by 2010 this had reached 9%. China’s ageing population will increase rapidly until 2030. From 2010 to 2030, the growth of the population over 50 years old will be faster than the growth of teenagers in China.  

Figure 4: *Age Structure of the Chinese Population, 2010 vs 2030 (unit: millions)*

By 2050, China’s ageing population will match that of many of today’s developed countries, and is set to exceed that of countries including Denmark, New Zealand, Australia and the US. As the 2011-12 wave of the China Health of Retirement Longitudinal Study noted that disability in Chinese people aged 60 years and older is substantial: 38% of participants in the report claimed to have difficulties with daily living, and 24% stated they required assistance with daily activities. The Global Burden of Disease Study claimed that the chronic pain and depression were two causes of disability.  

---

China’s vast population, the rapid growth of China’s elderly population, and rising cases of chronic diseases among elderly citizens provide business opportunities for the medical device market.

### 4.1.3. General Population and Income Data

By the end of 2014, China’s population had reached 1.36 billion; an increase of 7.1 million compared to 2013. In 2014, the urban population of China totalled around 749 million, which accounted for 54.8% of the overall population; a year on year increase of 1.1%.

According to data released by the National Bureau of Statistics of China (NBSC), per capita disposal income for urban dwellers rose 9.0% year on year to CNY 28,800 (EUR 4,056), and the figure for rural residents rose by 11.2% to CNY 10,490 (EUR 1,477).

### 4.1.4. Household Medical Equipment and Health Care Products

The medical device industry in China is maturing, due to China’s aging population, improvements in living standards and rising incomes. With improved health awareness, China’s focus is likely to move from medical treatment to prevention. Home medical equipment and health care products, are forecast to provide significant business opportunities for medical device brands and thus EU SMEs.

As consumption grows and the aging population increases in China, home massage equipment, become popular purchases. As a matter of fact, blood pressure testing machines and blood glucose meter are popular medical devices available for sale in retail channels in China. In this specific market area, at present, Chinese companies occupy a 15-20% stake of the Over-the-Counter (OCT) blood glucose meter market, with Sinocare being the most prominent domestic producer (foreign brands occupy a large share of the hospital market due to the high accuracy of their glucose meter paper).

As more Chinese consumers pay attention to health management, home health devices provide a relatively untapped market for the medical device industry.

Wearable medical/healthcare devices, are also growing in popularity and may present opportunities for EU SMEs. In 2015, China’s wearable devices market is expected to be worth EUR 380 million with the further development of devices. As foreign companies have more advanced technology, this may provide opportunities for companies.

### 4.1.5. Online Shopping

Although China’s e-commerce platforms are increasing in popularity for the purchase of home use medical devices, opportunities present in this retail channel should be considered a long-term plan as it will require a deep understanding of the market, financial investment and a reliable local partner.

### 4.1.6. Advanced Technology Cooperation

China’s ‘Made in China 2025’ strategy will span the whole manufacturing industry, applying advanced ideas, not only from Germany, but also from the US and Britain, among many other Western countries. Since the Chinese Government intends to strengthen cooperation between
domestic and foreign companies in healthcare-related areas, many Chinese companies may seek partners. Advanced technology cooperation is a promising way to conduct business in China, with a view for long-term development.

4.2. Challenges

Even though the Chinese medical device market provides huge potential for EU SMEs, overseas medical device enterprises have typically dominated 70% of the high-end device market. Thus, Chinese local governments are focusing on stimulating local enterprises and innovating new technologies so that Chinese SME’s can compete in this market.

4.2.1. Regulatory Barriers

The ‘Made in China 2025’ strategy proposed in this year's government work report plans to empower the manufacturing sector, while boosting innovation in China. It hopes that this will help the country achieve a medium-high level of economic growth. So far, ten manufacturing sectors have been given priority, including the medical devices sector.

4.2.2. Legal Barriers

The radical changes in regulations on medical devices, especially those outlined in the latest document known as ‘Measures for the Administration of Medical Device Registration’, which were implemented as of 1st October 2014, and are likely to create significant challenges and opportunities for overseas multinational medical device manufacturers.

Medical devices, are required to pass CFDA certification in China before a company is fully registered. Acquiring the CFDA certification can take up to one year, including clinical trials. Even if the product itself has already been sold in China, it may still require clinical trials if it has not been approved in China.

Registration certificates for imported medical devices have to be issued by China’s national level CFDA, regardless of their classification. Local medical device manufacturers can apply to register their devices at the CFDA’s municipal, provincial and national levels.

4.2.3. Market Barriers

According to ‘The Report of Chinese Medical Devices Trade in the First Half of 2014’ issued by the China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE), China’s recent dependence on imported medical devices has been worrying. However, the monopoly on medical devices by importers is expected to change in favour of the domestic medical device market. China’s President Xi Jinping visited Shanghai United Imaging Co Ltd in May 2014, and observed that some communities are unable to afford high-end medical equipment. He subsequently decided to accelerate the process of localisation in the high-end medical device market, to reduce costs, and to promote the continuous development of national brands. This development is hoped to stimulate the high-end domestic medical device market in the future.

At present, most Chinese hospitals have little or no awareness of western SME brands as the high-end medical device market has been dominated by large foreign players such as GE and

Siemens. Therefore, for EU SMEs entering the Chinese market, it is advisable to spend time and money on marketing. Marketing might either target the ‘academic’ market (marketing doctors and medical practitioners), or the commercial market (targeting retail distribution channels and end-users).

Language can also be a significant barrier to growth. English is not widely used in China, so translation is often required when marketing technical products, software and training materials.

4.3. Hospital Operations & Procurement Processes for Medical Devices

For large medical equipment acquisitions, open bidding is the most common method for procuring and testing medical devices. Many hospitals’ methods of procuring products tend to be via centralised online purchasing agents in accordance with relevant national or regional regulations.

Within a hospital, procurement processes typically follow this process:

- Directors in relevant departments make their purchase plans based on the needs of their department;
- Directors submit their plan(s) to hospital leaders for approval;
- After obtaining approval, plan(s) can go ahead and purchases are made.

According to interviews conducted with industry insiders, many hospitals have a specific procurement team that is responsible for procurement processes. For medical equipment valued under certain amount (dependent on the hospitals limits) some hospitals and clinics can submit an application and gain approval from the head of the equipment sector. For equipment valued over a certain limit an application should be submitted at the end of each year, and a bidding process is conducted within the hospital. Some hospitals also require public bidding for certain items.

4.4. Supply Chain Structure for Medical Devices

In China, medical device sales and distribution patterns vary by hospital; this is directly related to their operational scale and customer segmentation. Class 3 hospitals, which serve major cities at a provincial level, are equipped with high-end instruments, whereas Class 2 hospitals, which serve the county level, use more basic equipment. Class 1 hospitals, which are rural and community-based, are equipped with fundamental healthcare facilities and equipment.

Generally the main distribution channels for medical devices in China are via distributors. Regarding publicly-run hospitals that currently dominate China’s healthcare system, these tend to adopt different procurement processes depending on the different medical device-types.
5. Practical Advice on How to Access the Market

Entering the Chinese market is often both exciting and daunting for EU SMEs. SMEs generally have access to fewer resources compared to larger companies, and this increases the complexities and challenges when entering new markets, especially China’s medical device market. EU SMEs should assess the opportunities and challenges and develop informed decisions to identify if and how to enter the market. This section outlines practical advice for EU SMEs to consider when approaching the market.

5.1. Understand the Market

EU SMEs new to the market should conduct research before entering in order to understand the opportunities for their medical devices, identify challenges, competitors and a pricing strategy. SMEs should investigate and understand the specific demands generated by China’s health reforms and corresponding market opportunities. A clear understanding of the ongoing evolution of China’s healthcare regulatory environment will allow EU SMEs to better monitor potential challenges that may arise. As noted by interviewees, understanding China’s healthcare structure and regulations is vitally important.

In order to gain a further understanding of the market, many companies consult experienced support organisations, such as a local chamber of commerce, trade associations, or established consulting firms with local knowledge and proven networks.

The EU SME Centre has published a diagnostic toolkit entitled “Are you ready for China?”, which provides a step-by-step introduction to the Chinese business environment allowing SMEs to gauge their preparedness in conducting business in China. The documents can be downloaded from the Centre’s website at: [http://www.eusmecentre.org.cn/content/diagnostic-kit](http://www.eusmecentre.org.cn/content/diagnostic-kit).

5.2. Find a Local Partner

Newcomers to the Chinese market should choose a reliable partner or consulting company to understand the rules to conduct business in China. Companies conducting business in China must complete a complicated registration process for importing medical devices; this requires a good understanding of the Chinese government’s culture and import policies. Working with a Chinese company to complete these processes shortens the time it takes to register with the CFDA, and can assist EU SMEs devise practical strategies for entering into the market.

5.3. Distribution and Pricing

It is important to seek local partners, as the right local partner can assist by navigating the local business environment. It is important to choose a distribution partner with established distribution channels, industrial connections and good relationships with market insiders and the CFDA. EU SMEs should carefully identify suitable target regions as a starting point and should work with local partners to identify these. SMEs should remain in regular contact with distributions partners, as noted in interviews; this is of the utmost importance, as it not only provides an opportunity to understand the current market environment but also to identify opportunities as well as solutions to potential issues.

5.4. Branding & Pricing

Brand awareness is very important in China; as noted earlier the high-end market is dominated by large foreign companies. It is therefore advisable and efficient to promote a brand through professional seminars and public platforms. For instance, EU SMEs and their local partners could consider attending trade shows in order to attract attention to their products.
EU SMEs should carefully consider working with local partners to develop a pricing strategy and understand if patients can receive reimbursement for their medical devices.

5.5. Intellectual Property (IP) Protection & Due Diligence

Protecting Intellectual Property (IP) is extremely important in China. EU SMEs should work with IP specialists in order to protect their IP in China, especially when working with a local distribution partner. Furthermore, EU SMEs should conduct due diligence on any potential partner to understand their business and financial capabilities.

For further guidance on IPR related issues, the China IPR SME Helpdesk can provide you with free of charge, confidential, business-focused IPR advice. Reach their experts at: http://www.china-iprhelpdesk.eu/
6. Report Summary

### Medical Device Sector in China

| Overview | In 2014, China’s medical device industry was worth EUR 36 billion, a year on year increase of 20%; Europe was the largest exporter of medical devices to China.  
|          | Market structure: Chinese manufacture medical devices in low-mid end of the market, overseas medical device are mid-high-end market.  
|          | Buyer segment: Class 3 hospitals tend to purchase high-end medical devices, Class 1 and Class 2 hospitals end to purchase mid-low end medical devices.  
|          | Outlook and forecast: high growth with more competition. |
| Opportunities | China’s healthcare reforms and its relevance contribute to the demand growth in primary hospital construction and medical device procurement.  
|          | Ageing population: 262 million aged over 65 by 2030.  
|          | Income growth rate: GDP growth rate of 7.4% in 2014.  
|          | Household medical equipment and health care products.  
|          | Retail channel: e-commerce becoming popular, but should be considered as a long-term strategy. |
| Challenges | Regulatory barriers: rules and regulations.  
|          | Legal barriers: CFDA certification and registration.  
|          | Market barriers: hospital operation and procurement processes. |
| Key Success Factors | Medical consultancy/reliable partner.  
|          | Distribution, pricing, branding and IPR protection.  
|          | Understand the market. |
7. Exhibitions

<table>
<thead>
<tr>
<th>Exhibitions</th>
<th>Website</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The 73rd China International Medical Equipment Fair (CMEF Spring 2015)</strong></td>
<td><a href="http://www.cmeef.com.cn/en/index.html">http://www.cmeef.com.cn/en/index.html</a></td>
<td>China International Medicinal Equipment Fair (CMEF), founded in 1979, is held twice a year - spring and autumn. CMEF is the largest exhibition of medical equipment, related products and services in the Asia-Pacific region. The exhibition covers a wide range of products such as medical imaging, in vitro diagnosis, electronics, optics, first aid, rehabilitation nursing, medical information technology and outsourcing services. 15-18th May, 2015 (National Exhibition &amp; Convention, Shanghai) E-mail: <a href="mailto:chuanjun.ding@reedsinopharm.com">chuanjun.ding@reedsinopharm.com</a></td>
</tr>
<tr>
<td><strong>The 16th China (Shanghai) International Medical Devices Exhibition 2015</strong></td>
<td><a href="http://www.expo-medical.com/english/index.asp">http://www.expo-medical.com/english/index.asp</a></td>
<td>The China (Shanghai) International Medical Devices Exhibition covers a total area of over 20,000 m² with more than 1,000 standard booths, creating a global top-level event for medical device industry. It was awarded “China’s Most Valuable Industrial Exhibition for Participants” in 2012. 8-10th July, 2015 (Shanghai World Expo, China) E-mail: <a href="mailto:18930529086@126.com">18930529086@126.com</a></td>
</tr>
<tr>
<td><strong>The 5th China (Tianjin) International Medical Equipment Exhibition</strong></td>
<td><a href="http://www.chinacimee.com/en/">http://www.chinacimee.com/en/</a></td>
<td>It is expected that the exhibition area will reach over 20,000m², and it will exhibit over ten thousand products involving medical imaging, in vitro diagnosis (IVD), electronics, optics, emergency treatment, rehabilitation nursing, medical information technology and outsourcing service, etc. And it is also expected that about 50,000 professional visitors from more than twenty countries and regions will come together to CIMEE for business purchase, negotiations and technology communication. 25-27th June, 2015 (Tianjin Binhai International Convention &amp; Exhibition Center) E-mail: <a href="mailto:cidee@hengxinexpo.com">cidee@hengxinexpo.com</a></td>
</tr>
<tr>
<td><strong>2015 China Rehabilitation Show</strong></td>
<td><a href="http://www.rehabshow.com.cn/q1005.aspx">http://www.rehabshow.com.cn/q1005.aspx</a></td>
<td>The China Rehabilitation Show began in 2013. The aim of the China Rehabilitation Show is to develop the aging industry, and to establish service system for elderly care. The China Rehabilitation had 1,400 exhibitors in 2014. 30th July-1st August (2015 Chengdu Century City New International Convention &amp; Exhibition Centre) E-mail: <a href="mailto:hairong.zheng@reedsinopharm.com">hairong.zheng@reedsinopharm.com</a></td>
</tr>
<tr>
<td><strong>2015 Medtec China/2016 Medtec Source China</strong></td>
<td><a href="http://www.medtecchina.com/">http://www.medtecchina.com/</a></td>
<td>Medtec China has established itself as a leading forum for China’s medical device manufacturing industry. Medtec China is one of the most important medical device shows in China. 22th-24th September 2015 (Shanghai World Expo Exhibition &amp; Convention Centre) 20th -21st April 2016, Shenzhen Convention Centre Email: <a href="mailto:gerry.zhang@ubm.com">gerry.zhang@ubm.com</a></td>
</tr>
</tbody>
</table>
28th China Med International Medical Instrument & Equipment Exhibition
N/A
China Med is a specialised and state-of the-art exhibition where well-known companies can show their latest medical instruments and equipment to the world.

2016, Beijing – please note that dates have not yet been confirmed
China National Convention Centre
Email: cncc@cnccchina.com

China Health Forum
Website: www.chf-bj.org (not accessible)

The China Health Forum is an annual event focusing on health related topics and is held in Beijing in August. The Forum provides a platform to demonstrate the latest development, present research outcomes and international exchange with foreign experts. The event is hosted by the National Health and Family Planning Commission (NHFPC), China Food and Drug Administration (CFDA) and State Administration of Traditional Chinese Medicine (SATCM). The China Health Forum has a sub-event named China HOSPEQ, which is more focused on exhibiting medical devices.

For the 2015 event, the time and location has not yet been announced. It is expected to be announced in mid-June 2015.

Time and Location to be announced in mid-June

China HOSPEQ 2015

China HOSPEQ part of the China Health Forum and focuses on exhibiting medical devices and trading. The event is hosted by the International Communication and Exchange Centre of the National Health and Family Planning Commission, Chinese Hospital Association and China Association of Medical Equipment. The 2015 will be held in Xiamen in Fujian province rather than in Beijing.

20th -22nd August 2015 (Xiamen International Convention and Exhibition Center)
Email: info@chinahospeq.com
### 8. Relevant Associations

<table>
<thead>
<tr>
<th>Relevant Associations</th>
<th>English Website</th>
<th>Chinese Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>China Association for Medical Devices Industry (CAMDI)</td>
<td>[<a href="http://www.camdi.org/en/">http://www.camdi.org/en/</a>]</td>
<td>[<a href="http://camdi.org/index.jsp">http://camdi.org/index.jsp</a>]</td>
</tr>
<tr>
<td>China Medical Pharmaceutical Material Association (CMPMA)</td>
<td></td>
<td>[<a href="http://www.cmpma.cn/">http://www.cmpma.cn/</a>]</td>
</tr>
<tr>
<td>China Association of Medical Equipment (CAME)</td>
<td></td>
<td>[<a href="http://www.came-online.org">www.came-online.org</a>]</td>
</tr>
</tbody>
</table>

### 9. Useful Websites

<table>
<thead>
<tr>
<th>Useful Websites</th>
<th>English Website</th>
<th>Chinese Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>China Medical Device Information Network (CMDI)</td>
<td></td>
<td>[<a href="http://www.cmdi.gov.cn/publish/default/">http://www.cmdi.gov.cn/publish/default/</a>]</td>
</tr>
<tr>
<td>China Food and Drug Administration (CFDA)</td>
<td>[<a href="http://eng.sfda.gov.cn/WS03/CL0755/">http://eng.sfda.gov.cn/WS03/CL0755/</a>]</td>
<td>[<a href="http://www.sfda.gov.cn/WS01/CL0001/">http://www.sfda.gov.cn/WS01/CL0001/</a>]</td>
</tr>
<tr>
<td>The Medical Device Category</td>
<td></td>
<td>[<a href="http://www.sda.gov.cn/gyx02302/flml.htm">http://www.sda.gov.cn/gyx02302/flml.htm</a>]</td>
</tr>
<tr>
<td>The Lancet</td>
<td>[<a href="http://www.thelancet.com/">http://www.thelancet.com/</a>]</td>
<td></td>
</tr>
<tr>
<td>The Bio insight</td>
<td>[<a href="http://news.bioon.com/medicaldevices/">http://news.bioon.com/medicaldevices/</a>]</td>
<td></td>
</tr>
</tbody>
</table>
10. Annex

10.1. Annex I: Terminology

- **Active Medical Devices**: any medical devices that are operated using electric power or other forms of energy, excluding those directly generated by the human body or gravity.\(^9\)

- **Devices for Insertion**: devices that are entirely or partly inserted into the body through the surface of body by surgery. These devices come in contact with tissue, bone, the endodontium/dentinum system, the blood circulation system and the central nervous system, including blood vessels. These do not include reusable medical devices.

- **Reusable Surgical Instruments**: devices that are used to conduct a number of procedures during surgery. These include excision, sawing, clenching, scraping, clipping, drawing and clamping without using active devices. Medical devices defined within this category can be reused after treatments.

- **Implantables**: devices that are entirely or partly inserted into cavities or tracts (including openings) of the human body by surgery, or are used for the replacement of epithelial or ocular surfaces. These devices remain in the body for over 30 days.

- **Human Body Contacting Devices**: devices that directly or indirectly come in contact with the body of a patient or are inserted into the body of a patient.

- **Skin**: refers to a surface of unwounded skin.

- **Cavity** or opening – natural cavities such as the rectum, vagina, oesophagus and permanent artificial openings.

- **Wound**: refers to the violation of a structural integrity or a dysfunction caused by various kinds of injurious factors to the organism.

- **Tissue**: refers to human body tissue, bone and the dental pulp/dental system.

- **Blood Circulation System**: refers to blood vessels (excluding blood capillaries) and the heart.

- **Central Nervous System**: refers to the brain and spinal cord.

- **Stand-alone Software**: software with one or several medical purposes. Stand-alone software does not need to be embedded into any particular hardware medical device, nor does it rely on hardware for certain or specific medical purposes.

---

\(^9\) Following definitions refer to the Article 7 of Provisions for Medical Device Classification (revised draft), please click the word document to view the definitions, [http://www.sda.gov.cn/WS01/CL0779/110264.html](http://www.sda.gov.cn/WS01/CL0779/110264.html).
## 10.2. Annex II: Provisions and Regulations for Medical Devices in China

<table>
<thead>
<tr>
<th>Regulations and Provisions</th>
<th>Brief Intro</th>
<th>Full Context</th>
<th>Release Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special Procedures for Approval of Innovative Medical Devices (Trial)</td>
<td>Defined innovative medical device, application procedure, documents required, evaluation procedures.</td>
<td><a href="http://www.sda.gov.cn/WS01/CL0845/96654.html">http://www.sda.gov.cn/WS01/CL0845/96654.html</a></td>
<td>7th February 2014</td>
</tr>
<tr>
<td>Provision for Supervision and Administration of Medical Device Manufacturing</td>
<td>Pre-conditions for manufacturers to apply for license: technical staff, manufacturing equipment, venue, quality control, management system, after sales service capacity, product formula.</td>
<td><a href="http://app1.sfda.gov.cn/WS01/CL0053/103759.html">http://app1.sfda.gov.cn/WS01/CL0053/103759.html</a></td>
<td>30th July 2014</td>
</tr>
<tr>
<td>Provision for Administration of Registration of In Vitro Diagnostic Reagents</td>
<td>12 chapters with 90 provisions. Given definition of In Vitro Diagnostics and registration and filing process and requirements of applicants.</td>
<td><a href="http://www.sda.gov.cn/WS01/CL0053/103757.html">http://www.sda.gov.cn/WS01/CL0053/103757.html</a></td>
<td>30th July 2014</td>
</tr>
<tr>
<td>Provisions for Medical Device Classification</td>
<td>The newest draft version was released in December 2014 and sought for public opinion by January 2015. It is now under internal evaluation (but no timeline when it will be released).</td>
<td><a href="http://www.sda.gov.cn/WS01/CL0053/24454.html">http://www.sda.gov.cn/WS01/CL0053/24454.html</a></td>
<td>5th April 2000</td>
</tr>
</tbody>
</table>
### Annex III: Key Chinese Players

<table>
<thead>
<tr>
<th>No</th>
<th>Name</th>
<th>Segment</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Shinva</td>
<td>Sterilisers, radiotherapy equipment, digital diagnosis equipment, surgical instruments, disposable syringes, environmental protection equipment for medical use, sterilisation testing products, and pharmaceutical machinery</td>
<td><a href="http://www.shinva.com">http://www.shinva.com</a></td>
</tr>
<tr>
<td>8</td>
<td>Fosun</td>
<td>Therapeutic areas such as metabolism and alimentary tract, the cardiovascular system, oncology and immunomodulation, nervous system and anti-infection</td>
<td><a href="http://www.fosunpharma.com">http://www.fosunpharma.com</a></td>
</tr>
<tr>
<td>9</td>
<td>Andon</td>
<td>OEM for blood pressure monitors</td>
<td><a href="http://www.andonhealth.com/about.htm">http://www.andonhealth.com/about.htm</a></td>
</tr>
<tr>
<td>13</td>
<td>Wei Gao Group</td>
<td>Disposable medical devices: consumables (infusion sets, syringes, medical needles, blood bags, pre-filled syringes, blood sampling products, and other consumables), orthopaedic materials and blood purification consumables and equipment</td>
<td><a href="http://en.weigaogroup.com">http://en.weigaogroup.com</a></td>
</tr>
<tr>
<td>14</td>
<td>Improve Medical</td>
<td>Vacuum blood collection system and clinical immunodiagnostic system: biochemical test reagents, infusion pumps and syringe pumps</td>
<td><a href="http://www.improve-medical.com">www.improve-medical.com</a></td>
</tr>
<tr>
<td>15</td>
<td>ACF Group</td>
<td>Integrated digital operating room solutions provider, offering operating room products (anesthesia machine, ventilator, operating table, surgical lights), decontamination service of operating room, digital integration of operating room</td>
<td><a href="http://www.acfgroup.com">www.acfgroup.com</a></td>
</tr>
<tr>
<td></td>
<td>Company</td>
<td>Products/Services</td>
<td>Website</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>16</td>
<td>Meheco</td>
<td>Import and distribution of overseas medical devices</td>
<td><a href="http://www.meheco.com">www.meheco.com</a></td>
</tr>
<tr>
<td>17</td>
<td>Shanghai Medical Equipment Factory</td>
<td>Medical apparatus and instruments: product portfolio ranges from respiratory ventilator, anesthesia machine, operating tables, operating lamp, oxygen regulator, sphygmomanometers, aneroid sphygmomanometers and medical air compressors</td>
<td><a href="http://www.shmef.com">www.shmef.com</a></td>
</tr>
<tr>
<td>19</td>
<td>Bohui Innovation Optoelectronic</td>
<td>Medical treatment appliance products, such as human element detection systems, Vitamin D detection kits, and infection pathogen detection systems</td>
<td><a href="http://www.bohui-tech.com/en/index.html">www.bohui-tech.com/en/index.html</a></td>
</tr>
<tr>
<td>20</td>
<td>Ningbo David Medical</td>
<td>Infant incubator and baby care device: infant incubator, transport incubator, infant radiant warmer, neonate bilirubin phototherapy equipment</td>
<td><a href="http://www.chinadavid.cn/en/index.php">www.chinadavid.cn/en/index.php</a></td>
</tr>
<tr>
<td>21</td>
<td>Sinocare</td>
<td>Bio-Sensory Technology And Point-Of-Care Testing (POCT) products: blood glucose meters and test paper</td>
<td><a href="http://www.sinocare.com">www.sinocare.com</a></td>
</tr>
<tr>
<td>23</td>
<td>Lifetech</td>
<td>Minimally invasive medical devices for cardiovascular and peripheral vascular diseases and disorders</td>
<td><a href="http://www.lifetechmed.com/en/">www.lifetechmed.com/en/</a></td>
</tr>
<tr>
<td>24</td>
<td>Hokai Medical</td>
<td>Minimally invasive treatment of cancer, medical oxygen equipment and medical gas engineering, medical sanitation engineering, medicine imaging, blood purification, medical information technology and equipment leasing</td>
<td><a href="http://en.hokai.com/">http://en.hokai.com/</a></td>
</tr>
<tr>
<td>28</td>
<td>Kang Hui Medical</td>
<td>Orthopedic devices: trauma, spine, maxillofacial, craniofacial, artificial joints</td>
<td>N/A</td>
</tr>
<tr>
<td>29</td>
<td>Trauson Medical</td>
<td>Orthopaedic products, trauma products, and spine products</td>
<td><a href="http://www.trauson.com/index_e.asp">www.trauson.com/index_e.asp</a></td>
</tr>
<tr>
<td></td>
<td>Company</td>
<td>Products</td>
<td>Website/Link</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>31</td>
<td>Landwind Industry</td>
<td>Medical imaging systems, IVD products, life support products, blood purification products and medical IT products</td>
<td><a href="http://www.landwindmedical.com/">www.landwindmedical.com/</a></td>
</tr>
<tr>
<td>32</td>
<td>Da An Gene</td>
<td>Molecular diagnostics: offers products including qPCR, sequencing, e-DNA reader, and chip products, which covers molecular diagnostic products, cervical cancer screening, immunoassay products, food safety products, and blood collection tubes</td>
<td><a href="http://daan.joomcn.com/">http://daan.joomcn.com/</a></td>
</tr>
<tr>
<td>33</td>
<td>Ke Hua Bio-engineering</td>
<td>medical diagnostic supplies: in vitro diagnostic reagents, medical testing equipment, vacuum blood collection systems</td>
<td>English language website is not available <a href="http://www.skhb.com/home.html">www.skhb.com/home.html</a> (Chinese)</td>
</tr>
<tr>
<td>34</td>
<td>Sunray Medical</td>
<td>Obstetrics and Gynaecology (O&amp;G), with products such as fetal monitor, fetal doppler, patient monitor, Thinprep Cytologic Test (TCT) and consumables</td>
<td><a href="http://www.sunray.cn/En/index.asp">www.sunray.cn/En/index.asp</a></td>
</tr>
<tr>
<td>35</td>
<td>Mingyuan Medicare</td>
<td>Protein chip and gene testing products, operate medical centres</td>
<td><a href="http://www.mingyuan-hk.com">www.mingyuan-hk.com</a></td>
</tr>
<tr>
<td>36</td>
<td>Shandong Pharmaceutical Glass</td>
<td>Pharmaceutical glass manufacturer</td>
<td>English language website is not available <a href="http://www.pharmglass.com/Index.asp">www.pharmglass.com/Index.asp</a> (Chinese)</td>
</tr>
<tr>
<td>37</td>
<td>Golden Meditech</td>
<td>Blood-related medical devices, and medical software, like blood component separation equipment, disposable medical supplies, intelligent gauze, medical device software and medical management software</td>
<td><a href="http://www.goldenmeditech.com/eng/global/home.php">www.goldenmeditech.com/eng/global/home.php</a></td>
</tr>
<tr>
<td>38</td>
<td>Da Heng Medical</td>
<td>radiation therapy products, high frequency X-ray machine, high frequency high voltage generator, mobile C-shaped arms and gastrointestinal machine</td>
<td>English language website is not available <a href="http://www.dahengmedical.com/">www.dahengmedical.com/</a> (Chinese)</td>
</tr>
</tbody>
</table>
### 10.4. Annex IV: PET/CT Equipment Purchase approved by NHFPC in 2015

<table>
<thead>
<tr>
<th>Province/Municipality</th>
<th>No</th>
<th>Organisation</th>
<th>Type</th>
<th>Website (Chinese)</th>
<th>Website (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>Beijing Cancer Hospital</td>
<td>B</td>
<td><a href="http://www.bjcancer.org/">http://www.bjcancer.org/</a></td>
<td><a href="http://www.bjcancer.org/_English/Service.html">http://www.bjcancer.org/_English/Service.html</a></td>
</tr>
<tr>
<td>Inner Mongolia</td>
<td>2</td>
<td>Affiliated Hospital of Inner Mongolia Medical University</td>
<td>B</td>
<td><a href="http://www.nmgfy.com/">http://www.nmgfy.com/</a></td>
<td>N/A</td>
</tr>
<tr>
<td>Liaoning</td>
<td>3</td>
<td>Dalian Municipal Central Hospital Affiliated Of Dalian Medical University</td>
<td>B</td>
<td><a href="http://www.dlzxxy.com/">http://www.dlzxxy.com/</a></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Jinzhou Central Hospital</td>
<td>C</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Shanghai</td>
<td>4</td>
<td>Shanghai Tenth People's Hospital/Tenth People's Hospital Of Tongji University</td>
<td>C</td>
<td><a href="http://www.shdsyy.com.cn/web/index.php?classid=846">http://www.shdsyy.com.cn/web/index.php?classid=846</a></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Shanghai Tenth People's Hospital/Tenth People's Hospital Of Tongji University</td>
<td>C</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Longhua Hospital affiliated to Shanghai University of TCM</td>
<td>B</td>
<td><a href="http://www.longhua.net/">http://www.longhua.net/</a></td>
<td><a href="http://www.longhua.net/project/lh_website_e3_en/index.jsp">http://www.longhua.net/project/lh_website_e3_en/index.jsp</a></td>
</tr>
<tr>
<td>Zhejiang</td>
<td>5</td>
<td>Jiangsu Provincial People's Hospital</td>
<td>A</td>
<td><a href="http://www.jspb.net/">http://www.jspb.net/</a></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Zhejiang Cancer Hospital</td>
<td>A</td>
<td><a href="http://www.zchospital.com/">http://www.zchospital.com/</a></td>
<td>N/A</td>
</tr>
</tbody>
</table>

© 2015 EU SME Centre
<table>
<thead>
<tr>
<th>Region</th>
<th>Province</th>
<th>Hospital Name</th>
<th>Rating</th>
<th>Website</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anhui</td>
<td></td>
<td>Fuyang People's Hospital</td>
<td>C</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Jiangxi</td>
<td></td>
<td>Jiujiang NO.1 People's Hospital</td>
<td>C</td>
<td><a href="http://www.jxjsdrmyy.cn/">http://www.jxjsdrmyy.cn/</a></td>
<td>N/A</td>
</tr>
<tr>
<td>Hunan</td>
<td></td>
<td>Affiliated Hospital of Nanhua Medical University</td>
<td>B</td>
<td><a href="http://www.nhfyy.com/">http://www.nhfyy.com/</a></td>
<td>N/A</td>
</tr>
<tr>
<td>Guangdong</td>
<td></td>
<td>Foshan NO.1 People's Hospital</td>
<td>B</td>
<td><a href="http://www.fshospital.org.cn/">http://www.fshospital.org.cn/</a></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The First People's Hospital of Shunde</td>
<td>C</td>
<td><a href="http://www.sdrmyy.com/">http://www.sdrmyy.com/</a></td>
<td>N/A</td>
</tr>
<tr>
<td>Guangxi</td>
<td></td>
<td>Affiliated Hospital of Guilin Medical College</td>
<td>B</td>
<td><a href="http://hospital.glmc.edu.cn/">http://hospital.glmc.edu.cn/</a></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Panzhihua Central Hospital</td>
<td>C</td>
<td><a href="http://www.zxyy999.com/">http://www.zxyy999.com/</a></td>
<td>N/A</td>
</tr>
<tr>
<td>Shaanxi</td>
<td></td>
<td>Shaanxi Provincial People's Hospital</td>
<td>B</td>
<td><a href="http://www.sph-sx.com/">http://www.sph-sx.com/</a></td>
<td>N/A</td>
</tr>
</tbody>
</table>
10.5. Annex V: Medical Device Classification

<table>
<thead>
<tr>
<th>Passive</th>
<th>Time limit and body part</th>
<th>Forms of usage</th>
<th>Temporary use</th>
<th>Short-term use</th>
<th>Long-term use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin or cavity (apertures)</td>
<td>Wound or tissues</td>
<td>Blood circulation system or central nervous system</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>II *</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>–</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>I</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>I</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>I</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Forms of usage</td>
<td>Use status</td>
<td>Slight injury</td>
<td>Medium injury</td>
<td>Heavy injury</td>
</tr>
<tr>
<td>---</td>
<td>----------------</td>
<td>------------</td>
<td>---------------</td>
<td>---------------</td>
<td>--------------</td>
</tr>
<tr>
<td>7</td>
<td>Contraception and family planning devices (excluding reusable surgical devices)</td>
<td>II</td>
<td>II</td>
<td>III</td>
<td>III</td>
</tr>
<tr>
<td>8</td>
<td>Others</td>
<td>I</td>
<td>II</td>
<td>III</td>
<td>II</td>
</tr>
<tr>
<td>Active</td>
<td>Energy treatment equipment</td>
<td>II</td>
<td>II</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Diagnostic and monitoring equipment</td>
<td>II</td>
<td>II</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Liquid conveying equipment</td>
<td>II</td>
<td>III</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Ionising radiation instruments</td>
<td>II</td>
<td>III</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Active implantable medical devices</td>
<td>III</td>
<td>III</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Other active medical devices</td>
<td>II</td>
<td>II</td>
<td>III</td>
<td></td>
</tr>
</tbody>
</table>
### Non-Human Body Contacting Medical Devices

<table>
<thead>
<tr>
<th>Forms of usage</th>
<th>Influence</th>
<th>Insignificant influence</th>
<th>Indirect influence</th>
<th>Indirect significant influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nursing devices</td>
<td>I</td>
<td>II</td>
<td>–</td>
</tr>
<tr>
<td>2</td>
<td>Disinfection and cleaning equipment for medical devices</td>
<td>–</td>
<td>II</td>
<td>III</td>
</tr>
<tr>
<td>3</td>
<td>Other passive medical devices</td>
<td>I</td>
<td>II</td>
<td>–</td>
</tr>
<tr>
<td>Active</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Checking/testing equipment</td>
<td>I</td>
<td>II</td>
<td>III</td>
</tr>
<tr>
<td>2</td>
<td>Stand-alone software</td>
<td>–</td>
<td>II</td>
<td>III</td>
</tr>
<tr>
<td>3</td>
<td>Disinfection and cleaning equipment for medical devices</td>
<td>I</td>
<td>II</td>
<td>–</td>
</tr>
<tr>
<td>4</td>
<td>Other active medical devices</td>
<td>I</td>
<td>II</td>
<td>III</td>
</tr>
</tbody>
</table>

*Class I = I, Class II=II, Class III=III*
The EU SME Centre helps EU SMEs prepare to do business in China by providing them with a range of information, advice, training and support services. Established in October 2010 and funded by the European Union, the Centre has entered its second phase which will run until July 2018.

The Centre is implemented by a consortium of six partners – the China-Britain Business Council, the Benelux Chamber of Commerce, the China-Italy Chamber of Commerce, the French Chamber of Commerce in China, the EUROCHAMBRES, and the European Union Chamber of Commerce in China. All services are available on the Centre’s website after registration, please visit: www.eusmecentre.org.cn.

This report is compiled in partnership with the China-Britain Business Council (CBBC) and is an introduction to the medical devices market in China. It aims to help EU SMEs gain an understanding of China’s medical devices market and to identify opportunities that EU SME’s could consider exploring.

CBBC is the leading organisation helping UK companies grow and develop their business in China. CBBC delivers a range of practical services, including: advice and consultancy, market research, event management, an overseas market introduction service, trade missions and exhibitions, and setting up rep offices. For more information about what CBBC can do to help your business develop in China, please visit: www.cbbc.org.

Contact the Centre at
Room 910, Sunflower Tower - 37 Maizidian West Street - Chaoyang District - Beijing, 100125
T: +86 10 8527 5300; F: +86 10 8527 5093
www.eusmecentre.org.cn ; info@eusmecentre.org.cn

Disclaimer

This document is provided for general information purposes only and does not constitute legal, investment or other professional advice on any subject matter. Whereas every effort has been made to ensure that the information given in this document is accurate, the EU SME Centre accepts no liability for any errors, omissions or misleading statements, and no warranty is given or responsibility accepted as to the standing of any individual, firm, company or other organisation mentioned. Publication as well as commercial and non-commercial transmission to a third party is prohibited unless prior permission is obtained from the EU SME Centre. The views expressed in this publication do not necessarily reflect the views of the European Commission.

Date: June, 2015.