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# THE CHINESE MEDTECH SECTOR


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# THE CHINESE MEDTECH SECTOR WITH FOCUS ON NEW REGULATORY RULES

**Date: April 30, 2017**

**Language: English**

**Number of pages:** 31

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# 1. Executive Summary

Even though 95 per cent of the population is insured by basic medical insurance, the scheme does not address chronically ill patients who need long term treatment. China spends 5.8 per cent of its GDP on healthcare and the per capita expenditure is US$ 650, which is inadequate to provide for chronically ill patients. Since there is no gatekeeper in the Chinese healthcare system, the government is trying to channel patients to community health centers. The development of the private healthcare market is slow, because most doctors do not want to leave careers at public hospitals. Outbound medical tourism has reached a size of US$ 10 billion in 2015, as affluent people tend to avoid treatment in China. It seems obvious that in the future two different healthcare systems will coexist in China, namely: a large high-volume, low-priced public system and a small low-volume, high-priced private system. Since the large public system is controlled by the government, tender prices are bound to get lower.

In most medtech segments the Chinese market is between 2 and 10 per cent of the global market. Equipment fare better than implantable medical devices, the latter being not (or only partially) eligible for reimbursement at present. One would be well advised not to believe certain consultants and local distributors who claim that the market in China is huge. The potential is huge but not the market. Most international medtech companies, particularly in the field of implantable medical devices, have a Japanese subsidiary that at present is still larger than their Chinese operation in terms of turnover, despite the much smaller population in Japan compared to China. Nevertheless, the market in China keeps on growing because of urbanisation, the increasing middle class and an aging population with chronic diseases.

One of the major hurdles to enter the Chinese medtech market is the new regulatory rules under Order 650 which require clinical trials for innovative products. Registering a medtech product in China has become expensive and time-consuming because CFDA fees, testing fees and clinical trial fees for an innovative product are high. Clinical studies for an innovative product cost between CNY 7 to 10 million (USD 1 to 1.5 million) and it takes a total of 3 to 5 years to obtain the license. There is an innovation channel, also called «Green Channel», offering fast track review that requires the new products to meet a number of preconditions in order to qualify. GSP (Good Supply Practice) and GMP (Good Manufacturing Practice) guidelines have recently been published.

For many foreign medtech companies, particularly SMEs, the legal vehicle of a trading company is the preferred way to enter the Chinese market. Increasingly, however, SMEs look for partnerships with Chinese companies to reduce the risk and to benefit from the expertise of a local partner. There is no doubt that innovative products are liked by Chinese patients and leading doctors alike. Since the market is crowded with foreign and local companies, it is hard to succeed with «me too» products. As often quoted, it needs time, money and patience to succeed in China. Start-ups might prefer to focus on Europe, USA and Japan rather than China because reimbursed markets are generally preferable and technology in Western markets is protected.

The Chinese medtech market is still dominated by foreign players through imports or their locally manufactured products. Some domestic players, however, have developed well and have become local champions in several medtech segments. Local champions are often acquisition targets by foreign medtech players which want to get better access to the Chinese market. Mindray and Microport are two good examples of Chinese medtech companies which have successfully internationalised. The «Two Invoices System» is going to reshape the logistics and distribution channels in China and the landscape of the medtech industry. It looks as if «Government appointed suppliers (GAS)» will run the logistics and distribution channels in the Chinese healthcare system. The new «Two Invoices System» is an effort under the anti-corruption campaign to develop more transparent distribution channels.

# 2. Market overview

**In this chapter, government initiatives and the Chinese healthcare system are discussed. The current healthcare system covers 95 per cent of the population through the basic medical insurance scheme. The coverage, however, is not comprehensive and does not address expenditures caused by chronic diseases. It happens that patients with chronic diseases cannot pay their health bills and need to file for bankruptcy.**

**Currently, 5 per cent of China's GDP is spent on healthcare. The healthcare expenditure per capita is US$ 650 (OECD 2013). The Government has ambitious plans to reform the long-neglected healthcare system. A major initiative is to let patients enter the healthcare system through community health centers which act as gatekeepers and not through grade 3 hospitals as it is the case at present. Furthermore, private hospitals which only account for ten per cent of the patient volume today should double their capacity within the next five years. The Government is also allowing doctors from public hospitals to practice at multiple sites in pilot projects.**

**It is obvious that there will be two healthcare systems in China in the future, namely: 1. a large high-volume, low-priced public and 2. a small low-volume, high-priced private system. Currently, the first system is much larger than the second one in terms of medical device sales. In short, foreign medtech players have to learn to adjust to high volumes and low prices while domestic companies have to upgrade their products in order to compete.**

**Since privatisation is moving forward slowly, a sizeable outbound medical tourism market has developed, increasing 5-fold from the year 2015 to 2016. In the «Healthy China 2030 Reform» the Government tries to improve the healthcare system so that main health indicators reach the standards of high-income countries, which is a very ambitious target taking the limited resources available into consideration.**

**Undoubtedly, there is a trend to lower prices of medical devices through tenders and to favor locally manufactured products. As far as locally manufactured products are concerned, there is a distinction between foreign and domestic ownership in some tenders.**

**In most medtech segments, the Chinese market contributes between 2 and 10 per cent of the world market. Claims that the current Chinese medtech market is huge are unfounded, because reimbursement does not or only partially exist for implantable medical devices. Most typically foreign medtech subsidiaries of MNCs in China contribute 2 to 10 per cent of global sales and for most MNCs the size of their Japanese subsidiary is larger than the size of their Chinese one.**

## 2.1. GOVERNMENT INITIATIVES

The Chinese Government has announced four major plans and reforms. These are: the 13th Five Year plan, the Healthcare Reform 2020, Made in China 2025, and Healthy China 2030. Each of these policies address directly or indirectly the reform of the healthcare system. Some of these plans and reforms are short to medium-term while others are long-term policies. In the following chapters, the key points of these plans and reforms will be discussed with reference to healthcare.

China has seen great progress in the last five years by becoming the second largest economy with per capita GDP increasing to US$ 7,800. Undoubtedly, the «new normal» in economic growth is going to be 6 to 7 per cent or even lower. The 6.7 per cent reported in 2016 were achieved by substantially increasing the debt burden which is now standing at around 250 per cent of GDP. Some industries suffer from overcapacities or stagnate, while other industries continue to enjoy healthy growth rates. Generally, healthcare can be regarded as a promising sector for investment in China, even though there are vast differences between segments. Major driving forces are urbanization, increase in chronic diseases and aging of the population.

### 2.1.1. 13th Five Year Plan

The 13th Five Year Plan (2016-2020) addresses insurance, healthcare and hospitals, namely:

- Implementation of supplementary health insurance program for jobless rural and urban residents suffering from major diseases
- Retirees who live at places other than their workplaces to have hospitalization fees reimbursed under basic health insurance
- Advancing reform of public hospitals ending the system to seek profits through over prescription of medicine
- Set-up personnel and remuneration system appropriate for the healthcare industry

The basic medical insurance system in China which covers approximately 95 per cent of the population cannot be compared with Western healthcare systems that cover a wide range of medical treatments. In fact, the coverage is basic, leaving patients liable for about half of the total healthcare spending, with the proportion rising further for serious and chronic diseases such as cancer and diabetes. It is well known that cardiovascular disorders, cancer and diabetes dominate today's disease spectrum. Most innovative medical devices and pharmaceutical drugs are not or only partially reimbursed in China. Hence, it happens that health bills bankrupt families in China, particularly in poor areas and particularly when jobless people are affected, which is not the case in Europe where the social welfare system covers those in need.

The income of Chinese public hospitals consists to a large extent of mark-ups from pharmaceuticals and service fees. The government tries to introduce a zero markup policy for pharmaceuticals which means that a major income source is vanishing for hospitals. In order to compensate for the losses from mark-ups of pharmaceuticals, hospital service fees will need to be increased. There is no doubt that China has opted for a public healthcare system which treats high volumes for a low to moderate price. In such a system, obviously, the service level will be low to moderate too. The result is a poor and tense patient-doctor-relationship and wide-spread frustration about the healthcare system in the population. Currently, most Chinese patients have to endure when seeking medical treatment, characterised by long waiting times and short visits with doctors. It is common that rich Chinese increasingly seek medical treatment abroad which leads to outbound medical tourism which is discussed later.

Beside public hospitals there are a smaller number of private hospitals. These hospitals have mainly developed in niches such as gynecology/obstetrics, ophthalmology, dental and some other specialties. Even though doctors would be allowed to treat at several sites, administrative barriers are preventing the strengthening of the private sector. Doctors prefer to stay at public hospitals for carrier reasons.

Traditionally, Chinese doctors are not well paid at public hospitals and this is still the case today. It is easy for pharmaceutical and medical device companies to attract young doctors to join them, because the salaries at companies exceed those at public hospitals. Beside the official salary, doctors get commissions from patients, distributors and other sources to improve their income. The government and the public know about this and media have covered this topic in China extensively. Therefore, it is vital that the remuneration of healthcare professionals is improved in order to counter this behaviour. There is no doubt that the Chinese government is serious about the on-going anti-corruption campaign by piloting the «Two Invoices System» in the pharmaceutical and medical device sectors. The "Two Invoices System" is discussed below.

### 2.1.2. Healthcare Reform 2020

There are ten policies in the new healthcare reform (2015-2020) in China. These are:

- Infrastructure development
  - Open investment for private hospitals
  - Increase the number of hospital beds
  - Improve and standarize training of healthcare professionals
  - Improve healthcare services in rural areas
  - Provide more care facilities for senior citizens

- Cost reduction and broader insurance coverage
    - Wider and more comprehensive insurance coverage
    - Reduce out of pocket expenditures of patients by using locally manufactured medical devices
    - Work on doctors' liability insurance and develop patient-doctor dispute mechanisms

- New investment segments
    - Invest in e-healthcare and cloud systems
    - Invest in traditional Chinese medicine hospitals

The government's target is to increase the number of public hospital beds by 30 per cent and to double the capacity at private hospitals by 2020. In 2020, there should be 6 hospital beds per 1,000 people in the public and 1.5 per 1,000 people in the private sector, respectively. Some of the public hospitals have up to 10,000 beds which make them very customer unfriendly and difficult to manage. The government tries to reduce the size of some of those large public hospitals. In traditional Chinese medicine, the plan is to have 0.55 hospital beds per 1,000 residents.

There is a substantial shortage of qualified doctors in China in most disciplines. The fields in highest demand are pediatrics and psychiatry. Due to this shortage and the current set-up of the healthcare system which will be discussed below, the patient-doctor relationship is tense. The violence against healthcare providers in China has made headlines and is a tragedy. This is a reason why the guidelines foresee a new way to mediate disputes between doctors and patients and try to find compensation models for failed cases.

It is obvious that the majority of doctors in China have not reached the skill and education level of Western doctors. Chinese patients are going to grade 3 hospitals to be treated by the most skilled Chinese doctors. This is the reason why most public grade 3 hospitals are overcrowded, because patients seek medical treatment from the best doctors. These doctors have little time left for working with pioneering companies to develop new innovative medical device products. At weekends, these doctors often travel to other cities treating complex cases which the local doctors cannot treat.

It is now allowed for medical doctors to practice at multiple sites, meaning public doctors have the opportunity to treat at private hospitals too. This measure is, however, often ineffective because doctors have internal barriers at public hospitals to let them practice at non-public hospitals.

The guidelines foresee one clinic and one medical service centre for each community with a population of 30,000 and 1.2 hospital beds for every 1,000 residents in that community. Focus will primarily be on nursing and rehabilitation. In the communities, more emphasis has to be put on senior and home care. These community healthcare centers mirror the function of general practitioners in the Western system, which act as gatekeepers within the healthcare system.

The guidelines envision broader coverage under the basic medical insurance scheme with a stronger emphasis on critical illnesses to alleviate the financial burden of patients. Undoubtedly, the guidelines aim at reducing the share of imported medical devices and increasing the share of locally manufactured products. This will negatively affect those foreign medical device companies that import products and are facing competitors which manufacture in China (for example orthopedic products). This won't affect, however, foreign companies with highly innovative products that are not manufactured in China (for example pacemakers). The days of bringing «me too products» into China through imports are over. In some tenders, a distinction between domestic and foreign-owned local manufacturers is made. This implies that when a foreign company buys a Chinese company in order to get easier market access, the local subsidiary may be considered as a foreign entity after the acquisition is made.

It is planned to establish three digital national databases containing health information in the form of medical records by 2020. Included in these efforts is also the advancement of telemedicine.

It is interesting to see that private investments in new healthcare projects are often targeting the affluent Chinese and not the middle class and rural population. Hence, the role of the government will necessarily be to balance investments.

### 2.1.3. Made in China 2025

The «Made in China in 2025» initiative is based on Germany's «Industry 4.0». In a nutshell, «Industry 4.0» aims to create a «smart factory» in which computerized automation lets different parts of the factory communicate with each other in real time via the Internet of Things and cloud computing while being offered to and used by participants across the value chain.

The Chinese effort is challenging, because automation in Chinese companies has in most cases not yet reached the level of Western manufacturers and the quality and efficiency of Chinese producers often are still trailing behind their western counterparts.

Furthermore, the logistics channels in medtech in China are still too underdeveloped and intransparent (e.g. distributors without adequate IT systems) to support the progress of «Industry 4.0». Currently, this effort still seems to be driven rather by wishful thinking than practical concepts, because the fundamentals in automated manufacturing and IT-integrated logistics are not yet established.

What looks promising, however, is the fast development of e-commerce in China as the last step in the value chain. China has leapfrogged the rest of the world in the e-commerce field in a very short time and already has become one of the world leaders in this field.

In the «Made in China 2025» plan the healthcare sector is supposed to focus on biological medicine and high-performance medical devices as one of the priority areas among 9 sectors. So far, no Chinese medical device has made inroads into the developed Western markets (USA, Europe, Japan, Australia and New Zealand). Penetration of those markets is the ultimate test of whether a medical device is of high calibre or not because these countries account for 80 to 90 per cent of the entire medtech market.

### 2.1.4. Healthy China 2030

The Lancet (Reference 1) article says about «Healthy China 2030»: «Healthcare reform was also acknowledged to be approaching a very difficult stage with tremendous challenges». Generally, there appears to be a widespread frustration in the population about the current healthcare system. Too little attention has been paid to the healthcare system in the past. The wake-up call came in 2004 when the SARS epidemic made headlines in China and showed that the country was not prepared to handle this disease.

Driven by rapid urbanisation and industrialisation, the major medical challenges China is facing are:

- Severe environmental pollution (chronic lung diseases, cancer)
- Diet and lifestyle changes (obesity, diabetes, cancer)
- Aging society (dementia, osteoarthritis)

The second and third challenge are difficult for established Western healthcare systems too, but represent surely more serious challenges for a developing country like China with its current healthcare system that has not been tailored to deal with chronic diseases.

Air pollution has reached in certain parts of China hazardous levels which damage the health of people. The hectic lifestyle and adoption of western diets generate overweight, obesity, diabetes, cardiovascular disorders and cancer. It is fair to state that the current healthcare system is not in a position to handle these challenges and reforms are rapidly needed.

According to the plan, China will improve the healthcare system so that main health indicators will reach the standards of high-income countries by 2030. Another quote from the Lancet outlines: «…that the ultimate success of China's ambitious health reform depends on well-educated health professionals who have the clinical, ethical and human competencies to match the goals for quality and equity in China's health-care system.»

## 2.2. CHINESE HEALTHCARE SYSTEM

### 2.2.1. Explosion of Chronic Diseases and Aging

The fast adoption of Western diets and lifestyle changes has created an explosion of chronic diseases in China such as:

- > 100 million diabetes patients
- 184 million overweight people and 31 million obese patients
- Cancer as number 1 killer in China

In a recent study published in the Journal of the American Medical Association it was reported that people in China diagnosed with diabetes mellitus in middle age lost on average nine years of life due to inadequate treatment (Reference 2). The WHO chief, Margaret Chan from Hong Kong said: «The pattern of excess mortality revealed in this study points to significant weaknesses in the clinical management of diabetes, especially in rural areas, and in the effectiveness of population-wide interventions aimed at prevention».

Medtech and pharmaceutical companies which have developed products for diabetes (e.g. Medtronic, Ypsomed), cancer (e.g. Roche, Novartis), and obesity (e.g. Roche) get opportunities to benefit from these developments.

Currently, China spends about 5.8 per cent of its GDP on healthcare. The healthcare expenditure per capita based on purchasing power parity reached US$ 650 in 2013 in China, which is comparatively low compared to the OECD average of US$ 3,500. The low level of expenditure is particularly alarming in view of the high costs which chronic diseases such as diabetes and cancer create for patients. It is estimated that the out-of-pocket expenditures reach 50 per cent for those patients.

China has 230 million people suffering from cardiovascular diseases. In addition, China accounts for more than 20 per cent of newly diagnosed cases of cancer globally each year and more than 25 per cent of global deaths from cancer.

The age class of seniors 65 years and older encompassed 90 million people in the year 2000. This group will grow to 176 million in 2020 and a staggering 300 million by 2050 which corresponds to the current population of the entire USA. This elderly population is prone to be affected by chronic illnesses. Some 80 million elderly, or 60 per cent of all of the country's senior citizens, live outside cities and far away from good healthcare facilities. It is estimated that one fifth of rural elderly have incomes that fall below the official poverty line. In many cases the cost of treating chronic illnesses, which are common among seniors, plunges the household into debt. It can be said that major changes in healthcare need to occur in order to ensure that chronic diseases are managed adequately. The current healthcare system cannot successfully tackle this task.

### 2.2.2. Privatization in Healthcare

The current Chinese healthcare system lacks general practitioners which act as gatekeepers in Western healthcare systems. General practitioners in the West treat a large part of patients and refer the few patients they cannot treat. In China, patients seek treatment at the best grade 3 hospitals and these hospitals are overcrowded with patients. Lower grade hospitals, on the other hand, are under-utilised. This results in long waiting queues, poor service and short visits with doctors. Recently, the government has experimented with community health centers that are intended to act as the first stage in entering the healthcare system and strived to upgrade grade 2 hospitals. It remains to be seen if patients find this acceptable.

There are approximately 23,000 hospitals in China. Based on defined requirements such as size, function, management, quality assurance, and safety, hospitals are classified into grade 3, 2 and 1. Additionally, there are also ungraded hospitals. In the public sector, there are 12,200 hospitals (of which 1,550 are grade 3 hospitals) and in the private sector there are 9,800 hospitals (of which only 70 are grade 3 hospitals). Even though private hospitals have grown fast, they only account for 10 per cent of the patient volume. Most private hospitals have problems attracting high-calibre doctors. When Chinese patients seek treatment, they specifically look for high-calibre doctors and refrain from hospitals which do not feature such luminaries.

Table 1: Hospital classification

| Grade | Number | Size | Function | Imported healthcare products |
|---|---|---|---|---|
| 3 | 1,600 | >500 beds | Regional hospitals that provide high quality healthcare service and perform educational and research mission | Large share |
| 2 | 5,200 | 100-500 beds | Provide integrated healthcare service to multiple communities | Medium to low share |
| 1 | 2,800 | 20-99 beds | Provide healthcare service to local communities | No share |

Foreign health institutions are located in first tier cities such as Shanghai, Beijing and Guangzhou and target the small, but fast-growing, high-income patients which do not rely on the basic medical insurance system. The United Family Group of hospitals is a chain which has made major inroads as a private hospital. They have several hospitals and clinics in large cities. Increasingly, wealthy Chinese patients seek medical treatment in the neighboring countries and overseas. This topic, namely medical tourism, will be addressed below.

The pilot scheme which has been put in place in some regions of China to allow doctors to practice at multiple hospitals shows the willingness of the government to strengthen the private sector. Since there is a large middle class of more than 400 million Chinese, this sector should prosper. A lot depends on how these private hospitals can attract high-calibre doctors in order to attract patients.

### 2.2.3. Medical Tourism

It is estimated that outbound medical tourism was worth about US$ 10 billion in 2015. The spending was US$ 6.3 billion on medical treatment and US$ 3.4 billion on travelling.

The breakdown of the medical services provided are illustrated below in US$:

- Cosmetic: 1 billion
- Wellness: 400 million
- Oncology: 3.5 billion
- Cardiac: 740 million
- Others: 500 million

There are about 480,000 Chinese seeking wellness and medical treatment abroad annually. South Korea attracts 180,000 customers, Taiwan 150,000, Hong Kong 50,000 and other destinations in Asia together about 90,000. Japan attracts Chinese patients for health checks and cancer treatment with special visas. Overseas medical tourism to Western destinations is still small, with about 10,000 cases. The main destinations are: USA, Germany, Switzerland and UK.

Overseas medical treatment is rapidly becoming more popular in China. However, medical treatment in Switzerland contributes only a minor part to this. One of the key challenges remains that Chinese still associate Swiss healthcare primarily with anti-aging treatments. Switzerland's often world-class cancer, cardiology or orthopedic departments are still rather unknown in China.

## 2.3. MEDTECH SEGMENTS IN CHINA

### 2.3.1. Segment Sizes and Growth Rates

The Chinese medtech market accounts for US$ 25 billion in 2016 (USA is US$ 170 billion and Japan is US$ 50 billion). It has doubled its size since the year 2008. Overall, the growth rate is above 10 per cent but must be looked at segment by segment.

The six largest segments of the Chinese medtech markets are:

**Table 2: Major medtech segments in China**

| Medtech Segment | Size in Million US$ (2016) | Compounded Annual Growth Rates (%) |
|---|---|---|
| Ophthalmic devices | 6,700 | 11 |
| In-vitro diagnostics | 4,300 | 15 |
| Diagnostic imaging | 2,400 | 7 |
| Cardiovascular devices | 2,100 | 11 |
| Nephrology and urology devices | 1,500 | 7 |
| Orthopedics | 1,400 | 8 |

Switzerland is well positioned in some of the medtech segments which are: ophthalmic devices, in-vitro diagnostics, orthopedics, dental and hearing aids. In China, the fastest growing segment is healthcare IT with over 20 per cent growth annually. Healthcare applications, however, have so far been a huge disappointment for investors. There have been no big business successes in Chinese mobile health. In fact, most health applications have failed to create a sizeable number of active users. A typical healthcare application is only used less than three times a year for downloading information.

Foreigners coming to China often hear the phrase that the Chinese medtech market is huge. This statement is a misnomer and indicates that many Chinese medtech experts have little knowledge about Western markets and their sizes. The potential of the Chinese medtech market is certainly large but not its current size in most segments. The major reason that the Chinese market is not large for most implantable medical devices is the fact that reimbursement does not exist or only partially.

The orthopedic market worldwide, for example, is estimated to be US$ 40 billion. China contributes US$ 1.5 billion, which is 3 per cent of the world-wide orthopedic market and Japan contributes 10 per cent with an 11 times smaller population. Another example is in-vitro diagnostics. The world-wide market of in-vitro diagnostics is US$ 65 billion of which China accounts for 7 per cent.

The table below shows the segment sizes of some implantable devices comparing China with Japan, comparing a non-reimbursed with a reimbursed country (population of China is 1,4 billion people, population of Japan is 127 million).

**Table 3: Comparison of medtech segment market sizes between China - Japan**

| Segments of Medtech Market (in million US$) | China | Japan |
|---|---|---|
| Cardiovascular devices | 2,100 | 4,300 |
| Dental devices | 1,000 | 2,000 |
| Diagnostic imaging | 2,400 | 3,700 |
| Orthopedics | 1,400 | 4,200 |

Most foreign medtech MNCs in China have local revenues which contribute 2 to 10 per cent of their worldwide sales. As long as China has no full reimbursement of medical devices, the sales will be limited but nevertheless growing.

### 2.3.2. Prices and Tenders

The prices of medical devices in China are actually quite high for patients, sometimes higher than in Europe or the US. The reason for such high prices lies in the intransparent distribution channels from the suppliers (trading companies / manufacturers) to the hospitals which are handled by distributors, sub-distributors or agents. Price hikes of 2 to 10 times from the import price are possible depending on the innovative character of the device and the characteristics of the segment. Under these circumstances, the major beneficiary in the value chain is not the manufacturer but the distributor. This clearly is an inequitable state of affairs.

The government has realised that the current distribution channels are a major reason for the price hikes and is trying to counteract with tenders and the newly piloted «Two Invoices System» which will be explained later.

To be able to submit documents in local tenders, a company must have a legal entity in China in the form of a trading company. Usually foreign and domestic companies are applying in different tender groups. The documentation is different from province to province and contains legal files, certifications, quality and technical documents as well as prices. Currently, there are substantial price reductions required in tenders in some provinces (e.g. in Zhejiang) in order to qualify as a supplier. It has happened that companies had to discontinue the tendering process due to low prices. Foreign companies with local manufacturing in China not always qualify as «domestic», the definition of which is interpreted differently from province to province in tender submissions.

# 3. Important Market Players

**The Chinese medtech market is still dominated by foreign players through imports or their locally manufactured products. Some domestic players, however, have well developed and have become local champions in several medtech segments. If the orthopedic market is of any guidance, it can be seen that the three local champions in trauma (Trauson), spine (Kanghui) and joint replacement (Montage) have all been bought by large foreign medtech companies which shows that these three companies failed to internationalise. Successful examples of Chinese medtech companies that were capable to internationalise are Mindray and Microport. What happened in the orthopedic segment might well happen again in the dental implant market in China where recently several orthopedic companies have started to invest. While in most medtech segments local rivals have developed, there are some segments without relevant local players. This is the case for pacemakers, hearing aids, intraocular lenses, and contact lenses. The battle between foreign and domestic medtech companies happens in the value segment which is estimated to be 3 times as large as the high-end segment. The prices in the value segment, though, are lower than in the high-end segment.**

## 3.1. MAJOR INTERNATIONAL AND DOMESTIC PLAYERS

Most MNCs have a presence in China. They dominate the medtech market in most segments. The table below summarises the key international and domestic players in the largest segments as outlined above.

Table 4: Major medtech segments with key international and domestic players

| Segment | International Share | International Players | Domestic Players |
|---|---|---|---|
| Ophthalmic devices | 80 | Alcon / Essilor / Bausch and Lomb | N/A |
| In-vitro diagnostics | 65 | Roche / Abbott / Beckman Coulter | Mindray / DaAn / Fosun |
| Diagnostic imaging | 80 | Siemens / General Electrics / Philips | United Imaging / Neusoft / Wandong |
| Cardiovascular devices | 60 | Abbott / St Jude | Microport / Lepu |
| Nephrology and urology devices | 70 | Fresenius / Baxter | Wego |
| Orthopedics | 60 | DePuy Synthes / Zimmer Biomet / Stryker / Medtronic | Microport / Wego / Double Engine |
| Hearing aids | 90 | Sonova / GN Resound / Amplifon | Nurotron |

Domestic companies have gained substantial technical know-how over the last twenty years in several medtech segments. Some have become local champions. In other segments no major local competition has developed, such as in the field of pacemakers, intraocular lenses, contact lenses, and some others.

Foreign medtech companies enter the Chinese market by focusing on grade 3 hospitals while domestic players enter into the value segment. The value segment can be defined as a segment below the high-end segment with products that do not have as many functions as those from the high-end segment, but work. There are estimates that the value segment, once penetrated fully, is 3 times the size of the high-end segment in terms of turnover. The battle between foreign and domestic medtech companies often happens in the value segment. In this segment, products have to be localised. The foreign imaging companies (Siemens, Philips, GE) have successfully adapted their product offerings with localised products that sell for a substantially lower price which opens the door for grade 2 hospitals.

The orthopedics sector delivers a good example of what happened to the local champions. The following international companies were copied by local players: Synthes in trauma, Medtronic in spine and Zimmer in joint replacement. The three local champions which developed fast, however, were bought by major international players. Trauson, the domestic champion in orthopedic trauma was purchased by Stryker. Kanghui, the local champion in orthopedic spine was purchased by Medtronic and Montage, the local champion in joint replacement was acquired by Zimmer. In short, the local champions developed well and rapidly in the Chinese market, but all failed to internationlise and were eventually purchased. Obviously, the Western healthcare markets are not willing to have copy products from China which is a huge handicap for the internationalization of domestic companies. It can be expected that in other medtech segments similar developments are going to occur in the future.

## 3.2. CAN DOMESTIC COMPANIES INTERNATIONALISE?

Domestic medtech companies have four major tools to grow their businesses, namely:

- Penetrate the domestic market
- Expand abroad (on its own / buy foreign company)
- Acquire technologies and patents
- Diversify in new promising medtech segments

Two Chinese medtech companies have proven to be able to expand abroad.

1. Mindray, a Shenzhen based company is the largest medtech company from China. It has gained a strong foothold in patient monitoring equipment domestically and other areas in medtech (ultrasonosgraphy, etc.). The sales in 2014 amounted to US$ 1.3 billion.

2. Microport is the largest domestic orthopedic company because it bought the global joint replacement business of Wright Medical (headquartered in USA) and has now a worldwide presence. Originally, Microport was the leading company in the cardiac stents in China and has become with the purchase of Wright Medical a predominantly orthopedic company (60 per cent of sales). Microport's revenue in 2014 amounted to US$ 355 million.

The dental implant market is interesting. The government allowed private investment in dental clinics some years ago. The private market has developed fast. Today, the dental implant market related to private dental clinics is about equal to the size of the market related to public hospitals. Furthermore, the private market is transparent, clean and the dentists enjoy fair salaries, while the public market is the opposite. The dental implant market is dominated by imported products (Straumann / Nobel Biocare). Ninety five per cent of dental implants used in China are imported. Several domestic orthopedic companies have recognised this niche. An example is Trausim, a spin-off from the largest domestic orthopedic company Trauson. Naton, Wego and Kerunxi have also invested in the dental implant market. It can be expected that a development similar to orthopedics will happen in the dental implant market.

Other domestic companies to observe in the near term future are: Wego, Lepu, Shinva, United Imaging. They have expanded well in the domestic market, have financial resources and need to internationalise to realise the next growth step. As a matter of fact, no Chinese medtech company has so far developed a truly innovative product which has made it on the world stage, meaning the highly demanding Western medtech markets. The international sales component is a part of the definition of an innovative medtech product. Currently, the domestic companies sell their products in some of the emerging markets with low regulatory hurdles and less demanding patients as compared to Western markets. The international sales volumes are modest compared to domestic sales. This contrasts with the situation of established international medtech players, whose international sales share is typically 50 per cent or more.

Considering potential innovations of domestic Chinese companies, their chance lies in the value segment rather than in the high-end segment, because they do not have the expertise of developing medical devices that would be acceptable for the latter segment. This is going to remain the case and will be the largest handicap facing Chinese companies wishing to expand into Western markets which demand high-end products, particularly if implanted into patients.

# 4. Inbound and Outbound M&A

**Foreign players have refrained from inbound M&A activities after the large acquisitions of Medtronic and Stryker. The domestic M&A market, however, remains active, particularly driven by IVD. China's medtech outbound investments have been directed towards innovation and technology that is superior to those of the buyer and for which China will have a future market to offer.**

## 4.1. INBOUND M&A

Foreign players have refrained from investing heavily into Chinese companies. Since the large deals done by Medtronic and Stryker in 2012 and 2013, less than a handful of major inbound acquisitions materialized. In 2016, we could only register one single inbound deal (Southern Home Medical Inc. acquired the Taiwanese player CES Technology Ltd). This weak track record of international medtech players in China does however not reflect their intentions and strategic objectives. Almost all major international players are on the prowl to acquire Chinese competitors. However, three major reasons prevent real transactions from closing, or cause them to abort in early stages of initiatives.

Availability of leading local players: First of all, it is not easy to a make the case for acquiring either a market leader or a technology leader, as they often do not exist within a category. Chinese players are typically dominant in product categories that are more mature, but lag behind in latest technology generations. As such, MNCs have the choice between small (maybe) innovative local companies, or market share leaders ridden with low profitability. Most MNCs have been looking to penetrate lower price market segments by buying local players, but also often stepped back as they found the ROI less than ideal.

Valuation of local targets: Medtronic and Stryker have set the stage with deals valued at 14 – 15x of the targets' annual revenues, which were often the reference in discussions between Chinese sellers and new potential investors. At the same time, IPOs (although often more driven by pharmaceutical companies) in domestic stock exchange markets, as well as in Hong Kong, inflate valuations manifold, making an acquisition in China still expensive and tough to negotiate down to an acceptable value.

Compliance: Many partnership discussions between local and international medical device players died because of overseas headquarter deeming the activities of the local partner to be too risky. Furthermore, after a stage of due diligence, foreign companies are especially worried about sales compliance of the local players' sales channels.

**Table 5: Selected inbound deals. Excluding pharmaceuticals, CRO, nutritionals, hospital and medical services.**

| Year | Type | Acquirer | Seller | Product category | Deal value USD million |
|---|---|---|---|---|---|
| 2015 | Inbound | Echosens SA | Shenzhen Emperor | X-Ray, ultrasound equ. , abortion apparatus | 19 |
| 2015 | Inbound PE/ VC | SHC Capital | Tong Da Medical Device | Consumables | 88 |
| 2015 | Inbound PE/ VC | Right Faith Holdings | PW Medtech Group | Consumables, orthopedic implants | 129 |
| 2014 | Inbound | Beckman Coulter (Danaher) | Xitogen Technologies | Flow cytometry, analytical equ. | N/A |
| 2014 | Inbound PE / VC | Sequoia | Jiangsu Yuyue | Medical equipment | 139 |
| 2013 | Inbound | Stryker | Trauson | Orthopedics | 764 |
| 2013 | Inbound | Halma | Thinketron Precision Equ. | Peristatic pump in labs | 39 |
| 2012 | Inbound | Medtronic | Kanghui | Orthopedics | 816 |
| 2012 | Inbound | Getinge | Acare | Hospital beds | 26 |

Source: InterChina Consulting.

As such, cross-border M&A investments remain a risky business for medtech companies. Buying direct competitors in the Chinese market has become less an option, but gives way to companies seeing opportunities up and down the value chain (e.g. integrating backward into a parts producer), or expanding into completely new technologies that are beyond the company's core business activities.

Developing a carefully established strategy will become even more pressing for foreign brands and vendors within the future landscape. Local production capacities and registration platforms, securing a local production certificate, as well as utilizing an established Chinese brand are becoming increasingly critical. Valuations are rather on the decline and more favorable as sellers' expectations become more realistic (i.e. 3– 5x of annual revenues).

## 4.2. DOMESTIC-DOMESTIC M&A

At the same time, the domestic M&A market (local players buying or restructuring local players) remains active, driven especially by the IVD product categories.

**Table 6: Selected domestic-domestic deals. Excluding pharmaceuticals, CRO, nutritionals, hospital and medical services. Source: InterChina Consulting.**

| Year | Type | Acquirer | Seller | Product category | Deal value USD million |
|---|---|---|---|---|---|
| 2016 | Domestic | China National Medicines Co., Ltd. | Sinopharm Holding Beijing Co., Ltd. | Dealer | 455 |
| 2016 | Domestic | Yantai Dongcheng Biochemicals Co., Ltd. | Global Medical Solutions Ltd. /China Operations/ | Diagnostic imaging & services | 70 |
| 2016 | Domestic | Shanghai Runda Medical Technology Co., Ltd. | Shandong Xinhairun State Medical Supply Distribution Co. Ltd. | IVD | 30 |
| 2016 | Domestic | Modern Dental Laboratory Co. Ltd. | Dental Works World Wide Ltd. | Dental services | N/A |
| 2016 | Domestic | Forerunner Medical Equipment Technology Shanghai Co. Ltd. | MedSphere International (Shanghai) Co., Ltd. | Minimal invasive surgical products | N/A |
| 2015 | Domestic | Xinbang Pharm | Chinese Peptide | IVD | 288 |
| 2015 | Domestic | Jiangsu Yuyue | China Resources Wandong | Imaging Equipment (X-Ray, NMR) | 186 |
| 2015 | Domestic | Starway Bio-Technology | Masep Med Science & Techn. Development | Radiotherapy, imaging equ., gamma knives | 181 |
| 2015 | Domestic | Tianjin Chase Sun Pharma | Beijing Choice Electn Tech | Patient monitoring | 156 |
| 2015 | Domestic | Shenzhen Das Intellitech | Jiuxin Medical | Medical equ. | 140 |
| 2015 | Domestic | Zhongzhu Holdings | Shenzhen Yiti | IVD | 495 |
| 2015 | Domestic | Dalian Neusoft Holidings, Goldman Sachs | Shenyang Neusoft Med System | Imaging Equipment (CT, NMR-CT) | 442 |
| 2015 | Domestic | Shenzhen Qianhai Hongshan | Jiangsu Yuyue | Respirator, sphygmomanmeter | 139 |
| 2015 | Domestic | Chengdu Tianxing Meter | Laoken Med Tech | Infection control equ., CSSD | 130 |
| 2015 | Domestic | Beijing Leadman Biochemistry | DiaSys Diagnostic System | IVD | 82 |
| 2015 | Domestic | Boai NKY Pharma | Changsha Sanji Biotech | IVD | 68 |
| 2015 | Domestic | Shinva | Chengdu Yingde Biomedical | Equ. of blood product | 66 |
| 2015 | Domestic | Mindray | Wuhan Dragonbio Surgical | Orthopedics | 73 |

| | | | | | |
|---|---|---|---|---|---|
| 2015 | Domestic | Suzhou TA&A Ultra Clean Tech | Wuxi Yushou | Consumables / injectors | 73 |
| 2015 | Domestic | Dirui Industrial | Ningbo Rui Bio-Tech | IVD | 93 |
| 2014 | PE/ VC | Fountainvest Capital | Shanghai Kehua | IVD | 264 |
| 2014 | Domestic | Zhongyuan Union Stem Cell | Zhicheng Biological Technology | IVD | 139 |
| 2014 | Domestic | Mindray | Shanghai Long Island Biotechnology | IVD | N/A |
| 2013 | Domestic | Shanghai Kinetic | Jiangsu Ideal Med Science & Tech | Implants | 94 |

Some of the domestic deals have been results of governmental mandates (including the acquisition of clinical services / hospital businesses, and dealerships). Others, however, are often driven by the desire to enter better business growth areas (i.e. diagnostics) and may also involve non-medtech company investors (e.g. pharmaceutical companies, other diversified groups).

### 4.3. OUTBOUND M&A

**Table 7: Selected outbound deals. Excluding pharmaceuticals, CRO, nutritionals, hospital and medical services.**

| Year | Type | Acquirer | Seller | Product category | Deal value USD m |
|---|---|---|---|---|---|
| 2017 | Outbound | Shijiazhuang Yiling Pharma | HealthWatch (Israel) | Sensors / wearable monitoring | 20 |
| 2016 | Outbound | Modern Dental Group Ltd. | MicroDental Laboratories, Inc. (USA) | Custom dental restoration products and dental labs | N/A |
| 2016 | Outbound | Sinocare, Inc. | Polymer Technology Systems, Inc. (USA) | POC diagnostics | 200 |
| 2016 | Outbound | Venus Medtech Hangzhou | Transcatheter Technologies GmbH (Germany) | Interventional artificial cardiac valve system | N/A |
| 2016 | Outbound / PE | Everpine Capital | Eye Tech Care SA (France) | Non-invasive ultrasound treatment for glaucoma | 27 |
| 2016 | Outbound | Modern Dental Group Ltd. | Verwaltung Deradent Dental GmbH (Germany) | Distribution of dental prosthetic devices | N/A |
| 2015 | Outbound / PE | CITIC and others | Biosensors (Singapore) | Devices for interventional cardiology and critical care procedures | 787 |
| 2015 | Outbound | Shanghai Kehua | Technologenetics (Italy) | IVD | 32 |
| 2015 | Outbound | Sinocare | Nipro Diagnostics (USA) | IVD | 273 |
| 2014 | Outbound | Microport | OrthoRecon (Wright Medical Group) (USA) | Orthopedics | 290 |
| 2013 | Outbound | Fosun Int'l | Alma Lasers (Israel) | Laser resurfacing / aesthetic surgery | 240 |
| 2013 | Outbound | Mindray | Zonare (Israel) | Ultrasound equ. | 105 |

Source: InterChina Consulting.

Reminiscent to other sectors, China's medtech outbound investments have been directed towards innovation and technology that is superior to those of the buyer's and where China will have a future market to offer. Although Chinese players are too small to swallow large international groups, they keep targeting good technologies, and in some cases also distribution channels. Most of the prominent outbound deals have involved US and Israeli companies.

# 5. Regulatory Overview

**The times when foreign medical device products used to be registered by the dozens in China are well past. The cost of a class 3 imported medical device now amounts to US$ 90,000 without clinical trials. If clinical trials are required, 3 more years are needed and US$ 1 million has to be invested. The risk-based classification system in China is similar to Europe or the US, but there are exceptions occurring. A new innovation channel has been opened by the CFDA, called the «Green Channel». The prerequisites to use this channel are a Chinese patent and a first in-class medical device product. Recently, GSP and GMP guidelines have been published based on risk management considerations. It is noteworthy that recently it has become possible to obtain a product certificate prior to applying for a manufacturing license.**

## 5.1. ORDER 650

The Regulations on the Supervision and Administration of Medical Devices, known as State Council Order No. 650, have been approved by the State Council on February 12, 2014 and were put into force on June 1, 2014. The revised Regulation has brought a series of profound changes compared to the old regulation dealing with registration, manufacturing, distribution and use.

Significant changes have been made in the area of clinical trials. The revised Regulation requires that most Class II & III devices must undergo clinical trials before registration, with exemptions in the following three circumstances, namely:

- The medical device is a product having a definite working mechanism, finalised design and mature production process, while there have been similar devices of similar specification already applied clinically for many years without severe effect and its regular usage would not be changed;
- The safety and effectiveness can be proven through non-clinical assessment;
- The safety and effectiveness of the medical device can be proven through analysis and evaluation by using data obtained from clinical trial of similar product (comparator) or during clinical application.

It is important to emphasize that the CFDA won't release any data about registered products in China which might be used as predicate device. Besides, well written clinical evaluation reports, in accordance with CFDA requirements, are needed for submission. As a rule of thumb, a local clinical trial will add costs of US$ 1 million and delay the registration for 2 to 3 years.

## 5.2. FEES, CLASSIFICATION AND INNOVATION CHANNEL

The CFDA administrative fees were sharply increased on May 27, 2015 as per Announcement No. 53. For example: The cost for a class III imported medical device product increased from approximately US$ 39,000 to US$ 89,000. This figure includes local testing, agency fee, and the CFDA administrative fee for initial registration. The cost of samples is not included.

**Table 8: CFDA Product Registration fees in CNY (1 US$ = 6.9 CNY in March 2017)**

| Category | | Domestic products | Imported products |
|---|---|---|---|
| II | Initial Registration | - | 210 900 |
| | Change of registration | - | 42 000 |
| | Extension of registration (Every five years) | - | 40 800 |
| III | High risk medical device clinical tests approval | 43200 | 43 200 |
| | Initial Registration | 153 600 | 308 800 |
| | Change of registration | 50 400 | 50 400 |
| | Extension of registration (Every five years) | 40 800 | 40 800 |

Gone are the times of registrations by the dozens. Class II and III product portfolios will become slimmer and more focused. To understand which products are worth registering, foreign players will need to invest more into preliminary intelligence and market analysis. Furthermore, the CFDA requires companies to have a legal entity in China in order to begin registration work, meaning China cannot be purely served via exports from Europe or USA to China without a China-based legal representation (i.e. a representative office and own staff) or appointing the local dealer and importer with registration responsibilities. Hence, in reality, new market entrants will need to invest into their in-country regulatory know-how (own people, consultants or agents) that will drive registration work. Some small foreign players that toyed with the idea of entering China may shy away in the face of the costs and risks involved.

As far as classification is concerned, the latest issue is CFDA Order No. 15 from July 14, 2015. As a rule of thumb, most medical devices are classified the same way as in Europe or the US. But medtech companies are advised to check this carefully prior to making decisions about the regulatory path to be followed. Exemptions do indeed occur. In particular, innovative products are often placed in a higher classification group in China compared to Europe or the US. It also happens that overseas companies upgrade to the latest Western standard while China is still applying older or own versions of the standard which lead to difficulties in registering in China. Recently, class I medical devices need only undergo a filing procedure. The filing record will be valid permanently and therefore, Class I devices do not need re-registration any longer.

The CFDA has set up a fast track channel for innovative devices, called the «Green Channel», which was launched on March 1, 2014. The intention of this policy is to foster domestic innovation. However, foreign companies are also permitted to choose this expedited channel in certain cases. In order to qualify for the new channel, there are prerequisites which need to be fulfilled by the products, namely: Chinese patent, innovative product with design progress and record. Products qualifying for the «Green Channel» are given priority in the registration review and applicants will be able to communicate more easily with CMDE reviewers. No initial registration fee is charged. However, the policy states that the fast track channel will not curtail any requirements of the standard CFDA registration process. If a company has an innovative product, it is worthwhile to try utilizing the «Green Channel». As of 12 December 2016, there were 91 approved fast-track applications, of which 8 were from MNCs.

On 25 October 2016, CFDA also released a second Priority Review pathway for certain breakthrough devices, which took effect on 1 January 2017. Comparing this second track channel to the first fast track channel, the breakthrough devices no longer require a lengthy pre-qualification application process, but they also have no priority in local registration testing. Breakthrough devices must fall into one of the following three categories:

1. Devices included in the “National Science and Technology Major Projects” or “National Key Research & Development Plans”.
2. Devices to treat or cure unmet clinical needs such as orphan or oncology-related diseases, pediatrics, geriatrics, or other unmet urgent clinical needs.
3. Other devices determined by the CFDA.

It is worthwhile noting that if a device has already been accepted as an innovative device, the device is not eligible for this new priority review procedure.

As to be expected, the number of submissions to register imported medical devices dropped sharply in 2015, but recovered in 2016 with a total number of 8,653 applications, accounting for a 14.9 per cent increase over 2015. The highest number of submissions occurred in the group of implants and artificial organs (509), followed by optical and endoscopic instruments (406).

## 5.3. GSP AND GMP

On December 12, 2014 the CFDA released the new guidelines on Good Supply Practice (GSP) for medical devices. The Practice defines the basic requirements regarding the quality management of medical device distribution. It shall be applied by all trading companies and distributors operating with medical devices in China. The enterprises shall apply effective quality control measures in the purchase, acceptance, storage, sales, transportation, after-sales service of medical devices to

guarantee the quality and safety of medical devices along the distribution process. A risk management approach in accordance with the risk classification of the medical devices for distribution shall be applied and quality control measures implemented.

On December 29, 2014 the guidelines for Good Manufacturing Practice (GMP) for medical devices were released. Manufacturers are instructed to conduct risk management through the whole process of design and development, manufacture, sales and after-sales service and take the measures adapted to product risks. In this context, it is important to mention that recently it became possible to obtain the product registration prior to having the manufacturing license of a facility.

# 6. Logistics and Distribution

**The «Two Invoices System» is going to reshape the logistics and distribution channels in China. Prices will be affected for sure. It looks as if «Government appointed suppliers (GAS)» will run the logistics and distribution channels in the Chinese healthcare system. Small distributors and sub-distributors are going to have a hard time in the years to come. A very fragmented distribution business run by many private small companies is going to be replaced by large «Government appointed suppliers». This is all done under the auspices of the government's anti-corruption campaign. It remains to be seen how effectively and efficaciously these GAS businesses will manage medical device distribution. Hopefully, the markets will become cleaner. Key to the new regulation is that the hospital is authorized to demand the invoice from the supplier to the distributor («first invoice») which will transparently show the margins in the chain.**

## 6.1. CURRENT SYSTEM: INEFFICIENT AND FRAGMENTED

Undoubtedly, the current distribution channels in China from the supplier to the hospital are insufficient. Many of the family-run distributors have insufficient IT systems and lack the competence to educate doctors about sophisticated products aedequately. Most of these distributors have no certification in logistics.

Dangers associated with forward tracking of products, recalls and insufficient education accrue to the principle. Many family-run distributors have no appropriate IT system in place which could facilitate and improve logistics functions. Sadly, the only core competence of many such distributors is their relationship with key personnel at hospitals.

## 6.2. TWO INVOICES SYSTEM

The International Transparency Index shows that China suffers from a relatively high level of corruption by international standards. In the medtech arena in China such corruptive behaviours are happening to a large extent in the interaction between the distributor and hospitals. Chinese media have covered this issue and the government is trying to curb such behaviours with its anti-corruption campaign. Patients are aware of such practices too (Reference 4).

The government shall be lauded for piloting a new initiative which tries to curb these corruptive behaviours in the market. The «Two Invoices System», as it is called, is currently one of the hottest topics discussed among healthcare executives in China and has replaced the topic of regulatory hurdles recently imposed by the CFDA. The «Two Invoices System» limits the number of invoices from the supplier or trading company to the hospital to a maximum of two. In short, the first invoice would be from the trading company or manufacturer to the distributor and the second from the distributor to the hospital. Everybody familiar with the fragmented Chinese distribution system knows that there can be many layers of sub-distributors in the market. These sub-distributors only interact with a few hospitals with which they have a strong relationship. The expected outcomes of this policy are: cut corruption, consolidate distribution networks, and reduce prices, to the benefit of patients.

The «Two Invoices System» for medical devices was announced in January 2017 in Shaanxi Province by the Health and Family Planning Commission for orthopedics products starting on 1 February 2017, followed by other 13 consumables and implantables (examples: ophthalmic products, anastomsis products, pacemakers, etc.). For pharmaceutical products, several provinces have already implemented it.

Furthermore, there will be «Government Approved Suppliers (GAS)» interacting directly with the hospital equipment department. Companies such as Sinopharm, China Resources and others, maybe 10 to 15 in total, will be authorized to act as GAS. It is still unclear if any foreign invested enterprise will be approved in this role. In the future, trading companies and manufacturers will sell directly to those GAS which then resell to hospitals for a margin of approximately 10 per cent. Distributors will most likely become service agents for the principle. Many small-sized distributors and sub-distributors are

going to be pushed out of the market. It is to be expected that large Contract Sales Organisations (CSOs) will develop in the years to come.

It can be assumed that high-risk, high-value medical devices are the first one to be targeted in this new campaign of the «Two Invoices System». The pharmaceutical industry is already piloting the «Two Invoices System» (Reference 5) with some success as the Sanming city (Fujian Province) case shows. If successful, this transformation has the potential to reduce corruption in the medical device market. Hopefully, at the same time, the remuneration system of health professionals will be adjusted to create a fairer environment.

### 6.3. FUTURE: STATE-RUN OR PRIVATE?

It looks like the future of logistics and distribution will belong to state-run companies. This is unique. In Western economies private companies engage in the logistics business. The re-emergence of more public rather than more private investment is on the horizon in China as a general observation.

# 7. Opportunities and Challenges for Swiss SMEs

**The regulatory cost and market access restrictions caused by tenders have become a major challenge for foreign medtech SMEs pondering a market entry in China. To register a highly innovative product which requires clinical studies approval, an investment of CNY 7 to 10 million and a timeframe of 3 to 5 years are required. This is the «new normal» for innovative medtech products in China.**

**To benefit from the status of locally manufactured products, a partnership with a domestic company is a way forward for SMEs and start-ups. Under these circumstances, it is vital to protect advanced technologies and to define what exactly the local partner receives from the foreign medtech company in the technology transfer.**

**Since tenders are issued province by province, it is recommended to enter the Chinese medtech market also province by province. Even though for business purposes, the coastal provinces are more attractive than those in western China, the possibility to include a company's product in tenders ultimately decides where the business can start. A complementary strategy when entering the market is to give priority to the regions where the major competitor is weak.**

**Moreover, it is vital to carry out a proper market entry analysis before entering the Chinese medtech market. Often, there is too much euphorism and unfounded assumptions about the "real" size of this challenging market. For most medtech start-ups China is not a first priority, because sales in reimbursed, Western markets tend to be higher and intellectual property is better protected there.With its increasing middle class, China is nevertheless a strategically important country for established medtech companies to have a presence in. Included below is an interesting case of a start-up company partnering with a Chinese company which illustrates that there are also opportunities for foreign medtech start-ups in China.**

## 7.1. WHY TO ENTER AND WHY NOT TO ENTER?

There are several reasons why foreign medtech companies enter the Chinese market. These are:

- Sales of foreign-made medtech products through trading company (e.g. Straumann / Medela)
- Sales of high-tech parts / materials going into medtech products of local companies (e.g. Cendres+Métaux)
- Producing (assembling) medtech products locally through own (e.g. Sonova) / third party manufacturing (e.g. Ypsomed)
- Sourcing medtech products or parts from China (e.g. orthopedic instruments)

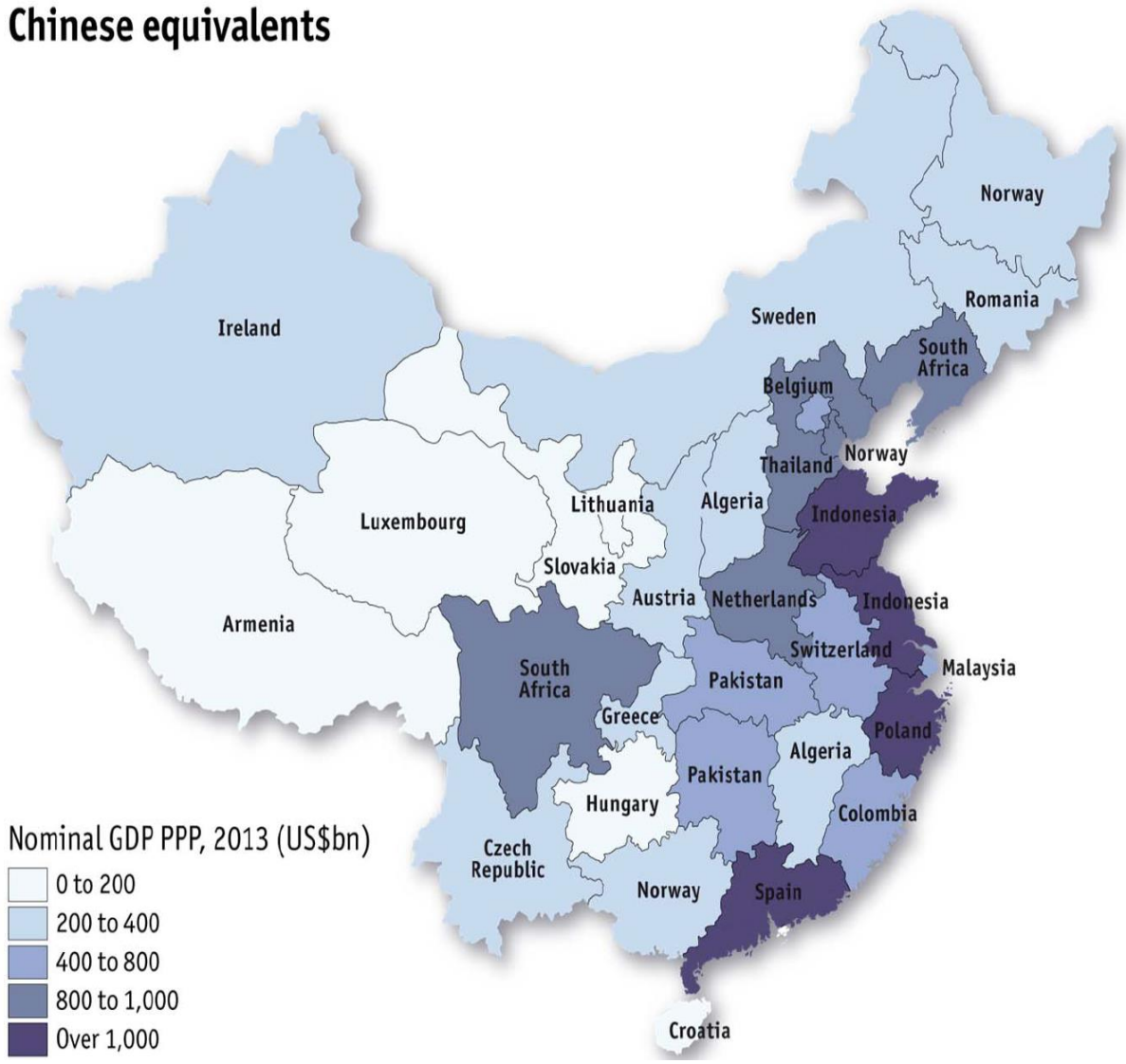
MNCs try to streamline their product portfolio and usually introduce innovative products without a Chinese competitor for a premium price (e.g. Medtronic, Johnson&Johnson). They have the financial resources to go on their own and invest in clinical studies, sales people and education. Many of the MNCs engage in local manufacturing of less advanced products usually on a global basis or for the Chinese market only (e.g. GE).

SMEs, however, have to be very careful nowadays to enter the Chinese medtech market and should focus on innovative products without Chinese competition. Increasingly, a partnership with a Chinese manufacturer is the way forward in order to get through the regulatory process and to benefit from the status of a locally manufactured product. To enter the market with «me too» type of products does not make much sense anymore, because domestic companies will outsell foreign companies. Some medtech SMEs use China as a global manufacturing base to produce less advanced products (e.g. Sonova).

There are only a few foreign medtech start-ups which enter the Chinese market at an early stage in their own development. A major reason for this reluctance is that they want to avoid their advanced technology being copied by local rivals. A partnership

with a domestic player is recommended in order to go through the regulatory process more easily and in order to benefit from the increasingly «buy local» mentality. An innovative product generates more sales in the US, Europe and Japan (which are reimbursed markets) as compared to China with no / partial reimbursement for most imported products. A partnership means that a local and a foreign company focus on their respective competencies and synergise their efforts.

Today, China is considered a strategically important market which requires a presence. The majority of medtech companies in China sell indirectly to the market for compliance reasons. They engage distributors on provincial or even city level in order to cover as much territory as possible, although this approach becomes increasingly difficult because of tenders. Nowadays, medtech companies should go province by province with strong distributors. The choice of province where to start business is dependent on the possibility to be included into a provinvial tender. The map below illustrates the size of the Chinese provinces in terms of GDP compared with similar-sized countries.




Graph 1: GDP size of Chinese provinces compared with countries.
Source: The Economist.

## 7.2. CHALLENGES OF MEDTECH SMES IN CHINA

This section presents the specific challenges which SMEs entering the Chinese medtech market are facing. The following aspects should be considered by a potential entrant:

- Product registration with or without clinical studies
- Innovation degree of foreign product
- Tenders
- Talent pool
- Partnerships

As outlined, it is obvious that there will be two healthcare systems in China in the future, namely: A large high-volume, low-priced public and a small low-volume, high-priced private system. Since the large public system is controlled by the government, tender prices are bound to get lower. This will be accelerated by the «Two Invoices System» which is going to be implemented and this will favor domestic companies. Highly innovative products, however, will have their place in the Chinese medical device market and can be placed in grade 3 hospitals with support by Chinese VIP surgeons who are early adopters. The word of a Chinese VIP doctor is extremely influential in the Chinese market in convincing other doctors to adopt a new innovative medtech product.

It is, however, unwise to bring «me too» products which are competing with domestic companies into the Chinese medtech market. A simple piece of advice: If the product portfolio of the foreign manufacturer is not superior to a domestic company in terms of product range and quality, the battle is lost. It must also be outlined that a foreign medtech SME must have sufficient quality and technical documentation ready to pass through the CFDA channels, which is surprisingly not always the case. Many SMEs underestimate this aspect and often the regulatory documents which are required in China are not readily available at overseas headquarters (example: 6-months animal studies for chronic toxicity). Often, medtech SMEs with short-to-medium product life cycles phase out “old” products overseas which are, however, still core products in China. Phasing out products at headquarters needs a good coordination with the Chinese subsidiary. If the group operates a Chinese subsidiary, it is vital to keep two product lines, a new and an old one. Furthermore, it is unwise not to renew a product certificate with the CFDA except headquarters decides to stop manufacturing.

Furthermore, local adjustments in product design and packaging size need to be considered for the Chinese medtech market. Often, the units in a package need to be smaller than in the West for economic reasons. In orthopedics, for example, the bone morphology of Asian patients is slightly different from that of Western populations. This needs smaller devices with different shape. In imaging, some functions are not included in a CT in order to make it less expensive. An interesting example is a Taiwanese start-up which developed anatomical orthopedic trauma implants based on CT / MRI data derived from Asian people. This company developed plates which are different for male and female patients due to different bone morphologies.

It is hard to find talented employees in the Chinese medtech market and highly skilled talents prefer to work for multinationals and Chinese start-ups. To retain these talents is equally challenging, particularly for SMEs which have a small pool of employees. This challenge needs to be addressed by developing a career plan for talented employees (career plan, coaching and mentoring, trainings at headquarters, company car, MBA, private health insurance, etc.). It is by no means only money which counts for talented staff.

Due to the high costs of registration and clinical studies, foreign SMEs increasingly start to cooperate with Chinese companies in order to share risks and costs. Some of the large domestic Chinese companies doing business in non-medical fields try to step into the medical device business with higher margins. Technology transfer and partnerships have become popular for many foreign SMEs. The roles in a partner could be allocated as follows: The foreign medtech company supplies products or a critical part of a product, deals with education and supports regulatory and clinical studies. The domestic partner focuses on local registration and clinical studies, marketing and sales. At a later stage, a technology transfer might be considered.

## 7.3. CASE STUDY: MEDTECH START-UP TO CHINA

This case is about a European start-up company with an improved technology over an existing medtech product sold by one of the medical device giants. The start-up company noticed that while China's patient population is large, the newest medicines are not available to treat patients as first line intervention. Hence, this start-up company considers engaging a domestic Chinese company as a partner in order to develop such a top-notch product through technology transfer. The innovative part in this medical device is protected through patents and manufacturing of that part is done in Europe. The Chinese manufacturer will invest in the assembly line and later the sales network. Due to the innovative nature of the device, the Chinese manufacturer is trying to use the innovation channel in order to be faster in the registration process. This device requires a local clinical study which the start-up is ready to carry out in order to gain access to the Chinese market. The company will supervise the activities of the Chinese partner with people on the ground in China, but without an own legal entity, in order to be present to recognise problems early and intervene accordingly. The start-up company undertook market research very effectively and found an appropriate partner to invest. In short, there are opportunities in medtech also for start-ups in China.

# 8. Conclusion / Call-for-Action

It is vital to get an in-depth understanding prior to entering the Chinese medtech market. The major issues which need to be addressed are:

- Regulatory path with or without clinical studies
- Two invoices system
- Tender process
- Go alone or partnering
- Technology transfer

Too often, medtech SMEs do not consider China as part of their overall Asia strategy. When looking from an Asian perspective, in many cases it becomes evident that Japan and often also Australia offer larger markets. Both are markets with reimbursement on a high level. It also must be understood that the privatization of healthcare in some of the ASEAN countries is far ahead of China's, thereby offering good opportunities as well. Besides, whereas the level of difficulty to register medtech products in Japan is similar as in China, once the products are registerd in Japan there are no changing government regulations and small prints to block the development of the business.

Switzerland Global Enterprise (SGE) with its associated partners is a good starting point to get familiar with the Chinese medtech market. To enter this challenging market without thorough planning is a sure path to failure. It is wise to spend some time and money to get familiar with difficulties in China and prepare well for the market entry. And a warning: Be skeptical of voices touting that the Chinese medtech market is huge. It is not, at least for the time being and near future.

# 9. Attachements

## 9.1. REFERENCE 1

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## 9.5. REFERENCE 5

**Challenges of the two invoices system for China's pharmaceutical industry. Grace Xie, Henry Ngai, International Tax Review by KPMG, p 1-6**

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