中国医疗设备制造商进入西方市场的战略

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Strategies of Chinese Medical Device Manufacturers When Entering the Western Markets

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摘 要

中国有三千多家医疗器械生产厂家，大多数都是上世纪九十年代末以后建立的公司。不同公司和产品类型之间，技术成熟度和质量水平差异很大。很多公司的目标锁定在国内市场，近些年来，越来越多医疗器械公司开始向海外扩张。迄今，已经有五家中国医疗器械公司在海外上市。一般说来，中国医疗器械生产厂家的海外扩张会首先选择在其他发展中国家开展，比如中东或者非洲，而后再进入西方市场。在海外市场，中国厂家的产品一般会被定义为中低端产品，功能简单，成本低廉。

本研究探讨了中国医疗器械生产厂家向西方市场扩张的瓶颈问题，在实地访谈和文献引述的基础上，为中国厂商的西方扩张之路提供了一个系统动态模型。研究发现，某些中国厂家已经拥有西方监管机构和消费者认可的产品，他们海外扩张的最大障碍是西方人眼中“中国制造多劣质”的刻板印象。中国食品或者玩具行业爆出的劣质新闻，造成西方人怀疑中国医疗器械的质量问题。我们访谈的中国制造商认为这种观念一时很难扭转，只能不断提高产品质量，提高自主研发能力，用优秀产品获得西方消费者的认可。另外一条西方扩张的战略是并购西方器械厂商。目前的经济危机为中国厂商的海外扩张提供了良好机会，很多政府买家开始寻求比西方器械品牌产品更加低价的产品。总之，一方面是不断壮大的中国市场，另一方面是西方市场不断增长的对廉价产品的需求，那些实力雄厚的中国器械厂家前景光明。

关键词：医疗器械；中国厂家；全球扩张；医疗健康；中国制造

Abstract

There are more than 3000 medical device manufacturers in China, most of them established in the 1990s or later. The maturity and product quality levels differ across both companies and product types. These companies primarily cater to the internal market, but more and more are aiming for global expansion and today at least 5 are listed on international stock exchanges. Generally the Chinese medical device manufacturers will start marketing their products in other developing countries in the Middle East and Africa before going to the Western markets. The products are considered to be mid- or low-end with simpler functionality and lower cost. The present report investigates the obstacles for the Chinese medical device manufacturers when trying to access the Western markets. Research is based on interviews and literature review, and a model of the system dynamics for the Chinese medical device manufacturers in the Western markets is presented.

The findings are that for the mature companies that have actually mastered the adequate product quality level required by Western regulatory bodies and consumers, the largest obstacle the Chinese medical device manufacturers face in the West is the perception of everything made in China being of poor quality. Reports on poor quality of unrelated products, like food or toys, makes the Western consumer skeptical to buying Chinese medical devices. The Chinese manufacturers find this perception difficult to meet directly, and are rather fighting it with trying to produce at higher and higher quality levels and by starting their own product development. They are of the opinion that if they continue to deliver products with high quality they customers will gradually become more accepting of Chinese devices. Another strategy for venturing abroad is through acquisition of Western medical device manufacturers. The current economic downturn represents an opportunity for the Chinese manufacturers as the Western buyers, which are usually the governments, will start looking for cheaper devices than what the Western market leaders have traditionally offered.

In conclusion the most mature Chinese medical device manufacturers have good prospects with a growing Chinese market and an increased need for more affordable products in the Western markets.

Keywords: medical devices; Chinese manufacturing, global expansion, healthcare, made in China

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1 Purpose and Scope

1.1 Purpose

The present thesis is serving as partial fulfillment of the requirement for the professional degree of Master of Business Administration at Tsinghua University School of Economics and Management in Beijing, P.R. China. It aims to investigate the strategies and prospects of Chinese medical device manufacturers when trying to enter Western markets.

1.2 Scope

The report focuses on medical devices of class II and III as defined by European and US legislation, excluding in vitro diagnostics. It is limited to studying Chinese companies that manufacture and sell their own brands, not OEM manufacturing or foreign companies sourcing from China. The work has been done in the period December 2011 to April 2012.

2 Introduction

2.1 Research Methods

Information has been collected through two resources: internet searches and interviews. All written information the thesis is based on is referenced throughout and can be found in the bibliography. Getting in touch with representatives of the Chinese medical devices manufacturers turned out to be fairly difficult. I have been looking at 29 Chinese companies which are basically companies that have been mentioned in other literature including all companies that are listed on foreign stock exchanges. These are listed in the index of appendix A. Still, by making phone calls, sending e-mails to their contact addresses and trying to contact representatives through LinkedIn I have only managed to get interviews with 4 Chinese companies and these are primarily companies where I already had some connection or network. In China, when the connections are there, it can be very easy to receive favors and get interviews, while, on the other hand, if an established connection does not exist it is very hard to get any response through cold calling. The language is a clear barrier too.

For reference and to learn more about the Chinese market I have also interviewed 4 foreign companies that have been active in China for several years. These companies were also primarily companies that I had the possibility to get in touch with through personal networks.

In addition I have been starting, following and participating in discussions in the LinkedIn Medical Devices Group with more than 100000 users. Here people with experience from dealing with Chinese medical devices both in China and abroad have answered questions and shared their experiences.

When no references are given in the text it indicates that the information is gathered in an interview. As some of my interview objects raised concerns about confidentiality no direct quotes or references to people or companies are made unless the information is already publicly available.

2.2 Organization of the Thesis

The thesis is divided in two parts. The first part is an overview of the medical devices industry in China and the general factors affecting it, including Western regulatory affairs and global market information. The second part is a system dynamics approach to describing how these factors work together to identify causes and effects in the Chinese medical devices companies pursuit of becoming accepted in the Western markets.

Part I: The Chinese Medical Devices Industry

3 What is a Medical Device?

3.1 What are Life Sciences?

The term ‘life sciences’ is fairly trendy and much used in media where it often refers to pharmacology or biotechnology. The term is usually signaling very advanced research or technology that some business is based on. It has the flair of high tech, invention, and complicated stuff smart people get rich from. When going back to the definitions, the term ‘life sciences’ is, however, plainly any science that has to do with living organisms, as exemplified through this Merriam-Webster definition:

“a branch of science (as biology, medicine, and sometimes anthropology or sociology) that deals with living organisms and life processes” (Merriam-Webster)

Wikipedia lists more than 50 science fields that would fall under the life sciences umbrella, medical devices being one of them (Wikipedia, 2012a). Medical imaging is also closely related to medical devices as the images originate from the devices. Biotechnology is, despite sometimes confused with medical technology, a different field. One could coarsely say that medical technology and medical devices handle macro systems (the body, organs) whereas biotechnology operates on microsystems (cells, genes).

3.2 Definitions of the Term ‘Medical Device’

In China issues concerning medical devices are enforced by the State Food and Drug Administration (SFDA) and governed by the Regulations for the Supervision and Administration of Medical Devices where one can find the following definition of a medical device (Chapter 1, article 3):

“ ‘Medical devices’ as defined by these regulations refers to: any instrument, apparatus, appliance, material, or other article whether used alone or in combination, including the software necessary for its proper application. It 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; the use of which is to achieve the following intended objectives:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease;
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap conditions;
3. Investigation, replacement or modification for anatomy or a physiological process;
4. Control of conception.” (State Council of the People's Republic of China, 1999)

This is a direct copy of the definition found in the European Union directive 2007/47/ec, which is an amendment to the ‘Medical Devices Directive’ (The European Parliament and the Council, 2007). Similarly the section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act defines a medical device as:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." (United States Congress, 1938)

The implication of these definitions are that the term ‘medical device’ is broadly used, and covers everything from simple bandages and condoms to complex diagnostic systems like magnetic resonance imaging (MRI), in-vitro test diagnostics, passive implants such as titanium hip joints or active implants like pacemakers or brain stimulators as well as surgical blades and needles. It will also include what can be characterized as ‘physical medicine’, substances

that are injected into the body but do not have any pharmaceutical or metabolic interaction. On example is hyaluronic acid, a clear, gel-like substance that constitutes the filling of the eye. Synthetic versions are used for lubrication in joints and to fill out and flatten wrinkles in the face. Another example is ultrasound contrast media, a fluid containing microscopic air bubbles that will make the blood give strong echoes when performing cardiac ultrasound. This fluid is injected, but will leave the body through the urine without any physiological interaction.

3.3 Classification of Medical Devices

Medical devices are classified in the following way in the Chinese Regulations for the Supervision and Administration of Medical Devices:

“Class I Medical Devices are those for which safety and effectiveness can be ensured through routine administration;

Class II Medical Devices are those for which further control is required to ensure their safety and effectiveness

Class III Medical Devices are those which are implanted into the human body, or used for life support or sustenance, or pose potential risk to the human body and thus must be strictly controlled in respect to safety and effectiveness.” (State Council of the People's Republic of China, 1999)

These are similar to the classifications used in the US and the EU. Classification is performed by the local regulatory board, but reference lists of previously classified products exist. Some examples of product classifications done by the US FDA are listed in Table 3.1 below.

Table 3.1: Examples of classification of medical devices in the US. (U.S. Food and Drug Administration, 2012)

Class	Device
Class I	Casts, tapes, bandages. Tongue depressor. Scalpel. Mechanical wheelchair.
Class II	General suture. Imaging: MRI, X-ray, ultrasound. Ventilator. Condom. Motorized Wheelchair.
Class III	Ophthalmic or cardiac suture. Anesthesia machine. Implantable pacemaker. Cardiovascular stents. Intrauterine device (IUD). Intra-articular hyaluronic acid. Ultrasound contrast media.

The classification will determine which level of regulatory approval is required. For instance, in the US a class III product will always require premarket approval by the FDA before being allowed on the market, whereas class II products will be subject to special controls such as postmarket surveillance and patient registers. Class I devices are only subject to general controls and can be put directly on the market. (Federal Government of the United States, 2011) In other words, the classification determines which type of process the product has to pass through in order to be sold in the market.

In China, the classification is not harmonized with the rest of the world, and generally the products will be classified in a higher risk category in China than elsewhere. Products like in-vitro diagnostic devices, imaging systems devices, dental supplies and implants are placed in higher risk categories than recommended by the Global Harmonization Task Force (GHTF), a worldwide network of national medical device regulatory authorities and the regulated industry. (The American Chamber of Commerce in the People's Republic of China, 2011)

4 Quality, Regulatory Environment and Approvals

In all developed and most developing markets medical devices need some official approval before the manufacturer will be allowed to sell in that market. Everywhere the regulatory processes are complicated and also often take years; hence this has become a field of dedicated lawyers and regulatory experts. This section is only intended to give a brief introduction of what is required of the businesses operating in this industry and is not intended to be neither detailed nor comprehensive.

The correct terminology for Western regulatory approvals is ‘FDA clearance’ and ‘CE marking’. Throughout this report I often combine these two as they from the Chinese perspective both represent regulatory means to access the Western markets. They are obtained in separate and different ways and have different implications as explained below, but I will generally refer to both by using the phrases ‘CE/FDA clearance’ or ‘CE/FDA approval’.

4.1 What does ‘Quality’ Mean for Medical Devices?

Everybody wants quality in their products, and when asked the Chinese medical device manufacturers all emphasize that their products must be of high quality before they can enter the Western markets. It is not always clear what type of quality they are pertaining to. Quality can be divided into several dimensions as shown in Table 4.1 below.

Table 4.1: Dimensions of Quality (Jacobs & Chase, 2010).

Dimension	Meaning
Performance	Primary product or service characteristics
Features	Added touches, bells and whistles, secondary characteristics
Reliability/durability	Consistency of performance over time, probability of failing, useful life
Serviceability	Ease of repair
Aesthetics	Sensory characteristics (sound, feel, look and so on)
Perceived quality	Past performance and reputation
Conformance	The product meets the expectations and works as expected

The most important thing for the medical devices is the performance quality. The product must be safe to use and should preferably also be efficient, i.e. it should add actual clinical value. Reliability and durability is also very important. Orthopedic implants are expected to last for maybe 15-20 years within the body and a ventilator can never break down during use or else the patient may die. These are the main dimensions of quality for medical devices which are common for all manufacturers and that the CE/FDA approvals are linked to.

Further on, the perceived quality and the conformance are the most important ones for the Chinese manufacturers. They need to gain trust in the Western markets, and that can only be done if the Western customers perceive them to be of good quality and also if the products meet the expectations. Here the Chinese manufacturers differ from the old Western manufacturers that have already gained this trust in the markets. On the other hand, the old Western manufacturers often compete on features, which the Chinese companies don’t.

4.2 The Regulatory System of USA

The Food and Drug Administration (FDA) is the enforcing agency of the

medical devices market in the USA, and it operates by the regulations of the Federal Food Drug & Cosmetic (FD&C) Act (United States Congress, 2010) which was first passed in 1938. To be sold in the USA a device needs clearance from the FDA. If there is a similar product in the market, this can be obtained by the 510(k) premarket notification that requires the firm to demonstrate that its device is safe and effective by proving substantial equivalence to a device that already has FDA clearance and is legally marketed. Finding an appropriate device in the databases may be complicated, but if all documentation is in place a 510(k) clearance can be gained in as little as 90 days (Sanchez, Regulatory Process Chart for US FDA Clearance, 2012b).

If the product is a class III device, it cannot go through the 510(k) process but needs a premarket approval (PMA). The PMA process is much more rigorous, and the company applying needs to provide clinical data to support that the device is not only safe but also efficient (Murphy, 2011). Clinical studies may take many years to perform.

For FDA clearance the company also needs to implement the FDA's quality system regulations (QSR) which is a production quality system similar but not identical to the ISO 13485 quality management system for medical devices accepted by the European Union. The FDA can and will come on unannounced QSR audits and inspections. If a company is found not to be in compliance with QSR warning letters will be issued, and in severe cases a product may immediately be pulled off the market until the response to the warning letter has been accepted.

Postmarket surveillance is handled by the FDA and any adverse events shall be reported to the FDA which will then take appropriate action.

4.3 The Regulatory System the European Union

To be sold in the European market, a medical device needs to have a CE mark. This means that the product satisfies the relevant requirements of the Council Directive 93/42/EEC, commonly known as the Medical Devices Directive (The European Parliament and the Council, 1993). This was the first common directive for the entire EU which in 1993 harmonized and replaced the regulations of the individual countries that were already in place. There is no

central agency in the European Union handling medical devices clearance or adverse events. Adverse events are reported to the local authorities in each country.

To road to the CE marking is dependent on type of device. For all products except class I non-sterile products a quality management system must be in place. For the CE marking the ISO 13485 quality management system for medical devices is accepted (Sanchez, 2012a). Depending on the type of device (i.e. for most class II and all class III products) the company's quality systems and technical documentation must be reviewed by a Notified Body. A Notified Body is an independent body appointed by an agency of one of the countries within the EU to perform conformance assessments. Notified Bodies are typically independent, private, companies, and may be qualified as Notified Bodies for one or more directives. Examples include several different German (unrelated) TÜV, Lloyd's or Det Norske Veritas (DNV) (DNV, 2011; European Comission, 2011).

If the Notified Body finds the product to be in conformance, it will issue the Declaration of Conformity and the company can place the CE mark on the product and place it on the market in the EU. Some countries may require additional registration (European Commision, 2012).

The CE mark shows that the product is in conformance with the regulatory requirements for its intended use and is not dependent on clinical data or efficiency. As this is an engineering rather than a clinical approach, the requirements have been clearly defined in the regulations, and CE markings are usually granted in much shorter time and at reasonable cost.

4.3.1 Comparison of the European and US Systems

The main difference between the European and the US systems is the engineering approach of the European system focusing on intended use as opposed to the clinical approach of the US system focusing on indications for use. As the need for showing the efficiency makes the US system less transparent, more time consuming and costly, more and more companies go to Europe for first revenue for their product. The clinical data gained in Europe

can then be used to support the application process in the US. This has led to the technology of the products in Europe often being a generation or two ahead of the technology in the US.

There have been some recent incidents where products that have been rejected in the US have gained CE markings and market access in Europe. For instance Johnson & Johnson in recalled 93 000 of their Depuy brand hip implants in August 2010 (DePuy, 2011). Already in August 2009 the FDA reviewed the clinical data and sent a letter to Johnson & Johnson stating that this data was insufficient. The implants were recalled in the US in November 2009 but Johnson & Johnson/Depuy continued selling them in Europe and elsewhere until the global recall August 2010 (Meier, 2012).

When visiting the production site for the PIP breast implants in 2000, the FDA sent the company a warning letter about deviations from good manufacturing practices and the implants were not approved for the US market. From this it took 10 years before it was discovered by the French authorities that industrial grade rather than medical grade silicone was used in the implants and they were globally recalled (Yukhananov, 2011). It has turned out that this was a case of pure fraud; the company used different silicone than they had approval for, which would be difficult for any system to defend itself against. The Notified Body of the case has actually issued legal proceedings against PIP for being actively deceived when they were on inspections (Sheridan, 2012). Still, it has again lifted the discussion about which system is “better”, the CE or the FDA, and it has caused the FDA and the European Medicines Agency (EMA) to review their routines of sharing information with each other and to issue a joint inspection program (Macdonald, 2011).

When systematically investigated the amount of recalls has been shown to be the same under the two systems (Davis, Gilbertson, & Goodall, 2011).

4.4 The Regulatory System of China

The Regulations for the Supervision and Administration of Medical Devices that was enacted in 2000 (Sun & Craig, 2005), which makes it a new law compared to the regulations of the EU and the US.

As the regulatory bodies and legislation in the EU and US is a hot topic of

discussion on-line, it is fairly easy to get an impression of how it works. This is not the case for SFDA in China, at least not if you're a foreigner who cannot read Chinese. In fact the Measures for the Administration of Medical Device Registration in which the details of the process are specified does not even have an official English translation. To be able to have a device registered one needs have an agent in China that can take on the legal responsibilities. Most of the foreign MNE such as Siemens, Medtronic, or Johnson & Johnson have their Chinese headquarters in Shanghai; still they all have offices in Beijing where their in-house regulatory affairs experts are located.

4.4.1 The Regulations and the Processes

To be able to sell a medical device in China, it has to be registered with the SFDA. The Product Registration Office under the Department of Medical Devices at the SFDA in Beijing has overall authority to accept or refuse applications for registration for Class I, II and III medical devices. Devices made abroad all have to apply for registration at the SFDA main office in Beijing, but for domestic products in class I and II the companies are not required to apply through the Beijing branch (Sun & Craig, 2005). The SFDA has offices at state, provincial and municipality level, and both at state and provincial level they have the responsibility of examining and approving the registration of medical devices (Shanghai Government, 2009; Guangdong Food and Drug Administration, 2008). At municipality level they work with supervision but not registration (Guangzhou Food and Drug Administration, 2012).

The testing of the medical devices shall be performed at test centers authorized by the SFDA in conjunction with the State Quality Supervision, Inspection and Quarantine and Quarantine Administration. Such test centers are located all over China and listed in a catalogue published by the responsible authorities. The type of device determines which test center can be used. The test results will be reported back to the Product Registration Office which will in turn accept or reject the registration application, or ask for more complementing information (Sun & Craig, 2005).

One problematic issue in the Chinese regulatory system is the combination

products. These are products that are comprised of both a medical device and a drug, such as coated stents. They are very difficult to get approval for, as the device and the pharmaceutical needs to obtain registration from two different institutions. In some situations it is literally impossible to have the device and the drug approved separately, because often the effect of the drug cannot be documented if administered without the carrying device. This is not in consistency with international practice. (The American Chamber of Commerce in the People's Republic of China, 2011)

Further on, in China all products have to be re-registered after 5 years, even though they have not gone through any significant change. The re registration process is quite similar to the initial registration process, as the company still needs to secure product standard approval and perform type testing for the re-registration. The type testing is performed by independent agencies that in test whether the product meets the specifications of very detailed test plans that the manufacturer has to provide, a both lengthy and costly process. The re-registration requirement has become a terrible burden on the SFDA, as a re-registration takes almost as much resources as the initial registration. Because of the ever growing backlog of re-registration applications the SFDA has recently extended the product licenses that were to expire in 2011 to 2012 to free up resources (The American Chamber of Commerce in the People's Republic of China, 2011). The short timeframe also increases the business risk for foreign companies as it may be hard to predict whether the license will actually be renewed or not, partially because the criteria for obtaining renewal are unclear (Lundy, Savage, Taylor, Davalos, & Chan, 2011).

4.4.2 Incident Reporting

Since 2009 both the public and manufacturers are to report adverse outcomes from the use of medical devices. Deaths must be reported within five weekdays and serious injury or events that might cause serious injury must be reported within 15 weekdays to the provincial/municipal medical device monitoring centers (Lundy, Savage, Taylor, Davalos, & Chan, 2011).

Incident reporting can be difficult in the Chinese cultural context. One company complained that they almost never got to hear about problems with

their devices in field. It should be noted that the problems that occur in field are almost always due to incorrect usage and not due to product failure; still the companies want reports on any potentially harmful incident to be able to make updates either to the product or the training to avoid it happening again. This company said that in China incidents are often covered up in order for the involved people to save face. Hence neither the manufacturer nor the SFDA might ever learn about incidents relating to a medical device. Similar experiences have been documented also in the automotive industry in China (Lockström, Schadel, Harrison, Moser, & Malhotra, 2010).

4.4.3 Some Concerns and Difficulties

The industry claims that it is very difficult to have products registered with the SFDA. It has been suspected that the registration difficulties are an intended trade barrier, but both foreign and local companies find that registration may take up to two years or even more. For example, one foreign manufacturer who does not have any local competitors in their segment have been able to get their products registered, but another manufacturer with a broader product portfolio that includes midlevel products which to some extent overlaps the products of the Chinese companies has not been able to get their registration accepted despite working on it for 3 years. A problem is that the SFDA has a lack of resources and it is difficult for the SFDA, as it is for any regulatory body, to have knowledge about everything. Some of the products only a handful of the developing engineers within the company understand completely.

Another example of a difficulty encountered was that the SFDA put a general ban on DEHP, a material used as a softener for plastics that can have adverse hormonal effects on males. The ban was general even though the risk of using it is extremely low when one is exposed to it through products that are only temporarily implanted, such as cardiovascular catheters that will be removed from the body immediately after surgery. It has also been used in food additives. In this case the SFDA did not make any distinction between different applications, causing difficulties for the industry. This reflects that the SFDA sometimes makes decisions that the industry has difficulties understanding the

reasoning behind, and that are also not in line with the practice in the west.

4.4.4 Voices from the Industry

When discussing medical devices with the players active in China, the relations to the SFDA always come up. Interestingly everybody seems to think that someone else is favored by the SFDA. The international companies believe the Chinese companies have all the advantages whereas the Chinese companies think the SFDA is favoring the foreign companies.

Someone from a foreign company was talking about how in China, devices produced by local manufacturers and classified in risk group I and II can be approved at provincial level, whereas all class III devices and all imported devices have to be approved in Beijing. This creates a large obstacle for foreign companies as the process in Beijing can take up to two years partially due to lack of resources. It may also be an extra benefit to the local manufacturers, as provincial protectionism is common. The performance of the local party is judged on how well it can maintain its local GDP; hence decisions at provincial government level are often made in favor of local manufacturers (Wang, 2006).

The reason why a local company was of the opinion that the foreign companies were favored was because they did not have to do clinical testing in China, which can shorten the application process by as much as three years. In these cases, however, clinical testing will have to have been performed somewhere else and be documented in the application process. I have also heard Chinese companies believing that the foreign product registration goes quicker because the SFDA representatives have more faith in equipment produced in the West.

A Chinese person I talked with expressed the relations to the SFDA like this: “The SFDA does not treat anybody differently as the procedures and rules are the same for everybody. The difference lies solely at the company side and is only dependent on how the company manages their relations to the SFDA. In this relation the foreign companies often suffer from communication problems.” Personally I believe this statement captures a lot the cultural difficulty for foreigners in penetrating the Chinese government systems. What is seen locally as fair and simply the way business is done, becomes opaque and awkward for

an outsider. Being a foreigner you might be unable to build the Chinese relations either because you don't speak the language, don't understand what is expected of you or how to invest in the necessary relationships, or because the company's code of conduct developed far outside China prevents you from having and intently building too close relationships with government officials. It's interesting how the Chinese in this case sees the SFDA as working in a correct manner, whereas the average westerner would see the need for relationship building as somewhat suspect. Based on their respective viewpoints and backgrounds they are probably both right.

4.5 Implications for Chinese Medical Devices

Coming from a system where the relationship you have with the government officials will affect the speed at which you gain approval might make the transition to the Western regulatory systems a hurdle for the Chinese companies. As the CE marking is easier to obtain than the FDA clearance, it also means that the Chinese manufacturers will in most cases go to the European markets first. There is generally no marketing value in the CE/FDA clearances in the Western world, as these are seen as prerequisites. However, in developing countries lacking good regulatory systems of their own like in Africa and some Middle Eastern countries, the CE/FDA approvals gives credibility to the products. One might see Chinese companies getting CE markings to use this to promote their products in developing countries rather than with the aim of selling in Europe.

There are reports that CE marking documentation can be bought in China (Murphy, 2011), and I have anecdotally heard about ISO certifications being for sale. This means that anybody acting as an agent for Chinese medical devices in the EU should take extra care in verifying with the Notified Body that the documentation provided is correct as they have the responsibility for the products they import into Europe.

5 Markets and Players

5.1 The Chinese Market Size

According to Andrew Chen at Deloitte Consulting in Shanghai, the Chinese medical devices market has been estimated to be worth US$11 billion with a compound annual growth rate of 30.6% in revenue and 28.3% in profit between 2004 and 2008 (Chen, 2010). The revenue growth rate figures are confirmed by the international medical devices companies I have interviewed, who all talk about growth figures in a similar range.

Espicom Business Intelligence, a market researcher focused on the global pharmaceutical and medical device sectors, estimated the 2011 medical device market size to be USD 8.6 billion (Episcom, 2011c) with a growth to be in the region of 13.1%; making it one of the fastest growing markets in the world. High rates of growth are not uncommon in the Asian region, but as the size of the Chinese market is so big, this growth is particularly noticeable (Episcom, 2012cn). There is an expectation that the Chinese medical devices market will reach USD 28 billion by 2014 (Knowledge@Wharton, 2009).

The medical device sales as part of overall healthcare sales in China was 9.7% in 2008, compared to a global average of 40%, indicating a significant growth potential (Chen, 2010). According to Episcom medical devices only take up 2.6% of the health care expenditure, and the annual per capita spend is only USD 6 (Episcom, 2011c).

5.1.1 China’s Trade Balance for Medical Devices

China has a positive trade balance for medical devices, and the value of their exports reached nearly 14 billion USD in 2010 whereas imports amounted to 7.3 billion USD according to reports from the China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE, 2011a). The detailed data broken down to different product categories can be seen in Table 5.1 below. The biggest export base lies in medical dressings, i.e. surgical gowns, gloves, table covers etc. where China is also nearly self-supported. The main category of imported products is ‘medical diagnosis and treatment’.

Table 5.1: Statistics of the import and export structure of medical devices in China 2010. Values in USD 1000. (CCCMHPIE, 2011a)

Trade name	Export value	Export value year-on-year growth	Share in total export volume	Import value	Import value year-on-year growth	Share in total import volume
Medical dressing	4 687 507	11,95%	34 %	207 768	25,63%	3 %
Disposable product	1 922 274	15,42%	14 %	880 761	27,73%	12 %
Medical diagnosis and treatment	4 543 599	25,56%	33 %	5 944 729	30,34%	81 %
Health protecting and recovering products	2 416 407	30,87%	17 %	149 372	83,83%	2 %
Dental equipment and material	288 820	16,51%	2 %	152 939	21,37%	2 %
Medical devices total	13 858 607	19,83%	100 %	7 335 569	30,45%	100 %

CCCMHPIE do not explain what the category covers, but one can assume that this includes imaging products and several ER/OR products. Interestingly this is at the same time a field where China has significant export.

When breaking down the figures geographically, one sees that the list of countries which buy Chinese medical devices is fairly well correlated with the list of which countries spend the most on medical devices (see section 5.2 for global market data). The US holds 38% of the global expenditure on medical devices, and in relation to this figure 28% of Chinese exports going to the US is proportionately small, but still significant. Further on one sees that the dominant buyers are Japan, Germany, and the UK, the countries that has the highest expenditures on medical devices in the world. Hong Kong, Vietnam and South Korea stand out as important customers. The detailed breakdown is found in Table 5.2 below (CCCMHPIE, 2011b).

Table 5.2: Top 20 import and export markets of Chinese medical devices 2010. Values in 1000 USD. (CCCMHPIE, 2011b)

Country	Export value	Export value year-on-year growth	Share in total export value	Import value	Import value year-on-year growth	Share in total import value
Total	13 858 697	19,83 %	100 %	7 335 569	30,45 %	100 %
Asia	4 669 958	12,87 %	34 %	1 938 773	29,28 %	26 %
Africa	503 054	40,83 %	4 %	1 937	86,30 %	0 %
Europe	3 631 065	18,53 %	26 %	2 861 376	34,38 %	39 %
EU	3 220 564	16,64 %	23 %	2 555 988	35,12 %	35 %
Latin America	710 055	32,03 %	5 %	167 489	47,05 %	2 %
North America	4 051 033	24,48 %	29 %	2 303 786	25,81 %	31 %
Oceania	293 442	36,05 %	2 %	62 096	28,56 %	1 %
US	3 867 606	24,72 %	28 %	2 252 637	26,48 %	31 %
Japan	1 440 075	-13,50 %	10 %	1 113 905	26,99 %	15 %
Germany	778 064	14,72 %	6 %	1 271 739	35,43 %	0 %
Hong Kong	601 346	3,22 %	4 %	23 734	21,45 %	2 %
UK	499 262	21,54 %	4 %	152 568	24,87 %	0 %
Vietnam	498 355	106,90 %	4 %	10 656	6,16 %	3 %
Netherlands	369 884	13,48 %	3 %	214 020	30,71 %	3 %
South Korea	322 987	37,73 %	2 %	243 639	39,66 %	1 %
Italy	316 758	22,97 %	2 %	99 766	5,01 %	3 %
France	291 482	3,12 %	2 %	210 628	33,37 %	1 %
Australia	255 676	38,05 %	2 %	59 180	28,64 %	0 %

Table 5.2: Top 20 import and export markets of Chinese medical devices 2010. Values in 1000 USD. (Cont.)

Country	Export value	Export value year-on-year growth	Share in total export value	Import value	Import value year-on-year growth	Share in total import value
Russia	238 026	48,12 %	2 %	1 206	-26,54 %	1 %
India	212 098	50,45 %	2 %	39 535	23,19 %	0 %
Belgium	203 403	30,41 %	1 %	7 887	51,55 %	1 %
Singapore	186 190	6,22 %	1 %	102 762	16,41 %	1 %
Spain	183 611	-1,87 %	1 %	38 455	16,15 %	1 %
Canada	182 957	19,42 %	1 %	51 149	2,03 %	0 %
Brazil	165 085	27,22 %	1 %	26 117	-28,68 %	0 %
Turkey	152 636	48,47 %	1 %	416	171,46 %	1 %
Malasyia	135 150	18,32 %	1 %	38 583	11,30 %	0 %
Others	0	-	0 %	113	7191,38 %	0 %

5.2 Global Markets

The global market for medical equipment and supplies was valued at USD 273.3 billion in 2011, equal to just over USD 49 per capita. The CAGR for the period 2006-2010 was 5.3%, a period which includes the economic downturns of 2008 and 2009 where growth was very small. The global medical device, technology and equipment market is forecast to be worth over USD 348.6 billion by 2016 (Episcom, 2011e). USA has the world's largest medical device market, estimated to be US$105.8 billion in 2011. Per capita expenditure, at US$339, is the third highest in the world (Episcom, 2012us).

A regional breakdown of estimated market sizes are found in Table 5.3 below, and when comparing to the breakdown by country of Table 5.4, one can see that in aggregate Western Europe is the 2nd largest market in the world, whereas by country Japan is number 2. These figures were originally published

in 2008, which is why they are slightly lower than other figures presented that are estimates from 2011 and 2012.

Table 5.3: Regional market sizes in USD billion. (International Trade Administration, 2010)

Region	**2009**	**2010**	**2011**	**2012**	**2013**
Americas	102,4	107,1	112,1	117,4	122,8
Western Europe	62,3	66,7	71,6	76,9	82,5
Asia/Pacific	42,5	46,1	49,9	54,3	58,9
Central/Eastern Europe	10,3	11,3	12,4	13,6	14,8
Middle East/Africa	5,7	6,0	6,3	6,7	7,0
Total	223,2	237,2	252,3	268,9	286,0

Market sizes on country level are included on the following pages. Figures for the African countries that Chinese companies are trying to enter are difficult to find. Still, African countries, which have a total population exceeding one billion, imported medical equipment and supplies at the worth of just over US$3.2 billion in 2010. The growing markets are found primarily in Northern and Western Africa (Episcom, 2012a).

Table 5.4: Market sizes of several countries in the world. *Per capita expenditure calculated using population numbers found in the CIA World Factbook (Central Intelligence Agency, 2012) and not fetched directly from the individually referenced source. The CIA population figures are estimates for mid-2012; hence the per capita expenditure for these countries might be slightly underestimated.

Country	Market size, USD billion	Per capita expenditure, USD	Year	Source
USA	105 800	339	2011	(Episcom, 2012us)
Japan	23 922	188*	2010	(Episcom, 2011b)
Germany	19 500	240	2011	(Episcom, 2012de)
UK	9 000	144	2011	(Episcom, 2012uk)
France	8 800	140	2011	(Episcom, 2012fr)
China	8 600	6	2011	(Episcom, 2011c)
Italy	8 200	135	2011	(Episcom, 2012it)
Canada	6 200	180	2011	(Episcom, 2012ca)
Russia	5 960	42	2011	(Episcom, 2011c)
Switzerland	4 700	592	2011	(Episcom, 2012ch)
Spain	4 500	96*	2011	(Episcom, 2012es)
Australia	4 026	183*	2010	(Episcom, 2011b)
South Korea	3 742	77*	2010	(Episcom, 2011b)
Brazil	3 600	18	2011	(Episcom, 2011c)
Mexico	3 500	30*	2011	(Episcom, 2011d)
India	2 700	2	2011	(Episcom, 2011c)
Austria	2 468	292	2011	(Episcom, 2012at)
Netherlands	2 300	139	2011	(Episcom, 2012nl)
Poland	2 013	53	2011	(Episcom, 2012po)
Malaysia	1 900	61	2016	(Episcom, 2012my)
Sweden	1 900	200	2011	(Episcom, 2012se)
Denmark	1 736	311	2011	(Episcom, 2012dk)

Correction: should be 'USD million', not 'USD billion'.
CS, 2012-06-29

Table 5.4: Market sizes of several countries in the world. (Cont.)

Country	Market size, USD billion	Per capita expenditure, USD	Year	Source
Belgium	1 530	141	2011	(Episcom, 2012be)
Taiwan	1 517	66*	2010	(Episcom, 2011b)
Czech Republic	1 454	139	2011	(Episcom, 2012cz)
Norway	1 000	211	2011	(Episcom, 2012no)
Finland	960	179	2011	(Episcom, 2012fi)
Thailand	950	14	2011	(Episcom, 2012th)
Israel	913	118	2011	(Episcom, 2012il)
Portugal	887	83	2011	(Episcom, 2012pt)
Colombia	864	19*	2011	(Episcom, 2011d)
Iran	765	10	2011	(Episcom, 2012ir)
New Zealand	704	164	2010	(Episcom, 2011b)
Ukraine	686	15	2011	(Episcom, 2012ua)
United Arab Emirates	672	127*	2011	(Episcom, 2012ae)
Vietnam	599	7	2011	(Episcom, 2012vn)
Venezuela	595	21*	2011	(Episcom, 2011d)
Hungary	573	58	2011	(Episcom, 2012hu)
Egypt	561	7	2011	(Episcom, 2012eg)
Slovakia	500	92	2011	(Episcom, 2012sk)
Chile	495	29	2011	(Episcom, 2012cl)
Hong Kong	463	65	2011	(Episcom, 2012hk)
Indonesia	421	2	2011	(Episcom, 2012id)
Romania	373	17	2011	(Episcom, 2012ro)
Singapore	355	68	2011	(Episcom, 2012sg)
Philippines	333	3*	2010	(Episcom, 2011b)

Correction: should be 'USD million', not 'USD billion'.
CS, 2012-06-29

Table 5.4: Market sizes of several countries in the world. (Cont.)

Correction: should be 'USD million', not 'USD billion'.
CS, 2012-06-29

Country	Market size, USD billion	Per capita expenditure, USD	Year	Source
Peru	318	11*	2011	(Episcom, 2011d)
Belarus	262	28	2011	(Episcom, 2012by)
Croatia	248	55	2011	(Episcom, 2012hr)
Pakistan	236	1*	2010	(Episcom, 2011b)
Serbia	199	27	2011	(Episcom, 2012rs)
Morocco	188	6	2011	(Episcom, 2012ma)
Jordan	178	27	2011	(Episcom, 2012jo)
Bulgaria	175	24	2011	(Episcom, 2012bg)
Lithuania	157	48	2011	(Episcom, 2012lt)
Estonia	120	90	2011	(Episcom, 2012ee)
Bangladesh	115	0,7	2011	(Episcom, 2012bd)
Latvia	109	49	2011	(Episcom, 2012lv)
Oman	91	27	2011	(Episcom, 2012om)

5.3 Chinese Medical Devices Companies

According to the industry publication China Medical Device Manufacturer, there are 12000 companies working with medical devices in China and the figure is growing by a 1000 per year (Chen, 2010).

There are several popular e-sourcing homepages in China, whereof Alibaba is the most renowned. Searching through a couple of these one will find thousands of Chinese medical device manufacturers. When turning to the renowned US supplier qualifiers QMed only 73 companies with manufacturing in China are listed there. Qmed is the world's only directory of completely pre-qualified suppliers to the medical device and in vitro diagnostic industries, and to be listed there the company has to apply and to have one of several certifications which may be ISO, CGMP or FDA. There are several reasons for

the discrepancy between the Chinese and the Qmed listings, the primary one being that they list different things. The Chinese listings include finished products whereas Qmed is a sub supplier list only. Also the Chinese companies might not be aware of or interested in this type of listing aiming directly at Western markets. Still the large discrepancy also to some extent reflects the difficulty for the Chinese companies to reach the Western markets.

Table 5.5: Amount of Chinese Medical Devices Suppliers found in different supplier search engines.

Homepage	**Description**	**Search criteria**	**Number of suppliers**
Alibaba (Alibaba, 2012)	"Global trade starts here"	'Medical device', China mainland, manufacturer	2438
Made-in-China (Made-in-China, 2012)	"Connecting buyers with China suppliers"	'Medical equipment', By company, All provinces	2497
China Medical Device (China Medical Device, 2012)	"China Medical Device Suppliers Directory"	Suppliers, Medical devices	4497
Qmed (Qmed, 2012)	"QUALIFIED Suppliers to the Medical Device Industry"	China, Supplier listing	73

5.4 Examples of Chinese Companies

Here I list a few examples of Chinese companies. The list consists of companies that I have been fortunate to have contact with and another few notable companies. A longer list can be found in Appendix A.

5.4.1 Shenzhen Anke High-Tech Co. Ltd

Shenzhen Anke High-Tech Co. Ltd (hearafter 'Anke') was founded 1986

in Shenzhen as a joint venture between the Chinese Academy of Sciences and the US Analogic Corporation which is today the primary shareholder. They were the first in China to produce MR equipment, and their portfolio also includes CT and radiotherapy equipment. They have between 200 and 500 employees and a turnover of 50-100 million USD (Made in China, 2012).

Anke is secretive about how many foreign countries they are selling in, but important markets include Russia, Turkey, India, and Syria. They are focusing on developing countries but wish to promote the machines in Europe. They do have contracts with agents in Europe, and have CE marking and FDA clearance for their products, but still no sales in the US (Anke, 2012).

5.4.2 Microport Scientific Corporation

Microport Scientific Corporation (hereafter Microport) was founded 1998 and listed in Hong Kong in 2010. They reported a revenue for 2011 of RMB 839 million and have 1200 employees. They produce vascular stents for all purposes, including cardiovascular, neurovascular and peripheral in addition to insulin pumps, ablation catheters for cardiac purposes and some orthopedic implants, all marketed under their own brand names. They have an office in the Netherlands. They have CE markings for some porducts and are looking for international merger and acquisition opportunities as well as collaboration with the industry giants (Microport, 2012).

5.4.3 Mindray Medical International Limited

Mindray Medical International Limited (hereafter ‘Mindray’) was established 1991 in Shenzhen and raised USD 270 million in their IPO on the New York Stock Exchange (NYSE) in 2006 as the 18th Chinese company to be listed there (Brakman, 2006). They have 1500 engineers, primarily based in China, which is approximately one fourth of the employees worldwide. Mindray might be the most famous Chinese medical devices manufacturer abroad, selling in more than 120 countries and with 25% of their revenue originating from developed markets, 42% from China and 32% from emerging markets. For 2010 they reported a revenue of USD 700 million (RMB 4.4 billion) and a net income of USD 155 million (RMB 975 million).

In 2008 Mindray acquired US manufacturer Datascope's patient monitoring division for USD 209 million, making them one of the world's largest players in patient monitoring. Sales in the US are now channeled through Datascope.

Their wide portfolio of products cover operating room and intensive care unit appliances, such as patient monitoring systems, ultrasound imaging, anesthesia machines, operating tables, ceiling supply units and surgical lights. They are aiming at providing good quality at a lower cost than the traditional medical device manufacturers, hence the slogan 'healthcare within reach'. Still, they have moved from competing on price alone, and rather emphasize value for money. (Mindray Medical International Ltd., 2010)

5.4.4 Naton Medical Group

Naton Medical Group (hereafter 'Naton') makes orthopedic implants, was established 1996, and is still privately held. They own the brands Irene, which are orthopedic implants, external fixators, and surgical instruments, and for dental implants they have acquired Beijing Leiden Biomaterials with the brand name BLBC. In 2011 they acquired the Finnish company Inion who makes high end biodegradable orthopedic implants which have distribution all over the world. They also own 40% of German high end manufacturer Link's factory in China. In total Naton has 7 factories, one in Finland, 4 in Beijing and 2 in Tianjin. They claim to have a huge market share in China, and that the 2nd and 3rd runners up combined do not even have half the market share Naton has.

Naton's own developed Iris brand is present in more than 40 countries, especially in the Middle East and Eastern Europe. The first country they ventured in outside China was Pakistan in 2009. They chose this as the first country because Naton was not aiming for the west with the Chinese products manufactured in China, and Pakistan and China already have good relations on a governmental level. They are so far still not aiming at the western markets with their Irene and BLBC brands, and do not have an English homepage.

Naton currently has 2300 employees worldwide, and the forecast is that there will be more than 3500 employees by the end of 2012. They started an R&D center 2008 working on implant and equipment design. The R&D center

has around 100 employees. Naton pays high salaries and offer good internal training and consider themselves to be an attractive employer. The expected turnover for 2012 is 400 million USD.

5.4.5 Shinva Medical Instrument Co Ltd.

Shinva Medical Instrument Co Ltd. (hereafter 'Shinva') was founded 1942 and has it's headquarter in the Shandong province with a total of 2300 employees. The company is listed in Shanghai, and in the 2010 annual report they presented a revenue of 1,3 billion RMB (212 million USD) and a total profit of 77 million RMB (12 million USD).

Their products include radiotherapy, treatment planning, X-ray imaging, and infection control (i.e. sterilizers), and they have a joint venture with German Aesculap International for producing and marketing surgical instruments and medical apparatus. They claim to have the largest researching and manufacturing base of sterilization and radiotherapy equipment in China. They have distribution in 60 countries for their sterilizers and washing machines. These are mainly exported to South America (Brazil and Argentina being important markets) and Africa. The machines are sold in some European countries but not in the USA.

Shinva entered into a 51/49 joint venture with GE in 2007 for the development and production of X-ray equipment for China's rural healthcare market, GE is also going to be the distributor for Shinva's digital imaging equipment abroad (General Electric, 2007). The venture had a total investment of $25 million and registered capital of $10 million. (Li, 2008)

5.4.6 Trauson Holdings Company Limited

Trauson Holdings Company Limited (hereafter Trauson) was founded in 2002 and listed on the Hong Kong Stock Exchange 2010. Their headquarter is in Changzhou in the Jiangsu province close to Shanghai. They produce orthopedic implants for trauma and spine (plates, screws, nails, etc.) which they are selling under their own brand names Trauson and Orthmed. They claim to be the largest domestic producer of trauma products and one of the top three domestic producers of spine products in China by market share. They have CE

and FDA approvals and have direct sales in 17 countries in South America, Middle East, Eastern Europe and Southeast Asia. For fiscal year 2011 they reported a revenue of RMB 385 million whereof export sales amounted to RMB 18 million, and they have 1047 employees (Trauson, 2011; Trauson Holdings Company Limited, 2012).

5.4.7 Shandong Weigao Group Medical Polymer Company Limited

The Shandong Weigao Group Medical Polymer Company Limited (hereafter Weigao) was founded 1988 and have their headquarters in Weihai in the Shandong province. Weigao has several series of products. They produce consumables for infusion, blood bags, dentistry and anesthesia, medical needles, and drug eluding stents. They also have a line of orthopedic implants for hip, shoulder, spine and trauma, and this section has a JV with Medtronic for marketing Medtronic's spinal products and Weigao's orthopedic products in China (Medtronic, 2007). At present, Weigao's is primarily selling in China, but they are actively exploring opportunities in international markets, and its products have been exported to 30 countries and regions, including the United States, Germany, Romania, Australia and the United Kingdom (Weigao Group, 2012).

5.5 Examples of Multinational Enterprises

The 6 largest medical device companies of the world are listed in Table 5.6 below. Other large companies include Roche, Covidien, Boston Scientific, Stryker and Abbott that all reported revenues above USD 6 billion in 2010 (Episcom, 2011a)

Table 5.6: The 6 largest medical device companies of the world.

Company	**Country**	**Products**	**Employees**	**Revenue USD**
Fresenius	DE	Dialysis, infusion	79 000	12,8 billion
GE Healthcare (GE Healthcare, 2012)	USA	Medical imaging and information technologies, medical diagnostics, patient monitoring systems	46 000	17 billion
Johnson and Johnson Medical Devices and Diagnostics (Johnson & Johnson, 2012)	USA	Orthopedic implants, contact lenses, sterilization and more	117 900 (entire J&J)	25,8 billion
Medtronic (Medtronic, 2012)	USA	Cardiac Rhythm Disease Management, Spinal and Biologics, CardioVascular, Neuromodulation, Diabetes, and Surgical Technologies	38 000	15,9 billion
Philips (Philips, 2012)	NL	Imaging, monitoring, home healthcare, oncology	38 000	12 billion
Siemens (Siemens, 2012)	DE	Imaging, diagnostics, therapy, healthcare IT	51 000	16,6 billion

5.6 Chinese Manufacturers' Strategies when Venturing Abroad

The Chinese companies I've spoken with all emphasize that the most important factor when going to foreign markets is the product quality. To quote:

"The priorities when accessing a foreign market are in order: quality, marketing and then price."

Concerning the marketing all companies also mention the difficulty of building a brand. The market for multiple use hospital equipment (imaging, monitoring, ventilation etc.) in the West is quite mature and sales are more often for replacement than for new investment. This means that the hospitals will have equipment that the doctors know and are trained on, and in this environment it is quite difficult to enter with a new brand. Doctors and nurses can be quite conservative and wanting to use products they know or recognize rather than being trained on new products. Marketing is difficult and costly, and there are many restrictions on which claims one might use and to whom one can market. One manager on this issue quite pessimistically said "All we can do is wait."

When deciding on which markets to go to first all the companies I have been in touch with have started in the closest regions in Asia and the Middle East. They also see Latin America and in particular Brazil as an attractive market. Many have sales in Africa. Going to the West is rather the second round of foreign expansion. The perception of 'made-in-China' is an obstacle even in the developing markets. There has been so many cheap and poor quality consumer products imported from China to Nigeria that Nigeria has put a complete ban on importing Chinese medical devices. With a population of 170 million Nigeria is considered an interesting market despite other issues. I did hear the same thing about Pakistan banning Chinese products from one company, whereas another company said that Pakistan had been their first market abroad thanks to good bilateral relations. Russia is also considered an important market which is also among the first markets the Chinese companies I have spoken to have even set up their own representation and services rather than going through distributors.

Before entering a foreign market one company said that they would investigate if there was already competition from other Chinese brands in the

specific country. If so, the Chinese companies would end up competing with each other on price until none of them could make a profit. This strategy might hold for some of the developing markets of limited size, but eventually there are going to be markets that you would want to enter despite fierce competition.

One company mentioned the language barrier and said that they did not have the competence to prepare necessary material in English for accessing the Western markets. There is, in fact, an abundance of poorly translated marketing material from Chinese medical devices companies, and the ability to handle information in English is one of the things that separate the best of the Chinese devices companies from the runners up. I even spoke with one *international marketing* manager who was hardly able to communicate in English. It seems that hiring native English speakers to prepare information in English has not been a priority so far. To enter Europe the Medical Devices Directive requires all user manuals to be in the local language. Similar requirements do not exist in all developing markets where medical devices regulations might be immature or non-existent.

A few companies mentioned acquisitions to grow abroad and to utilize the acquired international brands to penetrate Western markets. Mindray does this with Datascope, they use the acquired sales channels in the US and are still to some extent using the Datascope brand which is well known in the US to market their products there. Mindray is to some level hiding the fact that they are Chinese behind the Datascope brand in the US. Naton has used their acquisition of Finnish Inion the same way. Today it is only the Inion brand from the Naton portfolio that is sold in the US. They also express that they are aiming for more acquisitions abroad.

6 Production in China

6.1 Chinese Medical Devices Compared to Western

Chinese companies generally compete on having products with simpler functionality but they are striving for the same reliability. It is difficult to verify whether the Chinese products are of the same reliability and durability as the Western counterparts. Most of the information comes from the Chinese companies which will claim that their products are of equal quality as the Western ones, but this is often difficult to verify. There are no direct comparative studies. The Chinese are considered good at making simple devices and non-invasive devices like imaging, but have not penetrated sophisticated markets like implantable defibrillators (The Economist, 2011b). Concerning Chinese orthopedic implants they are said to last on average 5 years in the body, whereas a Western hip joint will last 15-20 years. This has been confirmed by a number of orthopedic surgeons and even the SFDA (LinkedIn, 2012b). I have not come across systematic differences in quality of this magnitude among other products, but one must keep in mind that there is a great difference between the best and the worst of the Chinese companies, and you will probably find the entire spectrum from very good to pure rubbish that only looks nice.

6.2 The Perceptions of ‘Made in China’

One of the main obstacles for the Chinese MDMs to conquer when entering the Western world, is the perception of the label ‘Made in China’. It is generally associated with poor quality, and even dangerous products. The reputation of Chinese products in general has suffered severe damage by recent scandals like first and foremost the case of the Sanlu milk in 2008. In this case, the supply chains were too long, not transparent, and the product quality control was poor. The farmers were paid according to the protein content of the milk, but this was measured indirectly through the levels of nitrogen in the milk. As melamine is a tasteless, odorless substance with high nitrogen content, this was added to the milk on different levels of the supply chain in order for the milk in

the tests to appear as being of high protein content. The melamine caused kidney disease in more than 53,000 children and several died. What chocked the public the most, was still perhaps that the management of Sanlu knew of customer complaints and suspected melamine contamination for several months before starting recall procedures and informing government and the public (Lu & Tao, 2009).

Another food related scandal was in 2007 when the FDA discovered contaminants in vegetables used for pet food, pets died, and hundreds of pet food brands had to be recalled (Roth, Tsay, Pullman, & Gray, 2008). Food is, however, not the only troublesome item coming out of China, a study from 2007 showed that imports from China were recalled by the US Consumer Product Safety Commission twice as often as products made everywhere else in the world, including the US. Of the 152 product recalls announced by the commission between January and June 2007, 104 were for products made in China, including toys, tools, electric heaters, ovens, batteries and more. Electrical products make up a significant percentage of the recalls (Farah, 2007).

Even though these events are not directly related to the medical devices, and also some of them are a few years old, they are still in the consumers' minds and do influence their view on Chinese products in general. Schniederjans et al. 2011 surveyed American consumers, and found that their perception was that the quality and value for money of Chinese products is far inferior to similar products made elsewhere. They also found that there was no change in this perception between two similar studies performed 2004 and 2011 (Schniederjans, Cao, Schniederjans, & Gu, 2011).

On the other hand, the consumers are also starting to get used to high quality electrical device being manufactured in China. One example is the Apple products such as iPods and iPads assembled by Foxconn in Shenzhen and Chengdu. Also, 120 million laptops is estimated to be produced in Chongqing in 2012 (Hao, 2011), which is more than a fourth of the total amount of PCs (including desktops) estimated to be sold globally in 2012 (Gartner, Inc., 2011). The largest manufacturers in Chongqing are Acer, HP and Asus, companies generally associated with delivering high end notebooks. This means, that despite China's reputation of manufacturing poor quality products, the

manufacturing of electrical appliances is quickly catching up to internationally expected product quality levels.

6.2.1 Perceptions of Medical Devices made in China

In order to get some information about how people working in the medical devices industry in the West view the Chinese medical devices, I started an open discussion on the 'Medical Devices' group on LinkedIn. This is a group consisting of more than 90,000 international professionals in the medical devices industry, with more than 25% coming from the USA. The question asked was:

What's your experience with Chinese medical devices? There are more than 3000 medical device manufacturers in China. Many of them are active in international markets where they often compete on price. Are their products of good quality and standard? What is the customers' perception of 'Made-in-China' devices? What do you think of the Chinese manufacturer's outlook in the international markets? I would be interested in hearing about any experiences with Chinese medical devices outside of China.

The question generated 23 comments from 20 individuals, whereof 3 living in China, one in Australia, one in the UAE, one in New Caledonia, one in the UK, and the rest in the US. In this forum many opinions were that the end customers are generally very skeptical to products made in China because of previous experiences and press around the scandals in the food industry, but that they on the other hand probably don't know where their devices originate. Some devices are OEM, so despite being produced in China they are marketed under Western brand names, and the Chinese companies still have a way to go in building customer confidence before they can start building their own brand names outside China. Still, the doctors probably would prefer Western devices, and there is a record of this being the case even in China. Also, it is noted that this doesn't necessarily mean that the Chinese devices are of inferior quality or reliability, but that it is very difficult to perform control in China. If sourcing from China one has to follow up very closely on the quality control, and also the opinion is that the regulatory control in China is weak, as one person says in his response: "The quality of output from a company often reflects their

response to their own market rather than their ability to produce the perfect device.” (LinkedIn, 2012c)

One of the companies I researched expressed this negative perception of Chinese made devices to be their main challenge. In China the ones who can afford it will also chose a foreign product, and the impression in this particular company was that even the administrative officials at the SFDA are in favor of foreign products. The problem with trust in the local brands is also partially due to that the Chinese companies are generally founded in the 1990s so they cannot compete with the over 120 year history of the likes of Johnson & Johnson, Siemens or GE when it comes to building the brand equity.

When even the home market prefers foreign products, it is easier to sell abroad and have control in the overseas developing markets, where there is less money and people need devices but there are no local competitors, than to try to change the perception of ‘Made in China’ in the home market.

Improving the situation through marketing is difficult and costs a lot of money in each market. One way to improve brand awareness is through the clinical research that is done in the hospitals, but this requires some relationship with the doctors and also some initial interest in the brand from the doctors. One company states that this type of independent data exists and shows that their products are of equal quality as the western ones; however, these white papers are mostly published by Chinese doctors in Chinese journals.

Even though the home electronics such as TVs and computers are generally considered in China to be as good as the foreign brands, one manager says that this does not help the medical devices business. When it comes to medical devices people are extremely cautious, and probably these are the last products that people will change their mind about. As he quite pessimistically states: “The only thing we can do is wait.” He thinks it will take 20-50 years for this perception to change, and that it will not happen during his career.

7 Medical Devices Sales in China

Selling medical devices in China is a complicated matter as it all goes through distributors, and the distribution system is known to be corrupt, and there are several reasons for this.

A Chinese doctor is paid around 4000 RMB per month. In direct exchange rate this is equal to 630USD, but in purchasing power parity this is equivalent to having around USD 1200 in the USA or EUR 970 in Germany (Heston, Summers, & Aten, 2011). For comparison a simple restaurant lunch can cost 15-20 RMB, a housekeeper in Beijing makes 2500-3000 RMB per month and an engineer 17000. In other words: the doctors are poorly paid. Some say this is a legacy from the Mao days when you should be happy to serve and fulfilled by that. Obviously this gives an incentive for doctors to make some additional earnings.

Further on there is the hospital structure. Most of them are publicly owned, but there are many different owners. There are universities, with the Ministry of Education in the background, the military, and several levels of government which will then probably be backed by the Ministry of Health. There can also be other state owned enterprises running hospitals. There is generally a lack of organized procurement and purchasing groups, and so the transparency is lost.

In China there are 12 distributors per manufacturer, which is 4 times as many as in the pharmaceutical industry (Chen, 2010). Another reason for the importance of the distributors is that the value of relationships can never be underestimated in China. The personal relationship is often more important than money. There are a lot of favors and favors in return and often a floating line between business and private life. Relationships and networks are passed on between generations. In China your opponent may well settle for a lose-lose solution of a negotiation if there is a trouble with your personal relationship. Cold calling is not a viable method in Chinese sales and marketing. The nurtured relationships with the doctors and hospitals are what the distributors bring to the table and that the medical device manufacturers pay them for. For a foreign company it will be nearly impossible doing the distribution in China by

themselves. Not only because of the reliance of relationships but also because of the vast size and different cultures and languages. It is important to note that China cannot be viewed as one market. The foreign medical device manufactures will say that they have their relationships with the distributors and what happens between the distributor and the doctor they just have to close their eyes to. They can send a sales rep together with the distributor to the customer and the sales rep will handle the training and the distributor everything else. If confronted the foreign medical device manufacturers will deny knowledge of what happens in the distributor/doctor relationship.

As the distributors have been able to put themselves in such key positions it means that a lot of the margin is lost in the distribution. In orthopedics the margin of the distributors is 60% (LinkedIn, 2012a). A company that sells Western branded and Chinese branded equipment told me that the price difference to the distributor was 75%. The price difference to the customer (i.e. patient) was eventually only 30% and the remainder would have been reaching other pockets on the way.

Western manufacturers have to comply with the Foreign Corrupt Practices Act which prevents them from engaging in bribery in foreign countries. Just this spring the U.S. Securities and Exchange Commission (SEC) charged the medical device company Biomet Inc. with violating the Foreign Corrupt Practices Act (FCPA) when its subsidiaries and agents bribed public doctors in Argentina, Brazil, and China for nearly a decade to win business for their orthopedic implants. In this case part of the evidence is e-mail correspondence from Biomet employees about how they pay expenses for influential doctors in China (SEC, 2012).

On the positive side, the government is well aware of how much money is lost in the distribution and has tried taking some measures in tidying up the market through the 2008 healthcare reform. It is considered the most difficult part of the reform and will take a lot of time. There are so many people dependent on the current system, so an immediate change would cause chaos and uproar among these people.

8 Innovation in China

The State Council has announced 7 Strategic Emerging Industries as part of the 12th Five Year Plan (2011-2015). Biotechnology, which includes medical devices, is one of these. The goal is to have these industries to account for 8% of the GDP by 2015 (Yang, 2010). China has also confirmed to invest 10 trillion RMB (USD 1.7 trillion) in developing these industries over the period of the Five Year Plan. Even though a lot of this money is expected to go to clean energy technology, this indicates a clear emphasis from the Chinese Government on developing these industries. Biotechnology will be a focus in China for the years to come (Buckley, 2011).

8.1 Effect of Changing Demography on Amount of Students in China

After the Cultural Revolution and the great leap forward ended in 1976 and Deng Xiaoping became the chairman of the Party in 1982 students started returning to the universities. At this time the Chinese population was still young with a bottom-heavy population structure (Feng & Mason, 2005), and many people were eager to get the opportunity to study. Most of the people who are in leading positions today were educated during the 80s and 90s.

The one-child-per-couple policy was implemented 1980 in order to reduce the tremendous and unsustainable population growth in China, and from then on couples of the han ethnicity, which is the largest group in China, were only allowed to have one child. This has resulted in that in 2000 the bulk of the Chinese population was in the working age, whereas the population is now growing to be a very old one, as shown in Figure 8.1 below. (Feng & Mason, 2005) The cohorts of students educated in the 80s are soon to retire, because the retirement age in China is in practice as low 56. Officially the retirement age is 60 for men and 50 for women (55 for civil servants), and has not been changed since 1951, when average life expectancy was 46 compared with today's 73 (The Economist, 2011a). The amount of young people entering the universities today cannot fully compensate for the knowledge lost with the now quickly retiring generation.

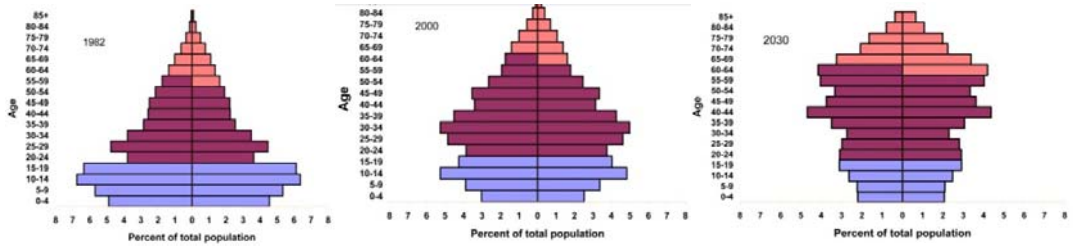

Figure 8.1: Population age structure for China for 1982, 2000 and 2030. Male to the left and female to the right. The colors indicate young people, working age and retired people (Feng & Mason, 2005).

China has in the last 10 years seen an impressive increase in output from the universities, much because of the "Compulsory Education Law of the People's Republic of China" which was implemented 1986 and makes 9-year education compulsory (China.org.cn, 2013). The amount of graduates from Chinese universities is illustrated in Figure 8.2. A much more worrying figure, though, is Figure 8.3 which shows that the number of students in secondary school reached its peak in 2005 and has been in slight decline since.

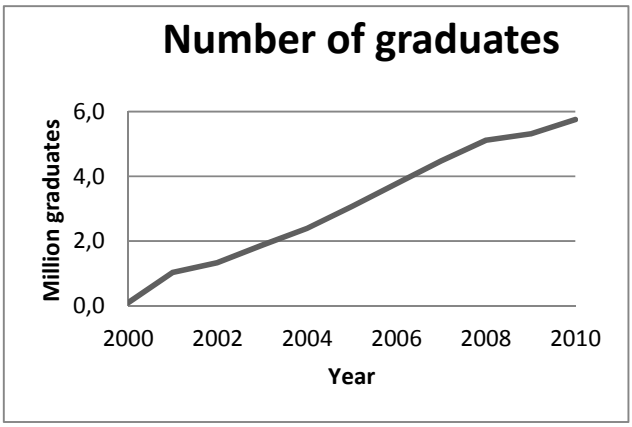

Figure 8.2: Number of graduates, including undergraduates and specialized studies, in China from 2000 to 2010 (National Bureau of Statistics, 2011).

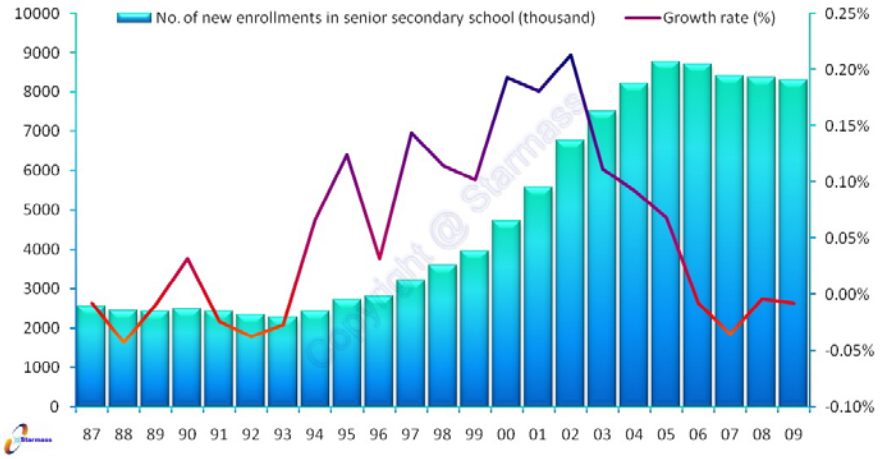

Figure 8.3: Number of new enrollments in senior secondary school in China (Starmass, 2011).

The number of children entering school is now also rapidly decreasing. According to Wang Feng of the Brookings Institution China's primary-school enrolment dropped from 25.3 million in 1995 to 16.7 million in 2008, and schools are closing down all over the country. He also expects the number of people between the ages 20 and 24 will drop by 50% during the next decade. (The Economist, 2011a)

The combined effect of the old generation retiring early and the new generation being very small is creating a talent gap, and also implies that a nation in previously unseen economic growth actually has a population that is old and declining. This trend is not only affecting the university output, but also the healthcare consumption patterns which will be discussed in section 9.1.

Another trend, however, is that the incomes are increasing and more people can afford education abroad, also because they have only one child to spend their wealth on. In 2010 6.3 million students graduated in China compared to 1 million in 1999 (The Economist, 2011a). In the past four years, the number of Chinese students in the USA has almost sextupled, and is now about 57,000. Even though India has had a long tradition of sending their youth to universities abroad, China has now surpassed both them and South Korea as the primary country of origin for foreign students in the USA. On the demand side, China produces vast numbers of highly qualified applicants whose families can afford to pay American fees. These students are reportedly not as the earliest Chinese students known for working in the library until they fell

asleep over the books, as they now have more money and are happy to spend it (The Economist, 2012c).

The one-child policy has created the 4-2-1 family structure, meaning that there are four grandparents and two parents per child, who have no other children to take care about than this one. These children have become known as ‘little emperors’, because they are so spoiled by their grandparents especially. The parents are usually working very long days, and it ends up being the duty of the often retired grandparents to look after the child, and I have anecdotally heard Chinese parents complain about their parents being too conceding with their children. When these children eventually grow up they are used to all focus being on them and the path laid clear the way a curling team will use brooms to sweep the ice for the stone. At the first challenge they meet in the working life they will just hop jobs, and many of these young people are considered practically unemployable.

In order to have a good environment for medical devices innovation, research and development, China must be able to produce young talent. With the sheer amount of people educated in China there is bound to be some hard working geniuses, but it is not obvious that China will be able to fill enough research positions to be at the forefront of development.

8.2 Frugal Innovation

There are high expectations on frugal innovation in the developing markets, particularly from India and China. Frugal innovation is a concept of making things simpler and more affordable for these markets, and potentially they will be brought back to the Western markets. Medtronic, GE and other Western companies already have R&D in China, and the idea is to develop in China for China, to utilize the ideas originating from the limited resources to develop new, simpler products.

The most famous example of this in the medical devices arena is the GE VScan ultrasound machine based on a PC which was sold for $ 7 900 when it was launched 2010 (Wasden & Mowen, 2010), whereas other handheld ultrasound systems cost $ 20 000-30 000 or traditional ultrasound may come with a price tag of above $ 100 000 (Immelt, Govindarajan, & Trimble, 2009).

One might expect these types of products to cannibalize the high end maximum functionality products previously sold, but what GE has actually seen is that the new, cheaper products are actually opening up new markets in the West. For instance, the smaller and cheaper ultrasound equipment can be sold to smaller clinics and private practitioners that would not afford buying the standard systems, and GE CEO Jeff Immelt expects it to become as indispensable as the stethoscope. Their cheap echocardiograms developed for the Indian market has also seen the same trend in the West (The Economist, 2012b).

So far, the R&D centers set up by the Western companies in China have been better at doing cutting-edge research while the local opponents have been focused on development (The Economist, 2011b). It is yet open whether the Chinese companies that have so far been market followers will be able to utilize their experiences from their home markets in developing new technologies. Mindray is about to launch a new series of patient monitors that looks, feels and is used very much like a tablet, which they claim to be the first on the market with, so they clearly have the ambition to also change medical devices innovation.

9 Trends and Events Affecting the Medical Devices Industry

9.1 Changing Demographics and Growing Middle Class

As explained in section 8.1 the demography of China has within a few decades change from a young and growing one to one that is old and in decline. The support ratio, i.e. the ratio of producing to consuming people has been rising slowly since 2000, but is expected to start declining already in 2013. By 2050 the support ratio will be 85% of what it is today (Feng & Mason, 2005). In 2005 there were 9 persons of working age to support every elderly above 65. This figure is projected to fall down to 2.5 persons per elderly by 2050 (Kaneda, 2006).

As the population ages chronic disease becomes more prevalent. This leads to a greater need of long-term care. The increased wealth and changing lifestyle has also increased exposure to major risk factors such as smoking, high-fat and high-calorie diets, and more leisure time without physical activity. The frequency of cardiovascular disease, respiratory disease, cancer and hypertension is increasing in China. The speed at which healthcare cost increases was reported to be faster than the growth of the national economy and individual earnings already in 2004 (Lee, 2004).

Out-of-pocket expenditure has increased at the same time as government spending on healthcare as a fraction of budget has decreased from32.2% in 1978 to 20.4% in 2008 (Chang, Wood, Xiaofeng, & Gifford, 2008). In 2009 China spent 4.3% of GDP on healthcare, less than half the average of the OECD countries (Knowledge@Wharton, 2009). This causes the Chinese to save a substantial part of their earnings for future expected healthcare expenses. At the same time the incomes in China has been increasing, and so has the middle class. This means that more people have more money to spend, and McKinsey has estimated the private healthcare expenditure to rise by at least 11% over the next two decades. The Chinese middle class consumers spend on average $500 annually on health care (Chang, Wood, Xiaofeng, & Gifford, 2008).

This means that the demand for healthcare and accordingly for medical

devices will grow tremendously in the coming years. However, with the decreasing support ratio it remains to see whether the Chinese will be able to support this increase in demand.

Right now the Chinese medical devices market is one of the fastest growing markets in the world (Episcom, 2011c; Episcom, 2012cn), still my personal suspicion is that the declining support ratio will cause stagnation in the market growth 10-20 years from now.

9.2 The Chinese Healthcare Reform of 2008

Currently the Chinese healthcare system is primarily composed of large public hospitals. They are run as independent companies and have a weak organizational structure, simple financial management and limited planning and organizational control (Chang, Wood, Xiaofeng, & Gifford, 2008). There is also a lack of modern equipment, 60%-70% of the hardware in the public hospitals is from the 1970s and 1980s (Knowledge@Wharton, 2009).

The government issued a healthcare reform plan in 2008 (effective from April 2009) where it allocated RMB 850 billion (USD 123 billion) over three years to improve the Chinese healthcare system. The plan was to have 90% of the population covered by health insurance by 2010 as well as to improve care facilities. The aim was to rebuild and restructure 3700 existing urban community health centers and 11,000 community health clinics and to build 2,400 new urban health centers. The idea was to pull people out of the large, overcrowded hospitals into the smaller, local clinics. Through the reform the government is also offering subsidies for hospital equipment made in China (Knowledge@Wharton, 2009).

There are so far not much written about the outcomes of the healthcare reform, but the refurbishing of the hospitals and the increased amount of hospitals gives business opportunities for the medical device manufacturers both in the short and in the long run.

9.3 Increasing Wages and Inflation in China

When asking a foreign company with medical device production in China

what their largest concern was, the answer I got was the increasing wages. It has been shown that industrial wages start to rise quickly when a country's rural labor surplus dries up, and China is very close to that right now (The Economist, 2011a). Labor-force growth will cease altogether by 2020 and turn strongly negative thereafter (Feng & Mason, 2005).

The American Chamber of Commerce believes the RMB will keep appreciating against the dollar because Chinese policymakers want to curb inflation and limit their accumulation of U.S. Treasury bonds. A rising currency makes exports more expensive. Wage increases in China and the appreciation of the RMB have already reduced the profitability of small industrial companies, and Chinese companies will not be able to utilize cheap labor to gain profits in the future (Drajem, 2011).

9.4 US Excise Tax on the Medical Devices Industry

In 2010 the US Congress passed the Patient Protection and Affordable Care Act (aka ObamaCare). Under this medical device manufacturers will have to pay an excise tax of 2.3% on revenues starting 2013. The tax is commonly referred to as the 'Tongue-Depressor Tax' and is expecting to amount to $20 billion for the entire industry over the three first years. The idea behind the act is to have more US citizens insured, hence the demand for pharmaceuticals and devices would increase, leading to revenue increases of the companies in these businesses. Hence, the tax is a means to pull back the increased revenue from the devices industry to finance the ObamaCare package. Some voices claim that the revenue increase is not expected to happen for the medical devices industry, as a lot of the people who will gain access to the new health insurance are young people with less demand for devices and additionally the former laws also required hospitals to provide medical devices to people without insurance. (Ponnuru, 2012)

Even though the tax amount may seem small, the key is that it is placed on *revenues* in addition to the taxes on profit. Professor Larry Davidson provides an example of what the effect of the tax would be on a company's income statement (Davidson, 2011):

	USD million
Revenue	40
Labor cost	10
Material, capital, energy, and other costs	27
Profit before tax	3
Tax, 25%	0,75
Net income before excise tax	2,25
Excise tax on medical devices	0,92
Net income after excise tax	1,33

The company in the example will have a profit reduction of more than 40%. This reduces reinvestment and growth opportunities, and will force the company to reduce cost. According to a study performed by the Advanced Medical Technology Association (AdvaMed), more than 10% of the jobs in the industry might be lost in the US. In 2009 there were 409,000 employees in the medical device industry in the US. The tax is estimated to double the industry's tax bill and make it one of the most heavily taxed industries in the world. As this tax will be applicable for all companies with revenues above USD 5 million independent of the income and profit taxes, this is a particular concern to smaller companies and innovative startups who are not expecting positive net income figures for several years, and the industry fears that the tongue-depressor tax will prevent innovation and lead to a poorer climate for start-ups. (Furchtgott-Roth & Furchtgott-Roth, 2011)

There are already reports that companies, such as Stryker (orthopedic implants) and Covidien (endoscopy, monitoring) are moving production out of the US to Mexico and Puerto Rico with reference to the tax. This might seem premature, but laying off is a time consuming process which will have to be started early. Other companies are also planning to increase activities abroad on expense of employment within the US. (Ponnuru, 2012)

There are forces working for a repeal of the tax, but if it is implemented this might pose an opportunity for the Chinese manufacturers in terms that they might become more attractive for outsourcing and OEM production for the US

market.

9.5 Financial Status of the West

The last years we have seen the European debt crisis unfold and several hundred billion Euros have been spent on bailing out Greece to prevent bankruptcy. The US budget deficits are as always large, and USA has not completely recovered from the 2008-2009 financial crisis. This means that the Western countries is expected to have less money to spend on healthcare at the same time as also the Western populations are growing older, and so they need to get more value for every EUR or USD they spend. This creates an opportunity for the Chinese medical device manufacturers as they are generally producing cheaper equipment with less functionality than their Western counterparts.

Part II:
A System Dynamics Model

10 System Dynamics Modeling

10.1 General Examples of Feedback Systems

System dynamics modeling is a method to describe how values of the output of a system affect the system itself. A very simple model of a dynamic system is going into the shower every morning and turning on the tap. The skin instantly senses the temperature of the water, and we subconsciously compare the measured water temperature with the actual water temperature to decide whether to turn the tap of the shower towards hot or cold. When the difference between the actual and the measured temperatures is zero we're happy and stop meddling with the water tap and the system has reached a balance. In this system we subtract the measured temperature from the desired temperature before making a decision to change the water temperature, which is showed graphically in Figure 10.1. Because of this this is called a negative feedback system, and all negative feedback systems will be self-balancing. Another example of self-balancing systems may be the number of X-ray machines in hospitals, as there is a limit to how many hospitals there are and how much they are willing to spend. In this case the amount of hospitals that already have an X-ray is the negative feedback into the system balancing the output of how many systems you can sell.

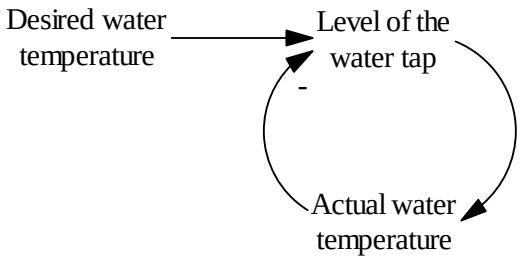

Figure 10.1: The actual water temperature is a negative feedback when adjusting the level of the water tap in the shower.

Positive feedback systems will spin out of control and break down. A good example is the Law of Laplace of wall tension in a vessel. This describes the tension of the wall as:

$$T = \frac{pr}{2t}$$

Here T is the wall tension, p is the pressure of the gas or fluid inside the vessel, r is the radius of the vessel and t is the wall thickness (Wikipedia, 2012b). The wall tension is in other words proportional to the radius of the vessel, so if for any reason the radius would increase somewhere in the vessel, the wall tension would also increase, and the stress on the wall might cause it to stretch more. The radius would then increase, as would the wall tension and the wall would stretch more, as illustrated in Figure 10.2.. This has several practical implications, an important one being blood vessel aneurysms. An aneurysm is a point where the vessel for some reason has started bulging, and as the radius here will be higher, the wall tension will be higher, causing the blood vessel too stretch at the very same point where it was already bulging. Then the radius and tension will increase more until the vessel eventually bursts, with in many cases a fatal outcome. These dynamics are also the reason why the optimal shape for large, high pressure, gas and fluid containers is a sphere.

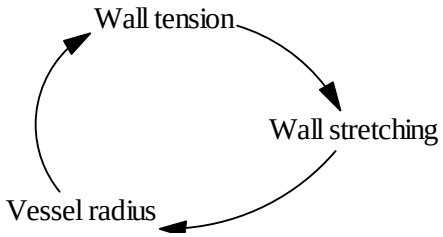

Figure 10.2: The positive feedback loop of increased wall tension causing a vessel wall to stretch.

One might also consider examples from financial systems as positive feedback loops when everybody starts believing in the same fad, be it dot-com companies, subprime mortgages or maybe right now the Apple Inc. share (The Economist, 2012a). These start with an expectation of that houses or Apple shares will keep increasing in price, and so banks lend more money to house buyers or hedge funds start buying more Apple shares. When more people get aware of the expectations and the previous upward trend, more people will start buying, thus increasing demand and driving prices upwards, again driving the signal that prices are increasing which attracts more share buyers or subprime lenders. Eventually some balancing force will kick in. The risk of the mortgages

will have become too high, defaults start, housing prices drop, and banks incur losses and increase interest rates to yield more defaults (BBC News, 2007). Market demand for tablets will be saturated or a new product will be introduced from a competitor, leading the expectations on the Apple share to drop and price will either stabilize or fall. These dynamics are immensely more complex than the shower water temperature or the wall tension dynamics described above, and would require large cause and effect maps to explain.

10.2 Business Applications of System Dynamics Modeling

Human understanding of the environment is limited, and events are often seen as sequential with straight lines from causes to effects. However, an outcome may change the environment a player is active in, leading the player to change himself, creating causal loops. This interaction between the agents over time has been described as *dynamic complexity*, and arises because systems are constantly changing as well as the agents within the systems being tightly coupled (Sterman, 2001). System dynamics modeling is applied to give a better overview of causes, effects and their mutual interaction.

System dynamics models have been developed on purely theoretical bases to illustrate market behaviors, like for instance how companies and customers may enter an industry until the market is saturated (Kunc & Morecroft, 2004; Weil & Utterback, 2005). With theoretical models computer simulations can also be run to study the outcome with different input parameters.

Another application of system dynamics modeling is to use it on an identified practical business problem or dynamics. In this case the researcher will perform interviews with parties with insight into how the problem develops, and after a series of interviews variables common to several parties will be identified and the causes and effects between the variables can be mapped. Ideally one would then also ask the same or new interviewees to confirm that the model established is valid. One area where this method has been used is to describe the relationships between entrepreneurs and venture capitalists to identify how they through honesty and frankness can improve the relationship whereas coercive control from the VC erodes trust and acceptance (Zhang, White, & Ye, 2012). Also the issue of why the pharmaceutical firms'

outsourcing of clinical research to contract research organizations has been edged by a lot of frustration and little success even though both parties believed that good performance was achievable (Azolay, Repenning, & Zuckerman, 2010).

11 Model of the Environment of Chinese Medical Devices

11.1 Method

Based on interviews and secondary research as presented in part I of this thesis, I have been able to identify several factors affecting the Chinese medical device manufactures and their venture into the foreign markets in general and the Western markets in particular. The focus has been trying to identify what is required to get acceptance in the Western markets. Both interviews in China and discussions on LinkedIn have been open-ended, so the variables of the model have been derived from issues that have been brought up in these forums as well as from secondary literature.

11.2 Full Scale Model

A comprehensive model is shown in Figure 11.1, but as this includes as many as 37 variables, it is too complex to be of any convenience. In this model I have been able to identify 3 important dynamics at play that will in turn be analyzed separately. The first one is the desired scenario when everything works smoothly and Western markets can be penetrated. The second one is the dynamics that will come into play if the products do not manage to live up to the desired quality, the quality failure scenario. The third set of dynamics is the one at play in the internal market in China, which is still the primary revenue source for the Chinese medical device manufacturers. All the variables are described in further detail in Figure 11.1 below. The minus signs at the arrows indicate an inversely proportional relationship between two variables, for instance if the average age of the Chinese population increases, more people will retire and the Chinese talent pool will decrease. These are balancing forces or negative feedbacks as discussed above.

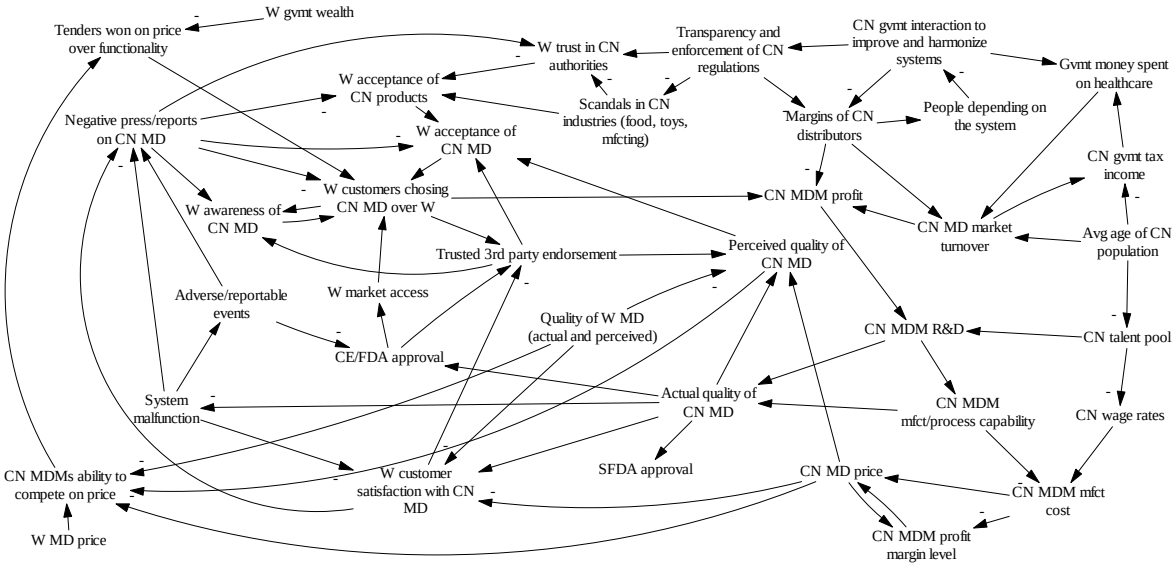

Figure 11.1: A comprehensive model of factors affecting the Chines medical devices manufacturers. Legend: CN: China/Chinese, MD: medical device, MDM: medical device manufacturer, W: West(ern).

Table 11.1: Alphabetic list of all variables of the model with descriptions

Variable	**Description**
Actual quality of CN MD	The quality (durability, safety of use, functionality, etc.) that the device actually has.
Adverse/reportable events	Amount of incidents, adverse, and reportable events in field.
Avg age of CN population	The average age of the Chinese population.
CE/FDA clearance	Whether the product can achieve CE/FDA clearance or not, a binary variable.
CN gvmt interaction to improve and harmonize systems	Amount of effort and interventions from the Chinese government to improve and harmonize legislation, regulations and enforcement.
CN gvmt tax income	Government tax income.

Table 11.1: Alphabetic list of all variables of the model with descriptions. (Cont.)

Variable	Description
CN MD market turnover	Total monetary size of the medical devices market in China.
CN MD price	Price level of a Chinese medical device.
CN MDM mfct cost	Manufacturing cost for a Chinese medical device.
CN MDM mfct/process capability	The manufacturing and process capabiltiy of the Chinese medical device manufacturer.
CN MDM profit	The profit of the Chinese medical device manufacturer.
CN MDM profit margin level	The profit margin level of the Chinese medical device manufacturer, i.e. the difference between the cost and the price.
CN MDM R&D	The amount of money and effort put into the Chinese medical device manufacturer's R&D
CN MDMs ability to compete on price	The ability of the Chinese medical device manufacturer to compete on price in relation to competitors price/value levels.
CN talent pool	The amount of employable talent in China.
CN wage rates	Wage level in China.
Gvmt money spent on heathcare	How much money the Chinese government is spending on healthcare.
Margins of CN distributors	Margin going to the Chinese distributors.
Negative press/reports on CN products	Press reports on Chinese products, including medical devices.
People depending on the system	The amount of people who get their salaries or other money throught the current distribution system in China.

Table 11.1: Alphabetic list of all variables of the model with descriptions. (Cont.)

Variable	Description
Perceived quality of CN MD	The quality (durability, safety of use, functionality, etc.) that the device is perceived by the public to have.
Quality of W MD (actual and perceived)	The quality of a similar Western device.
Scandals in CN industries (food, toys, mfcting)	The amount and severity of scandals in unrelated Chinese industries, like food, toys or other manufacturing. For example the San Lu tainted milk or the Foxconn suicides.
SFDA clearance	Whether the product can achieve SFDA clearance or not, a binary variable.
System malfunction	Some sort of unwanted, unexpected device malfunction or failure, like for instance breakdown while supporting a patient or low durability.
Tenders won on price over functionality	How frequently the buyers will be looking for good prices rather than good functionality at whichever cost.
Transparency and enforcement of CN regulations	Transparency and enforcement of the Chinese regulations, for instance the SFDA clearance process, but also IP issues.
Trusted 3rd party endorsement	Amount of independent people/organs that support and endorse the Chinese medical device.
W acceptance of CN MD	Acceptance level in the West of the Chinese medical devices.
W acceptance of CN products	Acceptance level in the West of Chinese products in general.

Table 11.1: Alphabetic list of all variables of the model with descriptions. (Cont.)

Variable	Description
W awareness of CN MD as an alternative	Awareness level in the West that Chinese medical devices exist and are a viable alternative. This is to capture positive awareness, and if the awareness is only of Chinese products as inferior and unacceptable this variable would hold a low value.
W customer satisfaction with CN MD	How satisfied the Western customer is with his/hers Chinese medical device.
W customers choosing CN MD over W	Amount of Western customers choosing Chinese medical devices over Western.
W gvmt wealth	How much money the Western governments have to spend.
W market access	Amount of Chinese medical devices that are actually sold in the Western markets.
W MD price	Price level of a Western medical device.
W trust in CN authorities	The amount of trust the Western public has in the Chinese authorities, legislation, regulations and law enforcement.

11.3 The Desired Scenario

The desired scenario occurs when the Chinese medical device manufacturers are able to produce at the quality levels required and expected in the Western markets. This is the good place to be, and is the desired scenario of all the Chinese medical device manufacturers aiming at the Western market. After eliminating all variables relating only to the internal Chinese markets and the dynamics that will come into play if the products fails to hold the expected quality, the desired scenario can be illustrated as in Figure 11.2.

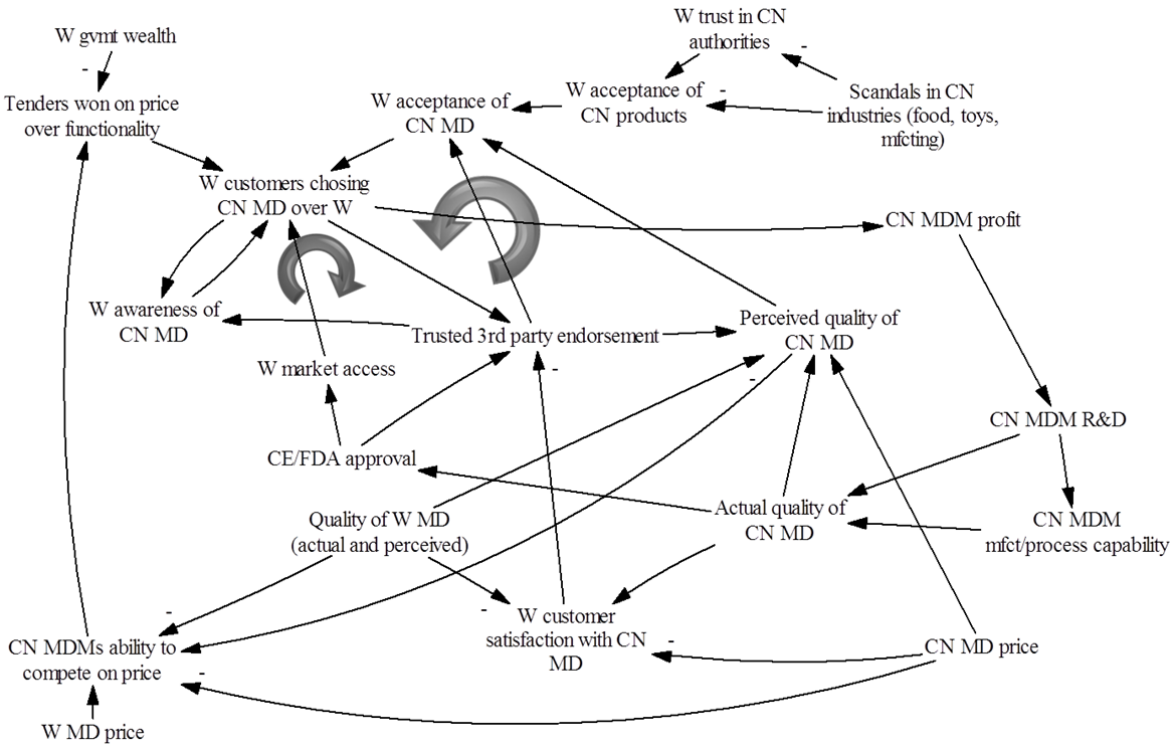

Figure 11.2: System dynamics if the Chinese medical devices are always at the required quality level. The grey arrows indicate word-of-mouth cycles that will start spinning if the Chinese companies are able to deliver at the expected quality level.

In this scenario the primary dynamics is that the Chinese medical device manufacturers deliver at a good quality, and the products will eventually penetrate the market. If the quality holds there will be a word of mouth cycle with the first market access through the CE/FDA clearances and then as some customers buy Chinese awareness will increase, more 3rd parties will start endorsing the products and acceptance will also increase.

The correct approvals are, however not what will initially drive the push towards Chinese products, that is rather the budgetary constraints of the Western governments. Parts of Europe is on the verge of bankruptcy and the US federal debt in relation to GDP is at its highest level since WWII (Congressional Budget Office, 2011), hence the demand for more affordable products is increasing and the era of buying the latest functionality at any cost is over.

In this scenario one should not dismiss the effect of competition. The quality and price of the Chinese devices will be compared to the ones of the incumbents, and the Chinese products cannot go too low on either. A too low

price will erode the perceived quality, as people expect cheap products not to last. Also, if quality in any way (durability, functionality, safety) is inferior to that of the competitors, the customer satisfaction will start dropping.

The influence of the CE/FDA clearance on the 3rd party endorsement is very weak. Having a CE/FDA clearance is required to enter the Western markets, but is a hygienic factor and not of any marketing value. The leading companies like Siemens or GE will not even mention their accreditations, whereas Chinese companies will typically list their accreditations on the 'About us' or 'Milestones' sections of their homepages. For the Chinese companies it might be necessary to state this as it might otherwise be doubted that they even have the CE/FDA clearances, but the large Western companies already have such a high trust that their approvals are implicit.

The most important damping factor for the penetration into the Western market is practically out of the Chinese medical device manufacturers' control, and that is the general perception of Chinese products in the West. This means that problems in unrelated industries may undermine the reputation of the Chinese products to a degree where people also refrain from buying medical devices. One example of this happening has been the San Lu melamine-tainted milk scandal (Lu & Tao, 2009). Even though the public is becoming aware of a lot of high quality electronics actually originating from China, this has also been edged with several reports of labor exploitation, and there have been large reports and discussions about how Apple is able to keep prices down as the workers in the Foxconn factories assembling the products are working inhumane hours. This has recently come in addition to the earlier reports of suicides in the Foxconn factories (Duhigg & Barboza, 2012). These events and stories of difficulties in sourcing from China are affecting not only Westerners trust in Chinese products, but also the trust in the Chinese authorities as these incidents make them seem incapable of protecting their own people.

Spillover effects from unrelated industries like this are not seen in the Western markets. The recent PIP implant scandal, where it was discovered that a French company had been using industry grade rather than medical grade silicone in their breast implants resulting in ruptures and potentially cancer, caused outrage among patients and public (NHS, 2012). The criticism was

directed at the authorities, who didn't discover and stop this earlier, but the general trust in French manufacturers is not much affected by this scandal.

11.4 The Quality Failure Scenario

If for some reason the Chinese products would fail to meet the desired and expected quality, the repercussions of the market would be severe. Failure in this sense would for instance be an orthopedic implant that only lasts for 5 years whereas the Western brands last for 15-20 years. There might also be direct adverse events where the patient is or could potentially be harmed. It is worthwhile noticing that product recalls and adverse events do occur even for the high end brands. Just this February there was a global recall of one of Philips' patient monitoring systems as it failed to transmit an alarm about a potentially dangerous condition (MHRA, 2012), and in 2010 the orthopedic implant brand DePuy owned by Johnson & Johnson issued a voluntary recall of 93 000 metal hip implants of the ASR series produced since 2003 and many patients have been both re-operated and reimbursed as it was discovered that too many patients needed revision within 5 years of receiving the implant (DePuy, 2011; Depuy Hip Replacement Lawsuits, 2012). The system dynamics for a Chinese company if any product failure should occur is illustrated in Figure 11.3.

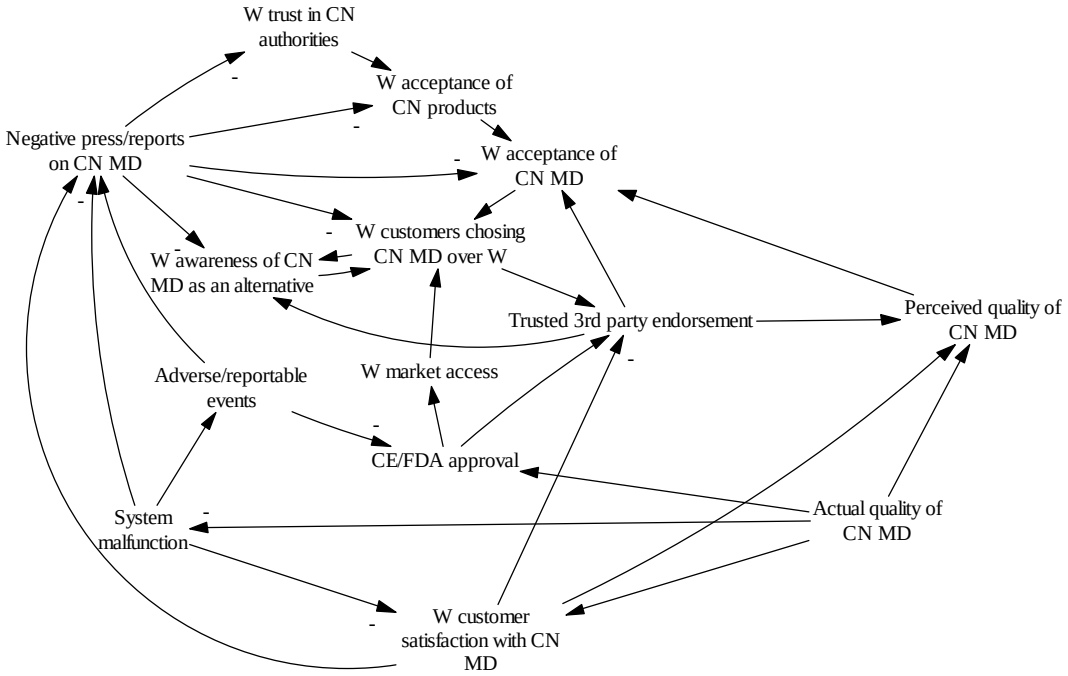

Figure 11.3: The dynamics of the markets if a system malfunction is introduced.

What we see in this scenario is that a system malfunction will as expected reduce the customer satisfaction, and in the case of adverse and reportable events the CE/FDA clearance might be revoked and the product has to be taken off the market. There may also be negative press. This is no different from the scandals of the Depuy or PIP dimensions described earlier.

What is unique for the Chinese manufacturers is the spillover effects between products and companies. Negative press on Chinese products will cause the already existing skepticism towards Chinese products to increase, hence negative press on one type of device will probably lead to problems for other devices, and press on unrelated products also leads to image problems for the medical devices. Any report of product failure in medical devices will lead to a sensation that this is what you get when buying from China. “I told you so.”

Another effect of negative press is that it undermines the trust in the authorities responsible for overseeing manufacturing and safety. The public will always ask why somebody didn’t intervene to protect them. In the case of China general reports of poor working conditions, pollution, corruption, Western (often naïve) buyers being cheated by their Chinese suppliers, and poor transparency in supply chains build the impression that the Chinese authorities do not have the situation in the home market under control. Any reports of

malfunction in Chinese medical devices will add to this Western distrust in Chinese authorities, which in turn leads to less acceptance of Chinese products.

11.5 The Dynamics of the Internal Chinese Market

In both of the previously presented scenarios the Western trust in the Chinese authorities plays a role. It is also seen that the Chinese companies compete on price, but they cannot do that on the expense of quality in the Western markets. The foundation of their ability of competing on price with reasonable quality is the resources they have in the home market. For these two reasons, the potential entry of Chinese medical device companies into the Western markets cannot be analyzed without also analyzing the situation in China. A system dynamics map for this is given in Figure 11.4 below.

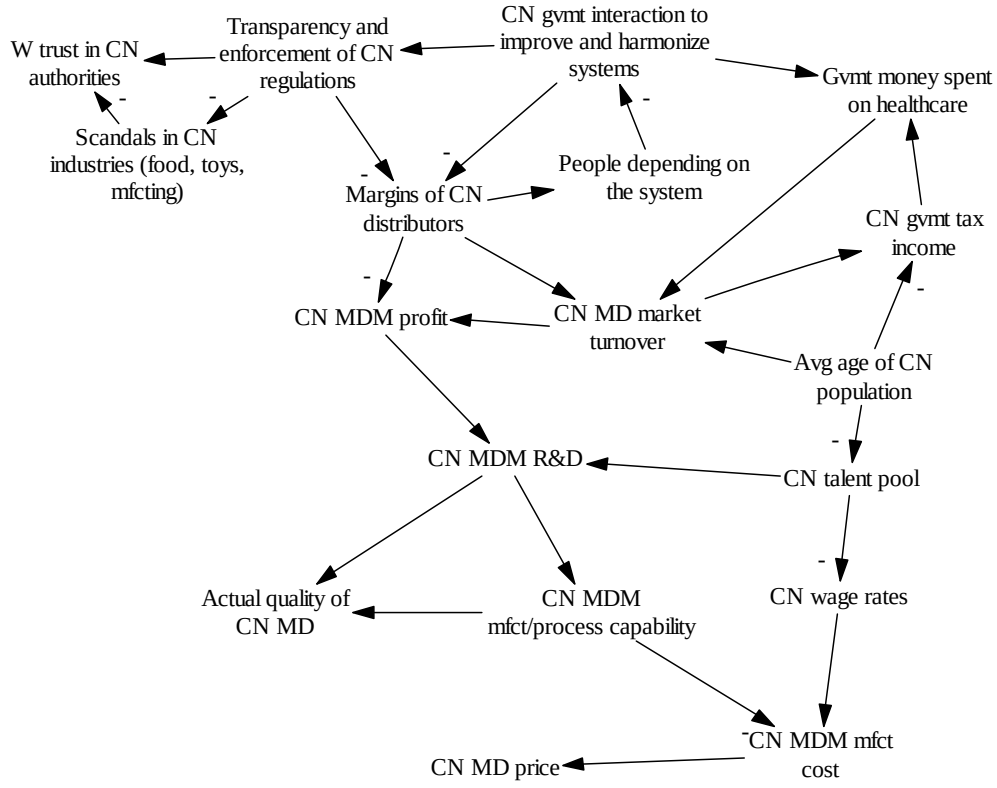

Figure 11.4: Dynamics of the internal Chinese medical device market.

The variable ‘Government interaction to improve and harmonize systems’ is a very general one, but it is the only one leading towards more general trust in the Chinese authorities in the West. As long as for instance the SFDA is

deemed intransparent, unpredictable and possibly even corrupt, the SFDA accreditation will have no value in the Western markets. Change of this has to come from within, but the question is whether the change has to be initiated by the government itself or if it should be driven by the market players.

When asking one company if they think they could influence the authorities to harmonize systems and improve law enforcement, they said that there were too strong forces working against changes, as there are too many people dependent on the systems as they are. One example here is the Chinese medical devices distribution system where there are so many distributors and potentially as much as 60% of the profits end up in distribution. Clearly a vast amount of people earns their livelihood from this, which is a significant damping force on system change.

Another issue, possibly the greatest overall problem in China, is the increasing average age of the population. This creates problems for the Chinese medical device manufacturers in several ways. As mentioned earlier the enrollment to primary schools is in rapid decline and the output of the secondary schools reached its peak in 2005. This effect has not yet penetrated through to the universities, but is likely to do so soon. In general the low birth rates and increasing average age of the population makes recruitment difficult. As industrial China keeps growing this also means that the competition over talent is increasing. These factors contribute to wage increases. This means that in the future the Chinese medical device companies will not only have difficulties recruiting the staff required to keep production and quality up, the cost of production will also increase with increasing wages.

The Chinese medical devices markets are forecast to grow quickly. However, there are clouds even on this sky. As the population grows older there will be a higher requirement for medical devices, but as the hospitals are mainly government funded, the question is whether the government will be able to keep healthcare budgets on a high level. The Chinese hospitals are still being improved as a result of the 2008 healthcare reform but this reform is soon to an end. Private hospitals are still scarce, and even though they were more available and more widely used, it is questionable whether, with the 4-2-1 family structure in China, the young would be able to afford buying care for their

parents and grandparents. Even though in the short term the Chinese market will grow as it is today so underserved, in the long run the question is whether China will grow rich or old first.

The implication of this is that the Chinese medical devices companies might be in a hurry to generate revenue in the foreign markets to compensate for the increasing costs at home and to ensure a steady revenue stream from more than their home market, where growth will eventually come to an end.

It is worthwhile noticing that in none of the three portrayed scenarios the SFDA clearance plays a significant role. It is required for entering the Chinese markets, but has no marketing value whatsoever.

12 Conclusions

The road to internationalization for the Chinese medical devices companies is not an easy one. There is low trust in Chinese products in general, and as the Chinese medical device manufacturers have a short history they have not yet been able to build their brands in the foreign markets. The Western perception of everything made in China being of bad quality is a major obstacle, and the Chinese medical devices manufacturers are affected by negative press on products and events unrelated to their industry.

We are now seeing the first Chinese companies successfully marketing their products abroad, and they are selling products that have simpler features but good quality, and so they are sold at lower prices than the high end products of the large, Western device companies. The Chinese companies are well aware that the quality, i.e. durability, ease of use and product safety, must be at least at the same level as other products sold in the Western markets. If they are able to produce high quality, low feature products at reasonable prices the current economic downturns in the Western world poses great opportunities for the Chinese companies. However, if quality were to fail, repercussions from the Western users and public would be hard.

The Chinese authorities have a role to play in improving transparency, regulations and law enforcement within China, as the Western perception of products made in China is linked to the trust in the Chinese authorities' ability to control their internal market.

Even though China has a large population, the medical device market of China is only around 10% of the size of the US market. This means that for continuous growth, the Chinese manufacturers should look outside China. If they are able to deliver high quality products, they will slowly gain acceptance and market share. The prospects for the best of the Chinese companies are good.

13 Suggestions for Future Research

The model presented in this thesis has only been through one iteration, i.e. the model has been built but it has not been presented in full through anyone in the industry for verification or adjustments. To improve and verify the model one should perform a second series of interviews.

Further on, the Chinese medical devices industry is very fragmented and there are great differences between different sections. Diagnostic devices like ultrasound or X-ray machines might have an easier way into the western markets than clinical devices such as implants or anesthesia machines. There are also big differences between class I, II and III devices. I have also found that there is a big difference in maturity between the Chinese manufacturers, from the ones who want to go abroad but are not even able to have their documentation translated to the ones that are making strategic acquisitions abroad and are contemplating whether to move from product centric to emotional marketing in their international campaigns. As the Chinese industry is so diverse, one might want to focus a specific sub-group.

This thesis is focused on the challenges for the Chinese companies venturing abroad, but it also includes several references to and information about the internal Chinese environment. One could use and build on this information to create a similar model for foreign companies doing business in the medical devices sector in China.

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Appendix A: List of Chinese Medical Device Manufacturers

On the following page is a list of the Chinese medical device manufacturers I have been looking at for this study. Information about these companies has been acquired from their homepages, through secondary sources and in some cases through interviews with employees.

As there are more than 3000 Chinese medical device companies the list is not in any way comprehensive, but covers the ones that have gained the most attention in international press. The information has been collected from the companies' homepages and annual reports and in a few cases through personal communication.

Appendix A: List of Chinese Medical Device Manufacturers

Company Name	Location	Homepage	Products	Listing	Intl sales	Foreign liaison	Employees	Revenue mUSD
AccuBiotech	Beijing	accubiotech.com	IVD, tests, fertility, drugs, lab equipment	-	Sales in 50+ countries		50-99	1-9
Anke High-tech Co., Ltd.	Shenzhen	anketech.com	MR/CT	-	Middle East, Europe	Analogic (primary shareholder)	200-500	50-100
China Medical Technologies Inc.	Beijing	chinameditech.com	In-vitro diagnostics	NASDAQ (CMED)	Global		971	129
Dehaier	Beijing	chinadhr.com	Homecare, X-ray, anesthesia, ventilation	NASDAQ (DHRM)	Homecare in Romania		150	23
Edan Instruments	Shenzhen	edan.com.cn	Monitoring, US, ECG	SZSE (300206)	120 countries		854	59
Golden Meditech Co. Ltd.	Beijing/HK	goldenmeditech.com	Blood related, infusion pumps	HKSE (801)			414	42

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Company Name	Location	Homepage	Products	Listing	Intl sales	Foreign liaison	Employees	Revenue mUSD
Hong Shen	Beijing	hongshengroup.com	Bleeding stop/washing, also pharma	-			3 600	
Huger	Shanghai	huger.cn	Endoscopy	-	CE marking, selling in Europe, South America, Middle East		50-100	5-10
Kanghui	Changzhou	kanghui.com	Orthopedic implants	NYSE (KH)	28 countries		742	52
Lepu Medical Technology (Beijing) Co. Ltd	Beijing	lepumedical.com	CV, stents	SZSE (300003)	South America, M East, Poland	Dealer of foreign equipment	1 000	122
Libeier	Beijing	libeier.com	Orthopedic implants	-		Acquired by Kanghui		
MicroPort Scientific Corporation	Shanghai	microportmedical.com	Stents, CV	HKSE (853)		Office in NL	1 204	133

Appendix A: List of Chinese Medical Device Manufacturers

Company Name	Location	Homepage	Products	Listing	Intl sales	Foreign liaison	Employees	Revenue mUSD
Mindray	Shenzhen	mindray.com	Monitors, US	NYSE (MR)	Global, 30+ foreign offices	Acquired US Datascope and others	6 000	700
Naton Medical	Beijing	naton.cn	Orthopedic implants	-	Middle East, South America	Acquired Finnish Inyon	2 300	400
Neusoft Medical Systems	Shenyang	medical.neusoft.com	Imaging, CT, MRI, US	SHSE (600718)	Global subsidiaries	JV with Philips	20 000	781
OrbusNeich	HongKong	orbusneich.com	Stents, CV	-	Distribution in 60 countries	HK based Acquired US Orbus	500	30
Red Eagle	Beijing	readeagle.com.cn	Anesthesia, ventilation	-	Developing markets	Cooperation with US UCA, an OEM supply chain specialist		
Shanghai Medical Co., Ltd.	Shanghai	smicc.com	OR, anesthesia, vent, endoscopy	Conglomerate: SHSE(600607)	SE Asia, Africa, East Europe and South America			

Appendix A: List of Chinese Medical Device Manufacturers

Company Name	Location	Homepage	Products	Listing	Intl sales	Foreign liaison	Employees	Revenue mUSD
Shanghai Viscon Medical Electronics co	Shanghai	weishikang.com	US, CT, endoscopy, diagnostics	-		Seeking global distributors		
Shinva Medical Instrument Co.	Shandong	shinva.com	Sterilizers, radio therapy, X-ray	SHSE (600587)	Middle East, Asia, South America	JV with GE	2 300	212
SinoMDT	Shenzhen	en.sinomdt.com	CT, Mammography, infusion pumps	-	Middle East, SE Asia, Europe, N/S America	Offer OEM	51-100	
Sunny medical	Shenzhen	www.sunnymedical.com.cn	Guide wires, syringes, CV	-	CE marking	Offer OEM	51-100	1-25
Trauson	Changzhou	trauson.com	Orthopedic implants	HKSE (325)	South America, Middle East, Eastern Europe and Southeast Asia During		1 047	61
Tyoptics	Shanghai	tyoptics.com.cn	Ophthalmic, optometry	-		Offer OEM	101-200	
URITest	Guilin	urit.com	IVD, urine/blood analysis	-	CE/FDA More than 100 countries		572	10-49

Appendix A: List of Chinese Medical Device Manufacturers

Company Name	Location	Homepage	Products	Listing	Intl sales	Foreign liaison	Employees	Revenue mUSD
Wandong	Beijing	wandong.com.cn	MR, X-ray	SHSE (600055)	FDA, CE approved		981	93
Weigao Group Medical Polymer Co. Ltd.	Shandong	weigaogroup.com	Consumables, needles, stents, orhtopedics	HKSE (1066)	More than 30 countries	Orthopedics JV with Medtronic	7 875	503
Wuxi Xinda Medical Equipment	Wuxi	xinda-medical.com	Surgical blades	-	Several countries		>1000	25-5

Resume

1976.12.20	Born in Trondheim, Norway.
1995.8-1999.12	Master of Science Norwegian University of Science and Technology, Trondheim, Norway
2000.5-2004.9	PhD Royal University of Technology, Stockholm, Sweden.
2004.10-2005.2	Karolinska Institute, Stockholm, Sweden
2005.4-2010.5	Maquet Critical Care, AB, Stockholm, Sweden.
2010.8-2012.7	Master of Business Administration Tsinghua University, Beijing, P.R. China