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# **EXPORTING FINNISH MEDICAL DEVICES TO CHINA**

**Focusing on small and medium-sized enterprises**

Master's Thesis  
in International Business

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## **ABBREVIATIONS**

B2B	Business to Business
CAMDI	China Association for Medical Devices Industry
FDI	Foreign Direct Investment
GDP	Gross Domestic Product
GEIP	Government Employee Insurance Program
HE	Health Expenditure
IPR	Intellectual Property Right
IVD	In-vitro Device
KELA	Kansaneläkelaitos/Finnish social insurance institution
LIP	Labor Insurance Program
M&A	Merger and Acquisition
NHCPR	New Health Care Program Reform
NRCMS	New Rural Cooperative Medical Scheme
OECD	the Organization for Economic Co-operation and Development
R & D	Research and Development
SFDA	State Food and Drug Administration
SMEs	Small and Medium-sized Enterprises
TCM	Traditional Chinese Medicine
WHO	World Health Organization
WTO	World Trade Organization





# 1 INTRODUCTION

This chapter includes three sub-chapters: global health care industry today, springing up of health care industry in China, and the purpose of research and the structure of this thesis.

## 1.1 Global health care industry today

During the past decades, the health care industry has been globalizing and modernizing, and it has become one of the world's largest and fastest-growing industries (Comparing Projected Growth... 2006). Health care industry mainly focuses on treating and tending to patients who are injured, sick, disabled or infirm (Health Care 2007), and the technology suppliers like the medical facilities and producers of devices are also being considered as a part of the health care industry. At present, more and more new technologies are used in the health sector and the budget for health care has been increasing in most countries. Health care has an important position in the country's economy in many developed countries (OECD 2003). In 2007, for the OECD countries the average of health expenditure of GDP was about 8.7 percent with the United States (16%), France (11%), Switzerland (about 11%), Germany (about 10%) and Belgium (about 10%) being the top five (OECD 2010). The total expenditure on health of GDP was 8.2% in Finland (OECD 2010; World Health Organization 2010, 132), and 4.3% in China (World Health Organization 2010, 130).

According to IMS 2008 global pharmaceutical and medical market forecast, in 2008 the global pharmaceutical market was increased at the growth rate of 5% - 6% (1% low comparing to 2007), and will reach US\$ 73.5 – 74.5 billions and the annual sale of drugs of facing patent expiration will be about US\$ 200 billion. The drugs with patent expiration will lead generic drugs' market to 14% - 15% of the growth momentum, reaching more than US\$ 700 billion. The aging population is one crucial cause of development of global health care industry. The most recent plans of the OECD suggest that the aging population will create a rise in age-related social expenditures from an average of under 19% of GDP in 2000 to almost 26% of GDP by 2050, with old-age pension payments and expenditure on health care and long-term care each responsible for approximately half of this increase. (Dang et al. 2001) However, according to OECD Health Data in 2008, the spending on health care is growing slowly in many OECD countries since 2003<sup>1</sup>. The global health care market is still slowing down because of the

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<sup>1</sup>Before the year of 2003, especially during the period of 2000-2003, the health care expenditure increased rapidly in OECD countries with an annual average growth rate of 6.2% (OECD 2008).

efforts to reduce the growth of health care costs, greater use of generic drugs and other regulatory barriers that make it harder for enterprises to bring new drugs to the markets, as well as safety issues that have led to product withdrawals. The health expenditure share of GDP on average of 8.9% across OECD countries remained unchanged in 2006 comparing to in 2005. A slow growth of pharmaceutical spending is the main reason why the increment of the whole health care expenditure is stagnant. (OECD 2008)

For all that, more innovative health care products, including new health care technology, new medical devices, and new medical drugs, are still strongly demanded. They play an important role in the current health care industry.

## **1.2 Springing up of health care industry in China**

While the health care spending grows slowly in OECD countries, the health care industry has been developed rapidly in China. China is emerging as a fast-growing health care market with a two-digit annual growth rate since 1990. Pharmaceutical sales in China grew by circa 20% to US\$ 11.7 billion in 2005 and the sales of medical devices also grew at a similar rate and reached US\$ 6.8 in the same year. China is now the second largest market of medical devices in Asia, just behind Japan (Liu & Lundin 2007, 4). Moreover, China is also forecasted to become the 5th largest drug market by 2010 and foreign firms may control half of Chinese market. Since the demand for health care is increasing rapidly, it leads to more international collaborations or co-operations on products' R&D. Many countries see China as their main export market of the health care products including medicine, medical devices and instruments. (IMS 2008 Global pharmaceutical... 2007) With more advanced research of medical products in the U.S.A. and many Western countries, China is becoming the second largest exporter of medical products (Biggs 2005; Liu 2004, 38). The amount of exports and imports of Chinese health care products has continuously maintained a rapid growth rate since 2007. Chinese medicine market is expanding and the environmental investment is also expanding. These facts promote that many foreign enterprises enter the Chinese market. Hence, a stronger international competitiveness has become a fact in China. (Investment and Forecast Report...2009)

Many foreign enterprises want to export their products to China. The main reasons are that China has a lucrative market at the bottom of pyramid (Jiang 2008), and population is aging (Li 2008; Tang et al. 2008, 1494), as well gross national product (GNP) is increasing. In addition, according to Chinese innovation system, more research on health care products or services is emphasized by Chinese government. Thus, the government will provide support in relevant policies. These prior policies have attracted lots of health care enterprises from foreign countries such as the U.S.A, Switzerland,

Germany and France. It means there has been a fierce competition in the Chinese market of health care. (SFDA 2008) In the past few years, when some Finnish enterprises have launched their products into the Chinese market, China has started to pay attention to Finnish health care products. Finland is one of innovation leaders in the global health care industry, especially in the field of biotechnology, diagnosis and medical devices. As one of the top biotechnology countries in Europe, Finland is 6<sup>th</sup> on the ranking list behind the UK, Germany, France, Holland and Sweden. There are many biomaterials for health care use which have been developed successfully in Finland, e.g. tissue engineering, drug delivery, implants and x-ray therapy equipment (image intensifier). Most Finnish biotech products could be called innovative health products. With the growth of business collaboration in the health sector between Finland and China, these innovative health care products not only compensate the limitation of homogeneous products, but also cover market niches in China. (TEKES 2003)

### 1.3 Purpose of research and structure of thesis

Werner (2002, 277) says that international entry modes are the third most researched field in international management at the moment, foreign direct investment and internationalization are ranked as the 1<sup>st</sup> and 2<sup>nd</sup> position respectively. Some studies provide theories and conceptual frameworks on entry mode choice, for example, *transaction cost* (e.g. Cheng 2008; Chang & Rosenzweig 2001); *culture and cultural distance* (e.g. Sun 1999); *control theory* (e.g. Osland et al. 2001); *internationalization theory* (e.g. Ekeledo & Sivakumar 2004); *risk factor* (e.g. Osland et al. 2001; Sun 1999); *resource-based* (e.g. Park & Sternquist 2008); *organizational competitive capabilities* (e.g. Cheng 2008); and *knowledge consideration* (Chang & Rosenzweig 2001).

However, most of these researches have a limited viewpoint as they only examined conceptual frameworks or specific theories and their measures (Canabal & White III 2008, 267). Until 2006 the first three positions on all industries or sectors examined in entry mode research are multiple manufacturing or service, manufacturing, and service respectively, following chemical, computer software, hotels, other specific service, electronic and other specific manufacturing (Canabal & White III 2008, 275). The United States, Japan, Great Britain, the People's Republic of China and Western Europe are countries which were studied in entry mode research (Canabal & White III 2008, 274-275), among of these countries, China is ranked on the 8th place (home countries studied) and the 3rd place (host countries studied). For service firms, Blomstermo et al. (2006, 212) indicate that they may enter foreign markets using same entry modes as manufacturing firms, for example, exports, licensing, joint ventures, or establishing a subsidiary abroad. But, it is too large topic to discuss international entry modes of Fin-

nish manufacturing and service enterprises simultaneously on this paper. Therefore, this study only discusses the entry modes of Finnish enterprises manufacturing medical devices, and entry modes for Finnish service enterprises are excluded.

As described before, crucial gaps are observed in the literatures. Firstly, articles concerning medical devices between Finland and China in entry mode research are quite few, although there are lots of articles concerning entry modes, most for manufacturing such as auto, chemical and electronic. Secondly, most mentioned influencing factors to entry modes are control, transaction cost economics, culture, uncertainty and competition (e.g. Chang & Rosenzweig 2001; Sun 1999). Main factors influencing Finnish SMEs entering the Chinese market are less described. Thirdly, Finnish SMEs' marketing mix in China is also less discussed. Thus, the purpose of this research is *to study how to export Finnish medical devices to China*. Besides, in this study, the business-to-business (B2B) marketing mix of products is discussed since end customers are Chinese distributors, retailers or wholesalers in the field of medical devices, and Chinese hospitals. Circa 99.7% of Finnish enterprises are SMEs (SBA Fact sheet Finland 2007). According to Finnish Life Science Organizations Listed (2008), the amount of enterprises manufacturing medical devices in Finland is 21 involving only one large enterprise, which has over 250 employees. In other words, 20 enterprises belong to SMEs. This is why only the medical device SMEs are discussed under B2B marketing in this study.

The main objective of this study is discussed through three sub-objectives as follows:

- To describe main factors influencing Finnish medical device SMEs on the selection of entry modes to China;
- To discuss main entry modes for Finnish medical device SMEs to enter the Chinese market;
- To analyze the adaptation of marketing mix for Finnish medical device SMEs on the Chinese market.

The theoretical part of this study will be collected from literature reviews, electronic articles from published books, journals, magazines and the official websites of Finnish and Chinese institutions. Empirical data will be collected through the qualitative research method by a case study of a Finnish SME in the field of in-vitro devices (IVD). This thesis consists of three main theoretical chapters, Chapter 2 to Chapter 4. The whole structure of thesis is presented next page.

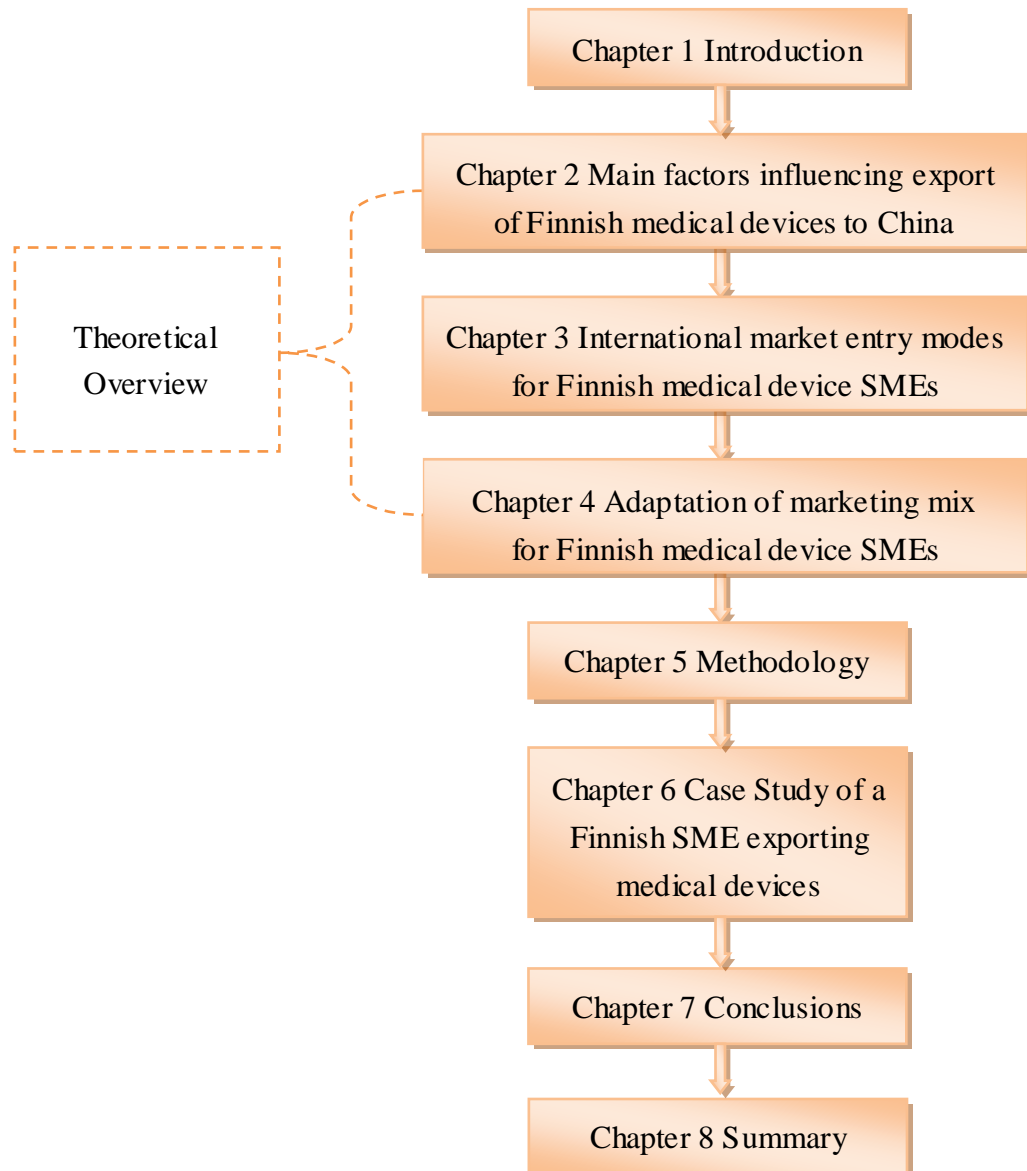


Figure 1: Structure of thesis

As shown in the Figure 1, main factors affecting the export of medical devices to China are presented after the chapter of introduction. They include Chinese health care system and regulations concerning medical devices, Chinese medicine culture and integration of Chinese and Western medicine cultures, current Chinese market situations of medical devices, as well as resources factor from Finnish SMEs. In chapter three, international market entry modes are discussed in detail. In the fourth chapter, different theories of ‘marketing mix’ for medical devices are reviewed primarily. Generally 4P’s marketing mix (i.e. product, place, price and promotion) is known widely. However, there are still other ‘marketing mix’ theories such as 6Ps - 10Ps marketing theory on the basis of 4Ps, 4Cs marketing theory and 4Rs marketing theory. How is marketing mix

for Finnish medical device SMEs adapted in the Chinese market? This problem is further discussed. The fifth chapter presents the methodology of qualitative research. In this part, research approach, case selection, data collection, data analysis and research evaluation are discussed respectively. A case study in chapter six presents how to export more effectively and efficiently medical devices by a Finnish SME manufacturer to China.

## 2 MAIN FACTORS INFLUENCING EXPORT OF FINNISH MEDICAL DEVICES TO CHINA

*‘If you know the enemy and know yourself, you need not fear the result of a hundred battles. If you know yourself but not the enemy, for every victory gained you will also suffer a defeat. If you know neither the enemy nor yourself, you will succumb in every battle.’<sup>2</sup> (Sun Tzu 6<sup>th</sup> century BC<sup>3</sup>, 10<sup>4</sup>)*

China is a huge market for medical devices. Many multinational corporations and SMEs from OECD countries want to export their various health care products to China in order to gain a profitable market position. However, it is impossible for all enterprises to enter the Chinese market successfully. In this chapter, there are mainly two types of factors discussed: micro factors (resources of SMEs) and macro factors (China). From an angle of industry-level view of international entry modes, macro factors directly influence launching foreign medical devices into China (cf. Albaum et al. 2002, 412). Many Finnish enterprises may be not familiar with these macro factors, therefore failures may occur. The macro factors may be summed as Chinese health care system, Chinese medicine culture and current situation of medical device market in China, for example, market size, market competition, structure of distribution, government regulations on medical devices, and Chinese import regulations (cf. Ekeledo & Sivakumar 2004, 68-90). Since this study researches how to export Finnish medical devices to China, basic data of China and Finland are referred in Appendix 1. This basic data include country profile, GDP, health expenditure, life expectancy, and export and import of goods and services.

### 2.1 Chinese health care system

Chinese health care system is different from Finnish health care system. Before Finnish SMEs export medical devices to China, the health care system should be learnt. The health care system involves some hidden information, for example, insurance programs and health care development in the future, which may influence directly or indirectly the import of medical devices to China, as well may influence on the selection of entry

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<sup>2</sup>This idiom is written in the Chapter 3 of the Art of War by Sun Tzu.

<sup>3</sup>The name of dynasty is called ‘the Spring and Autumn period’ in China.

<sup>4</sup>The page number is according to the translated edition of ‘Sun Tzu on the Art of War: the oldest military treatise in the world’ by Lionel Giles, M.A. in 1910.

modes and setting price for Finnish medical devices. Hence, an overview of Chinese health care system is expounded here.

### ***2.1.1 Features of health care system***

Recently, the health care system is dominated by Chinese central government. The Ministry of Health manages the system, directs the research, makes the policy and supervises the implementation of government policies. (Haruo 2007, 1; Gu 1999, 203-204) Since 1949 the goal of health care programs has been to provide health care to every citizen through using limited health care personnel, medical devices/equipment and financial resources. China achieved enviable improvement in the health status of its people between 1952 and 1982 and was internationally recognized as a superior health performer (Hsiao 1995, 1047; Tang et al. 2008, 1496-1497). With changing economic system from plan-orientation economy to market-orientation economy in the 1980s, a long-term transformation of Chinese health care industry including health care system reform was implemented at the beginning of the 1980's too. In the last twenty-five years, Chinese government's health care expenditures have dropped from 36% to 15%, with the burden of managing this decrease falling largely on the patients. (Yuan 2007, 49)

The latest health care system reform in China happened in 2002. The central government has decentralized more power to the provincial governments. Health care policy followed economic policy. China made three major policy changes in health care. First, the government had to limit the public funds available for health care because of the drain in its budget resulting from the large losses incurred by state enterprises. Second, the government altered financing of hospitals and township health centers, giving them a large degree of financial independence. Consequently, hospitals use more drugs to generate greater profits. Finally, the government liberalized the private ownership of medical devices and private clinical practices. Until now, a small proportion of state-owned hospitals have been privatized; private ownership of medical devices and clinical practices are allowed due to Chinese economic reform; and privatization of health care and foreign investment in hospital (up to 70% ownership) has been encouraged (Yuan 2007, 50). Private investment in new hospitals, especially in the form of foreign joint-ventures, is encouraged and is promoted by allowing them to charge much higher fees, sometimes 10-20 times more than what is allowed for public hospitals. The tax relief to privatization is offered by the government during the period of first three to five years. (Chu & Rask 2002, 20-21; Hsiao 1995, 1051-1052)

Some local health care programs has been launched, for instance, a proposed health care reform was performed in Shanghai. The financial cooperation on medical care program was performed in the rural sector before the year of 2005 (Carrin et al. 1999, 961;



Hsiao 1995, 1049-1050). Since the rural cooperative financed Medical Care program had virtually ceased to exist after 1993 (Chu & Rask 2002, 19-21), the Chinese government initiated a project to re-establish the Rural Cooperative Medical Scheme (RCMS) in March 1994. The re-established RCMS was planned to be a joint financial effort by government, the villages and the rural population to meet the basic health care needs (Carrin et al. 1999, 962). But, many rural patients under this re-launched RCMS could not still afford the high medical expenditure. Hence, a New Rural Cooperative Medical Scheme (NRCMS) was launched in 2003, and it aimed particularly to reduce risk exposure and to provide more affordable medical services using medical devices for the rural poor (Wagstaff et al. 2009, 2). According the Ministry of Health announcement, under the NRCMS, the proposition of annual cost of medical expense is depending on the age-group of patients and tiered of hospitals. In September 2007, about 80% of the whole rural population of China had signed up the NRCMS (Wagstaff et al. 2009, 5-10). The system is divided according to the location. If patients go to the third-class hospitals in their local town, the scheme will cover 70-80% of their bill. If they go to the second-class hospitals (also called municipal- or country-level hospitals), the percentage of the cost coverage is about 60%. And if they see consultation of specialists in the first-class hospitals, which are located in large modern cities (such as Beijing, Shanghai and Guangzhou), they have to bear most of the cost themselves. The scheme would cover about 30% of the bill. (Carrin et al. 1999, 961-969)

However, Chinese economic reform leads to disordered organization and financing of health care (Hsiao 1995, 1048-1051). Chinese health care system is at a crossroad now (Haruo 2007, 1-2; Yip & Hsiao 2008, 460-466). After the health care policy was changed, China's health inequality is getting more and more attention (Tang et al. 2008, 1497-1499). The most serious problem is a surge in health care costs (Haruo 2007, 2). This is because of inadequate health insurance and the spreading of rampant commercialism among medical institutions. There are three main factors causing the health care costs to increase, i.e. less investments; uneven distribution of health care resources; and weak government supervision. (Haruo 2007, 1-2; Hsiao 1995, 1052-1053) The ratio of government expense in national health care has declined from 36.2 percent in 1980 to circa 16 percent in 2000 and after. In contrast, patients' expenses in health care increased from 21.2 percent in 1980 to more than 50 percent in 2000. (Haruo 2007, 2) This directly leads to public dissatisfaction, especially for most residents who live at 'the bottom and in the middle of the pyramid' in China, that is, residents living under the average standard of living in China (Lazarus 2004, 913-915).

These relatively poor residents are afraid of seeing a doctor because they cannot afford expensive medical charges, so an unequal opportunity of seeing a doctor has virtually been formed. Unequal health status exists between the people in urban and rural areas, rich and poor, and among different geographic regions and communities, as well

as between different income groups. Many patients, who are able to pay, can afford domestic advanced treatment. In other words, better health resources are allocated to these patients. From the view of hospitals, they need patients' flow to maintain financial solvency. (Hsiao 1995, 1053-1054)

Concerning prices of health care products and providing services, a two-track approach is operated in China. One track is to be centrally determined by Chinese central government. The government sets prices for basic health services on the basis of historical fees established in the 1950s with a level below actual costs, such as office visits, surgical operations and daily hospital rates. The other track is to have liberalized operation in prices, i.e. hospitals, clinics or other health centers can set prices for drugs and new medical devices with high-technology, diagnostic and therapeutic treatments above actual cost with a profit margin. For example, hospitals, township health centers and village doctors are allowed to mark up their drugs by 13-15% above the wholesale price for Western drugs, and 25% for Chinese herbal drugs; or the prices of services provided by new equipment, such as computerized tomography, magnetic resonance imaging, and multi-channel blood analyzers, are set according to the average cost. (Chu & Rask 2002, 21; Hsiao 1995, 1051)

Table 1 shows an overview of Chinese health care system in the urban sector and in the rural sector. As seen in the table, the population in the rural sector until 2008 has exceeded half of total population. The 'three-tiered' health care system is involved in both of the urban sector and the rural sector. The nature of 'three-tiered' in the rural sector is similar to that in the urban sector, although the names of 'three-tiered' are different. As a matter of fact, the system of 'street health stations' in the urban is equivalent to the system of 'village stations' in the rural. The new health care program (NHCPR) has been performed in the urban sector since 2002. In the rural sector, the NRCMS was launched one year later. However, there are still lots of urban (19% of the whole urban population) and rural (20% of the whole rural population) residents, who are not able to enjoy the systems of NHCPR and NRCMS. They have to pay for health services by themselves. (Carrin et al. 1999, 961-969; Chu & Rask 2002, 16-17; Liu & Yi 2004, 6 & 35)

Table 1: Comparison of health care system between the urban sector and rural sector in China

(adapted from Carrin et al. 1999, 961-972; Chu & Rask 2002, 16-17; Hsiao 1995, 1049-1051; Liu & Yi 2004, 6 & 35)

	in the Urban Sector	in the Rural Sector
<b>Population (until 2008)</b>	circa 42% of total population	circa 58% of total population
<b>Covered population under the health care system</b>	81% of the whole urban population	80% of the whole rural population
<b>Three-Tiered Health Care System</b>	1) Street clinics (primary care); 2) District hospitals (secondary care); 3) City hospitals (tertiary care)	1) Village clinics (primary health); 2) Township hospitals (secondary care); 3) Country hospitals (tertiary care)
<b>Insurance Program</b>	- New Health Care Program Reform (NH CPR) (since 2002); - Commercial insurance	- New Rural Cooperative Medical Scheme (NRCMS) (since 2003); - Commercial insurance

The situation of uneven distribution has occurred since 1980's. The number of general hospitals in China has increased steadily. Most of these hospitals are located in urban areas. On the contrary, the number of small public health clinics in rural areas has been declining annually. (Haruo 2007, 1) Residents living in the rural areas have to go to urban areas when they are infected with serious diseases. It is inconvenient and costly for these residents. This implies also an inequality between patients. The distribution of and access to health services is becoming increasingly unequal. (Hsiao 1995, 1052) When residents, who are living under the average standard of living, suffer from indispositions, normally some of them may choose to take medicines at home by themselves, and give up seeing the doctor because they want to save money; others may go to see the doctor with relatively low fees. In case residents get fatal illness, it is an absolute catastrophe for them. Two situations may occur. One is that rich residents become poor if they accept treatment; another is that poor residents wait for death. The epidemiological transition in the Chinese countryside has already shifted from infectious to chronic

and degenerative diseases as the major cause of death. There is however still a high prevalence of infectious disease in poor rural and urban areas in China (Hsiao 1995, 1053). Hence, lots of medical devices are demanded, which could be used to diagnose and cure these infectious, chronic, and degenerative diseases. It creates a business opportunity for Finnish medical device manufacturers.

Commercial insurance is available in whole China, although Dudek et al. (2004, 24) indicate that only relatively wealthy Chinese and foreigners could afford commercial insurance. With insurance industry developing rapidly in some large and mid-sized cities in China during the last ten years, more and more Chinese residents can afford commercial insurance due to relatively low insurance price and favorable terms for consumers. But most rural residents in relatively poor areas are not aware of commercial insurance, or do not want to buy it because of lack of money. Besides, the urban residents, who are employed under the state-owned enterprises or government, can benefit from the labor insurance program (LIP) and the government employee insurance program (GEIP). The LIP mainly covers state-owned enterprises' employees, retirees and their dependents. Employees are reimbursed for almost 100% of their health care costs and 50% of their dependents' health care costs. The state-owned enterprises set aside before tax an amount equal to 11-14 percent of total wages as a welfare fund to financing health expenditure and retirement benefits incurred by their LIP's beneficiaries. Comparing with the LIP, the GEIP covers civil servants, employees and retirees in public agencies and universities, handicapped military officers, and university students. All of them are reimbursed for close to 100% of health care expenditures, but dependents are not covered. (Liu & Yi 2004, 31-32; Chu & Rask 2002, 15-20)

With supervision power weakening, Chinese government has promoted a self-support accounting system for medical institutions. The aim is to reduce the financial burden on the state (Haruo 2007, 1). But, this system directly leads to commercialism among medical institutions, and significant waste and inefficiency in the production of health care and in primary care service (Haruo 2007, 1-2; Hsiao 1995, 1053). In order to generate more profits and look for additional funding, hospitals prescribe higher volume of drugs, use more expensive drugs and new medical devices/equipment, and sell more medicines (each hospital has its own dispensary), as well as run a business. As mentioned in Table 2, it can be seen that patients have to afford a certain amount of medical fees when patients go to see doctors at the government-owned hospitals. Prescribing and dispensing drugs are direct products to the patients, and medical devices, which are used during the period of hospitalizing, are indirect products. (Hsiao 1995, 1053-1054)

Table 2: The proportion of Chinese hospitals' revenues

	Hospitals' Revenue	
	Personnel Basic Wages (from government)	Remaining Revenues (from patients by out-of-pocket <sup>5</sup> )
Government-owned Hospitals	25%	75%
Township Health Centers	60%	40%

The performance of Chinese health care system was ranked 144 out of 191 WHO member countries in 2000 (Dudek et al. 2004, 24), and China is still seeking to find an integrative way to solve the above mentioned problems in the reform of health care system. Some effective measures, such as providing better access to basic health care, have achieved good results (cf. Liu 2004, 38). In the next section, there is a brief comparison of Finnish and Chinese health care systems.

### 2.1.2 Comparison of Finnish and Chinese health care system

Finnish health care system has developed along population-based responsibility. Public medical services at clinics and hospitals are run by the local government. Patient access charges are subject to annual caps, and they can claim reimbursement of part of their prescription costs from KELA<sup>6</sup>. Private sector patients can claim a contribution from KELA for their private medical costs (including dentistry) if they choose to be treated in the more expensive private sector, or they can benefit from private insurance funds. (Health Care and Medical Profession in Finland 2007) However, private health care sector is mainly in the primary care sector. The main hospitals are funded by municipalities from local taxes and five university hospitals<sup>7</sup> are funded jointly by the municipalities and the national government. Primary health care service is under the supervision of the local authority. It is organized around the basic unit of the health center. All primary health services are planned regionally. (Health services in Finland 2007) There is spe-

<sup>5</sup> World Health Organization (2010) defines that 'out-of-pocket payment is any direct outlay by households, including gratuities and in-kind payments, to health practitioners and suppliers of pharmaceuticals, therapeutic appliances, and other goods and services whose primary intent is to contribute to the restoration or enhancement of the health status of individuals or population groups. It is a part of private health expenditure'.

<sup>6</sup>KELA means Finnish social insurance institution.

<sup>7</sup>Five university hospitals are located in Helsinki, Turku, Tampere, Oulu and Kuopio respectively.

cial program involving a personal doctor, and care for the elderly in a commune as a cooperative effort of social welfare and health services. (Koskinen et al. 2006; Kuori 2005)

In the table 3 the health care system in China is compared with the health care system in Finland by five different aspects: administrative departments, administrative structure, health expenditure, quality control and existed problems. There are main five levels of administrative departments with decentralization in China. On the top level there is the Ministry of Health. The ministry department is responsible for managing the health care system; directing the research in the field of health care; providing general policy guidelines; decentralizing the power to the provincial level so that there are different policies of health care in the different provinces; and supervising the implementation of government policies. The second level of administrative department is provincial department of health, which is mainly in charge of accepting technical guidance from Ministry of Health and providing technical guidance to City Department of Health. The function of the next three levels is similar to provincial department of health, which organizes and finance public health services, as well enters a contract system concerning the hospital management. (Liu & Yi 2004, 20) In Finland, there are three administrative departments from the top level to the bottom level with similar responsibilities as in China. Decentralization allows more power to the provincial governments: one reason may be each province has its own fiscal independence (Hsiao 1995, 1050). Health expenditure<sup>8</sup> (HE) lacks a well-organized approach in China. The Ministry of Health adopts the laissez-faire policy, and there is a budget for health care from the Chinese central government every year. Patients' health expenditure main resource is from public health expenditure<sup>9</sup> and out-of-pocket payment.

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<sup>8</sup>Health expenditure is defined as *'the sum of public and private health expenditure. It covers the provision of health services (preventive and curative), family planning activities, nutrition activities, and emergency aid designated for health but does not include provision of water and sanitation'*. (World Health Organization 2010)

<sup>9</sup>Public health expenditure is referred as *'consisting of recurrent and capital spending from government (central and local) budgets, external borrowings and grants (including donations from international agencies and nongovernmental organizations), and social (or compulsory) health insurance funds'*. (World Health Organization 2010)

Table 3: Comparison of health care systems in China and Finland

(adapted from Chu & Rask 2002, 13-43; Gu 1999, 203-208; Haruo 2007, 1-3; Hsiao 1995, 1047-1055; KELA 2010; Liu & Yi 2004, 12 & 17-20; Tang et al 2008, 1493-1501; Wagstaff et al. 2009, 1-19; World Health Organization 1994, 144 – 147)

	China	Finland
<b>Administrative Departments</b>	<ul style="list-style-type: none"> <li>• Ministry of Health</li> <li>• Provincial Department of Health</li> <li>• City (Country) Department of Health</li> <li>• Township Health Administration</li> <li>• Village Health Administration</li> </ul>	<ul style="list-style-type: none"> <li>• Ministry of Social Affairs and Health</li> <li>• Departments of Social Affairs and Health</li> <li>• Board of Health</li> </ul>
<b>Administrative Structure</b>	<ul style="list-style-type: none"> <li>• decentralization</li> <li>• central supervision &amp; direction</li> </ul>	<ul style="list-style-type: none"> <li>• decentralization</li> <li>• central supervision &amp; direction</li> </ul>
<b>Health Expenditure</b>	<ul style="list-style-type: none"> <li>• NHCSR (since 2002)</li> <li>• NRCMS (since 2003)</li> <li>• social insurance: LIP &amp; GEIP</li> <li>• commercial insurance</li> <li>• out-of-pocket payments</li> </ul>	<ul style="list-style-type: none"> <li>• State government (58%), KELA</li> <li>• Local government (5%)</li> <li>• National insurance fund (37%)</li> </ul>
<b>Quality Control</b>	<ul style="list-style-type: none"> <li>• lack of a good system</li> <li>• weakened public health inspections</li> </ul>	<ul style="list-style-type: none"> <li>• quality control activities</li> <li>• central management &amp; evaluation of complaints</li> <li>• the approval of electronic equipments</li> </ul>
<b>Existed Problems</b>	<ul style="list-style-type: none"> <li>• inadequate funding &amp; health care resources</li> <li>• inequality</li> <li>• inefficiency &amp; waste</li> <li>• weakened government supervision</li> <li>• not meet patients' demands</li> </ul>	<ul style="list-style-type: none"> <li>• without consideration of residents' views or needs</li> </ul>

On the side of quality control, China lacks a good system, which can monitor and improve the quality of health care. Conversely, Finnish government runs quality control

activities at all relevant levels of health care. Complaints of health care are managed centrally, and are evaluated at the national level. There are relevant authorities to approve electronic equipment in health care. The supervision of Chinese government is weakened on the quality of health products, such as adulterant. Moreover, there is a similar problem, which also exists in Finland. All health care policies seem to be made without consideration of residents' views or needs (Kuori 2005). For example, many nurses spend a lot of time working on computer, such as input patients' data, so that they have less time for patients. It is considered a relatively serious problem at hospitals in Finland.

Chinese health care system is controlled by governmental policies which influence Finnish medical devices' entering the Chinese market to a certain extent, and pricing medical devices in China. On the other hand, Chinese medicine culture is expounded in the following sub-chapter, since culture is as an important macro factor, which directly affects the selection of international entry modes (cf. Bilkey & Tesar 1977, 93).

## **2.2 Chinese medicine culture**

Each country has its own unique culture. Traditional Chinese medicine (TCM) is one kind of special culture in China. *'The professional culture of medicine can be viewed as the language, thought processes, styles of communication, customs, and beliefs that often characterize the profession of medicine'* (Boutin-Foster et al. 2008, 3). In this sub-chapter, two different cultures of TCM and Western medicine (WM) are briefly described. TCM culture could be seen as one factor influencing Finnish SMEs on preparing to enter the Chinese medical device market. Market behavior culture can hint why some medical devices can be demanded largely in the Chinese market (cf. Albaum et al. 2002, 407). As TCM has a long history in China and in a number of Asian countries (Xue et al. 2006, 775), it is impossible that TCM is explained in detail in one sub-chapter. Therefore, an overview of Chinese medicine culture is introduced to readers. Through comparing with Western medicine, two relative questions are dealt with, i.e. why western medical products have a demand in China, and what kind of entry modes may be opted due to cultural differences.

### **2.2.1 An overview of Chinese medicine culture**

China is an old country with five thousand years of its own culture. Confucianism as one main emblem in China is a foundation of Chinese medicine culture, especially for traditional Chinese medical ethics (Feldman et al. 1999, 778). Guo (1995, 239) said:



*‘Confucian theories on morality and ethics, with ‘goodness’ as the core and ‘rites’ as the norm, served as the ‘key notes’ of the traditional medical ethics of China.’* Thus it can be seen that the Chinese medicine culture compromises Confucianism. In general, the above mentioned Chinese medicine culture is regarded as TCM culture at the moment. It is the quintessence of the Chinese culture heritage (Qian 2005, 4). TCM has been practiced in China for over 2000 years (Lam 2001, 762). *‘TCM remains as one of the world’s oldest and most popular forms of primary care’*, Qian (2005, 5) said. In the beginning, the accumulated knowledge of TCM was handed down from generation to generation in a verbal form until 2698 B.C., when the first written record ‘Basic Questions of Internal Medicine’ (‘Neijing Suwen’ in Chinese) emerged, which was much more grounded in a spiritual and philosophical base. This book described mainly that acupuncture, herbal medicines and Tui Na (also called acupressure) are used as main methods of treatment and prevention of diseases. (Beijing digital museum of TCM 2007)

TCM theory is based on Chinese archaic scientific culture and conclusions of clinical experiences, which delivers the indispensable philosophical thinking and discrimination. The basic theory is guided by a ‘Yin-Yang and five elements’ theory under the traditional philosophy. (Sun 2007, 214) In other words, maintaining a state of health equilibrium is emphasized between the various systems and functions of the person as a whole (Wong et al. 1993, 278).

Therapy methods<sup>10</sup> can be used together to treat and prevent one disease, for example, combination of acupuncture and herbal remedies can have better result than using only one of those therapy methods<sup>11</sup>. According to examples of combination, one very important element is herbal remedies in the TCM. There are two kinds of herbal remedies. One is ‘food herbs’. They are generally eaten as part of the diet and mainly used for prevention of disease and illness and keeping fit. The other is ‘medicinal herbs’. They are prescribed by a TCM doctor and they are specially prepared for patients’ own needs. Though it could be used solely, herbal medicine is usually used in conjunction with acupuncture. Because all things are interconnected, pains and conditions in the body have a lot to do with one’s emotions and thought process, TCM doctors will often give the patients herbs to help relax or calm them during the period of acupuncture treatment. (Qian 2005, 15-20)

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<sup>10</sup> Main therapy methods include 1) medicinal herb & dietary therapy; 2) acupuncture & cupping; 3) moxibustion; 4) Tui Na; and 5) qigong (Beijing digital museum of TCM 2007). For more information, see <http://en.tcm-china.info/home/index.shtml>.

<sup>11</sup> One thing is still fresh in my memory. When I was studying in the elementary school, my father’s rheumatic arthritic on the knees happened for the first time. At first, father accepted the western medical therapy, but the result was not optimistic. Later, my father changed to accept traditional Chinese medical therapy, i.e. ‘acupuncture with fire cupping & herbal medicines’ therapeutic method. Father’s tumid situation on the knees got into remission, and he could walk in two weeks. After three months, my father was recovered from the rheumatic arthritic on the knees.

Xue et al. (2006, 775) mentioned: *'TCM has been gaining a foothold in the Western world over the last three decades.'* Nowadays more and more medical experts from western countries are very interested in TCM. They combine Western medicine with TCM to find out therapy solutions to difficult and complicated cases of illness, such as cancers and tumours. In China, Chinese medical experts and scholars also want to borrow from the theory of Western medicine and combine with TCM, thus researching the same or similar medical problems. (Gao & Wu 2008, 231) Whether combining Western medicine with TCM, or combining TCM with Western medicine, all of them can be regarded as integration of TCM culture and Western medicine culture.

### ***2.2.2 Integration of traditional Chinese medicine culture and Western medicine culture***

TCM and Western medicine do not conflict one another, they just integrate each other. In comparison to the TCM, Lee (2008) said, *'Western medicine is based on evidence, rigorous scientific and medical research, and the basis for diagnosis and prognosis for Chinese and Western medicine practitioners are different by nature.'* Western medicine is influenced by atomism and reductionism which are coming from European traditional ideational culture (Sun 2007, 214). TCM culture and Western medicine culture are being integrated gradually due to strengths of both parties. At the moment, there are some projects or successful cases of integration of TCM and Western medicine, like as somatostatin's usage at the beginning of short-term treatment can improve the condition of patients with severe acute pancreatitis (Xia et al. 2005, 1073); integrated TCM and Western medicine treatments is beneficial for the treatment of SARS (Chen et al. 2007, 7); and integrative cancer therapy exists in combination of TCM and Western medicine (Gao & Wu 2008, 231-234). More new therapies for scarce illnesses are likely to be innovated during the integration.

The traditional Western medicine could be dated back from the period of the time of Hippocrates<sup>12</sup>, when it began to break down under the impact of major changes in medical theory and therapeutics (Conrad et al. 1996, 608). Current Western medicine is also called modern medicine. Its research field includes basic medicine, clinical medicine, laboratory medicine, preventive medicine, medical care, rehabilitation medicine and so on. After Western medicine came into China with missionaries in early 20<sup>th</sup> century, Western medicine culture has gradually been accepted by many Chinese people because there have been obvious effective results of treatment, for example, most successful

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<sup>12</sup>It is 5<sup>th</sup> century B.C.

recovery cases in the surgical operations, in which TCM is not involved (Cheung & New 1985, 309). After the 1950's, when conventional western care became dominant, the Chinese recognized Chinese medicine could be a complement to western conventional care. Since then, all hospitals provide Western and Chinese medicine. Patients can select their favorite treatment. (Muse 2007, 7-8) Many Chinese hospitals, including large and small state-owned hospitals in the developed and developing cities and areas, have applied western health care products of effective antibiotic, innovative drugs and many advanced medical devices or equipment<sup>13</sup>. Most of medical devices or equipment is needed in the operations, health examinations and clinical researches. Since western medical products were not invented in China, Chinese hospitals and other medical institutions have to import these products. Many medical device manufacturers in China have to do R&D and/or import relative technologies for producing products with similar functions or innovative products. Currently Chinese medical level is close to western developed countries. (China Association for Medical Devices Industry 2006) The integration of TCM and Western medicine can promote the development of Chinese medical science further.

TCM and Western medicine have their own diagnostic methods<sup>14</sup>. Therefore, TCM and Western medicine are using in the totally different methods to organize and process the collected information on a patient's symptom. (Fan 2003, 213) Some people believe that Western medicine is best at dealing with accidents, and curing the acute illnesses; while TCM is good at treating chronic diseases and preventive treatment. Appendix 2 presents a concise overview of comparison of TCM and Western medicine. Presently, diagnostics of TCM is facing the challenges of Western medicine in China (Sun 2007, 214).

TCM is often used as a supplement to Western medicine in China. When Western medicine fails or when patients are desperate and want to try anything, TCM will be considered. However, sometimes it is too late to treat the patients. After all, diseases should be cured as early as possible, and TCM is promoting preventive medicine in this respect. Hence, TCM is not only taken into account for some milder illnesses, but also for clearing the cause of the diseases after consulting the Western medicine's doctors for recovery. According to Lam (2001, 763), '*Chinese herbal medicines are better at curing diseases completely*'. Comparing between side effects of chemical-based medicines and herbal medicines, the side effects of herb medicines are much milder.

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<sup>13</sup>Due to funding shortage, undeveloped transportation, and medical personnel scarcity, advanced western devices and equipments are difficultly applied in the poor areas of China.

<sup>14</sup>Chinese diagnostic methods include 1) looking; 2) listening and smelling; 3) asking; and 4) pulse-taking (Beijing digital museum of TCM 2007). For more information, see <http://en.tcm-china.info/home/index.shtml>.

TCM has also some obvious disadvantages. For instance, herbal medicines have to be boiled before taking them; certain food has to be avoided because the food may affect the result of herbal medicines; and treatment in acupuncture takes a longer time (Lam 2001, 763). On the other hand, these TCM's weaknesses could be changed to Western medicine's strengths. Most of western chemical-based medicines are in the forms of pill or capsule; patients take pills or capsules much easily and more conveniently than herbs. Western medicine can cure some acute diseases such as headache immediately after taking pills and/or capsules, and/or after injections. Moreover, Western medicine is also considered better for certain diseases (Lam 2001, 764), such as tuberculosis, because injection is available. But Western medicine is sometimes thought to be too powerful for the body. For example, patients may feel dull after taking the medicines, or they may lose much hair, e.g. in the situation of Chemotherapy. (Lam 2001, 764)

Presently over a quarter of the population of the world accepts the TCM treatment and prevention. The role of TCM in primary health care has been recognized by the World Health Organization (WHO). (Wong et al. 1993, 278) Yan (2008) said, *'both Chinese and Western medicine with different cultural backgrounds began in the complementary advantages and common development. In the exchange of Western medicine, TCM with a profound cultural accumulation became more and more scientific.'* Simultaneously, the TCM culture affects the Western society. The WHO believes that TCM is a feasible alternative to Western medicine. In order to integrate TCM and Western medicine better, Chinese doctors sometimes use Western medicine to control the symptoms firstly, and then use TCM to cure the diseases completely. At the moment, there are difficult and complicated diseases that cannot be cured completely, such as some cancers. Doctors thus treat this kind of disease in China using Western medicine's chemotherapy and taking TCM's herb for restoring body. (Gao & Wu 2008, 231-234; Sun 2007, 215; Lam 2001, 764)

As mentioned above concerning comparison and integration of TCM and Western medicine, cultural distance is seen as one main problem between two medicine cultures. Furthermore, cultural issues also exist in working with the partners overseas. Cultural distance means the differences in culture between home and host countries. It is an important factor to consider when a Finnish SME decides to enter the Chinese market (cf. Bilkey & Tesar 1977, 93-95), and to opt for a suitable entry mode. Generally speaking Finnish SMEs prefer to enter foreign markets where the culture is similar to their domestic markets (cf. Johanson & Wiedersheim-Paul 1975, 329; Kogut & Singh 1988, 320-321), especially that the enterprises with little foreign market experience prefer foreign markets at a short cultural distance (cf. Blomstermo et al. 2006, 216). Cultural distance creates high information costs for Finnish SMEs selling medical devices because enormous information is needed of unfamiliar culture environment of China. A

lot of knowledge of the Chinese medical policies and culture of medicine and business have to be acquired. With cultural distance increasing, the Finnish enterprises' business uncertainty and unpredictability also increase. That is because some enterprises do not trust Chinese local management or local partners, and prefer sufficient control to 'do it their way'. On the basis of cultural backgrounds (involving in medicine culture) and geographic adjacency, foreign investors can be classified into three groups in China: 1) from Hong Kong, Macau and Taiwan; 2) from other East Asian countries including Japan, Singapore, Malaysia and South Korea; and 3) from Western countries. (Sun 1996, 643-644) Finland belongs to the third group from Western countries.

Nowadays lots of advanced medical devices are produced in developed countries. These modern medical devices support WM's diagnoses and treatments in China, for example, blood examinations, body examinations, and surgery. It can be said that medical devices are necessary when western medical doctors in China diagnose illnesses of patients to be cured. After using medical devices, Chinese doctors of Western medicine can diagnose illnesses more objectively and accurately since some medical devices can test the internal body and analyze the results of examination. In order to integrate this strength of WM, many medical devices have been imported to China. Currently import of medical devices is focused on advanced or high-tech products. The next sub-chapter is to introduce a main situation of medical device market in China.

### **2.3 Current market of medical devices in China**

The medical device market in China continues to grow rapidly (Dudek et al. 2004, 18). According to China Association for Medical Devices Industry (CAMDI 2006), the amount of sales reached US\$22.9 billion in 2007, and there are 12,600 Chinese local manufacturers who have produced US\$27 billion worth of medical products. During 2004-2007, the amount of import of medical devices rose from US\$3.1 billion to US\$4.3 billion with annual increase of 12%, and the amount of export of medical devices also rose from US\$4.1 billion to US\$8.47 billion with increase of about 35% annually. The unique difference between the import of products to China and export from China is that over 80% of high-tech medical devices rely on import business, and mainly low-tech medical products focus on export business. Before the sub-chapter 'market trend, competition and challenges' is presented to readers, some basic types of medical devices have to be described concisely.

### 2.3.1 *Types of medical devices*

In general, medical devices are summed up in five basic types (see Table 4) according to medical device's functions: 1) diagnostic devices; 2) therapeutic devices; 3) life support devices; 4) medical monitors; and 5) medical laboratory devices. (U.S. Food and Drug Administration 2010) A medical device manufacturer can produce one or more medical devices in order to meet market demands. However, a hospital cannot rely on only using one medical device for diagnosing illnesses due to various diseases and new emerging diseases. Thus, hospitals require various medical devices with different functions. As described in the table below, each type of medical devices is described with its own functions and examples.

Table 4: Basic types of medical devices  
(U.S. Food and Drug Administration 2010)

Types	Functions	Examples
<b>Diagnostic Devices</b>	to aid in diagnosis	ultrasound, magnetic resonance imaging machines, performance evaluation test & computerized tomography scanners, x-ray machines
<b>Therapeutic Devices</b>	to treat patients on the operations or in hospital	infusion pumps, medical lasers, laser assisted in-situ keratomi leusis surgical machines
<b>Life Support Devices</b>	to maintain a patient's bodily function and to control diseases	medical ventilators, heart-lung machines, extracorporeal membrane oxygenator, dialysis machines
<b>Medical Monitors</b>	to allow medical staff to measure patients' symptoms	electrocardiograph, electroencephalogram, blood pressure, dissolved gases in the blood
<b>Medical Laboratory Devices</b>	to automate or help analyze data of human body	blood, urine & genes analyses

The first type of medical devices is diagnostic devices for medical imaging. Western medicine doctors could see clearly what happens in the body through diagnostic devices. In other words, disease sources or disease symptoms can be found more easily after using medical imaging devices. The therapeutic devices are one of major types of medi-

cal devices. Patients need this kind of medical devices to recover. For example, a cancer patient is treated by medical lasers; or when a patient with leg injury needs physiotherapy, relative therapeutic devices will be used to recover health. Then, the life support devices are also important medical devices in hospitals. Normally the size of life support devices is large, and this kind of devices is used for patients, who are critically or seriously ill. A patient with failing living function needs respirator assistance on his or her breathing. Or a patient with diabetes mellitus needs a dialysis machine to control his or her disease. The medical monitors are to allow medical staff to measure patients' symptoms, like using electrocardiograph to observe patients' heart situation. The last type of medical devices is medical laboratory devices including in-vitro devices. This kind of devices is not used by patients directly. Under usual conditions, nurses take a sample of blood, urine, or genes from human body to check the data of body in laboratories, and doctors can educe etiological factors through this data of the body. (U.S. Food and Drug Administration 2010)

In addition to five basic types on the Table 4, there is a kind of medical devices, which is used only for auxiliary function, for instance, surgical knife, syringe, and operating table. These auxiliary medical devices are absolutely essential in hospitals. They belong to low-tech devices, whereas most of medical devices on the Table 4 are high-tech devices. At present, Chinese medical device manufacturers are researching and developing high-tech devices under encouragement and support from the government, and import high technology for producing high-tech devices. (China Association for Medical Devices Industry 2006) Besides, there is a market niche in Chinese traditional medicine, in areas such as skin diseases, metabolic disorders, chronic diseases and functional disorders (Lee 2008). In the following subchapter these challenges, competition and market trend are discussed.

### ***2.3.2 Market trend, competition and challenges***

Since 2009 the new health care reform plan in China has been launched, and it is expected to result in the following trends: 1) providing basic medical insurance for all urban and rural residents by the year of 2020; 2) key emphasis on major diseases and in-patients; 3) greater efforts to control and treat chronic diseases; 4) prevention as the primary tool for health care service; 5) priority given to improving health care infrastructure in rural and remote areas; 6) higher importance placed on developing community health centers for urban residents; and 7) focusing and supporting development and modernization of TCM. (Boyd 2009; Li 2009) Liu (2004, 38) said: *'health care reform, rising income and increasing affordability of imported products have contributed to a growing market for medical devices in China.'* In order to meet the needs of health

screening for whole population, the medical device market will continuously expand in the medium to long term (Liu 2004, 39). Some advanced western medical devices from western countries could have market share in China because western medical practice differs from Chinese medicine essentially, i.e. it is based on evidence, rigorous scientific and medical research (Lee 2008). As a result, the current market trend of medical devices is positive for Finnish SMEs, that is, there is still a large market for foreign medical devices.

Fierce competition then emerges in the Chinese market due to lots of domestic and foreign manufacturers. With Chinese government investments on research and development of domestic medical devices, local manufacturers, who dominate many low-cost segments, are increasing rapidly. These local manufacturers are competitors for foreign producers in China. Facing strong competition from local suppliers and manufacturers, some foreign enterprises have to make corresponding strategies to solve this kind of situation, for instance, parts of devices are produced in China for domestic sales; or new markets will develop in the middle-sized cities in China. For instance, key emerging markets of some US multinational medical device enterprises are in Tianjin, Shenzhen, Nanjing, Chongqing, Dalian, Qingdao, Hangzhou, and Xiamen. (Li 2009) However, the option above (i.e. manufacturing in China) may be not the best for Finnish SMEs due to the scale of enterprises.

Nowadays the amount of major buyers in China is huge with 19,852 hospitals, 80,500 urban and rural health centers, and 3,585 centers for disease control. An average of 322 new hospitals was built each year during 1990-2007. Circa 400 new hospitals are expected to be built or rebuilt annually in the next 10 years. About 30% of total investments of these new hospitals are used for purchasing medical devices. The 3,585 centers for disease control also need to be rebuilt, relocated, or expanded, while township health centers will also receive more attention to upgrade their facilities and devices. (Li 2009) For Chinese hospitals, full automation for laboratory equipment and networking devices<sup>15</sup> are inadequate. Because of huge investment, lack of expertise, and infrastructure support, these high-tech systems are difficult to be implemented fully by Chinese manufacturers. The market for fully automated devices is still led by foreign suppliers, because local producers are mostly capable of manufacturing semi-automated systems. (Liu 2004, 38-39) The Chinese government offers attractive policy for foreign enterprises in medical device market, which brings more and more foreign medical device manufacturers to China for sharing the big cake. There are many international enterprises actively competing on the Chinese market, such as GE Healthcare, Siemens, Philips, Johnson & Johnson, Beckman Coulter, Medtronic, Abbott, Baxter, BD, Tyco, Roche,

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<sup>15</sup>Networking devices are used for information sharing among hospital departments; and for remote monitoring and maintenance by suppliers (Liu 2004, 38).



Drager, Auscult, Zeiss, Hitachi, Toshiba, Shimadzu, and Olympus. (Li 2009) The United States is the leading importer of medical devices in China (China Association for Medical Devices Industry 2006).

In the major cities, Beijing, Shanghai and Guangzhou as examples, many public hospitals operated by the government and the military start using tendering systems for their purchases. Most hospitals have their own purchasing rights. Medical devices can be directly purchased from manufacturers or distributors. Therefore, the power of price competition is increasing. Consolidated purchasing between hospitals is not common at present. (Liu 2004, 38) In order to strengthen competitive capability in the Chinese medical device market, Boyd (2009) suggests, foreign enterprises should build a good and harmonic relationship with local agents and distributors. On the side of medical products, customers' demands should be met and be focused on. Unfit products may lead to an incapable competition. One thing worth noting is that all medical products must be registered under the State Food and Drug Administration (SFDA) before products are sold in China. Besides, Finnish medical enterprises can acquire more market information of medical products at the China Medical Equipment Fair too, which is held twice for each year. According to China Medical Equipment Fair's data all previous years, the amount of distributors visiting is over 50% of all visitors, and visitors from hospital management and staff is about 22%. (Boyd 2009)

Presently the Chinese medical device market is facing three main challenges from business, economic and operational point of view (Jiao 2009). Several sub-challenges are under the main challenges, for example, to develop a sound infrastructure for health care insurance; to build an effective partnership between the academic and industrial sectors; to finance sufficient funds in medical device research and development; and to enhance satisfactory support for the oversight of medical device safety (Ministry of Health of the People's Republic of China 2006). These challenges may affect Finnish SMEs' decisions on selection of entry modes and marketing mix. Therefore, the SMEs have to take account of an optimal portfolio to reduce investment risk. Besides, the distribution of structure in China should also be considered by the Finnish SMEs (cf. Yip & Mahal 2008, 921-929).

### ***2.3.3 Distribution of medical devices***

At present most hospitals in China are equipped with basic medical devices. The demand for medical devices rockets due to replacement and upgrading. The area of fastest growth is in East China, followed by North China and South China respectively. Major top-class hospitals tend to purchase foreign leaders' products because patients think that they work better. Many second-class and third-class hospitals may select medical device-

es from foreign SMEs for replacing low-cost local products because of quality and reputation issues. Certainly, many hospitals also combine local consumables with imported equipment to save costs. (cf. Liu 2004, 38)

Distribution for medical devices is complex. Throughout China, there are over 140,000 registered distributors of medical devices including retail stores, but only about 5% of distributors have trans-regional distribution capability (Li 2009). More direct selling takes place in major cities. Normally some foreign SMEs rely on local agents for distribution and after-sales support of their products in China. Major distributors typically sell directly to larger hospitals, or rely on sub-distributors selling medical devices to smaller hospitals. But, some large foreign manufacturers, such as GE health and Roche, sell their products directly to the end-users in major cities such as Beijing, Shanghai and Guangzhou, where these overseas manufacturers have founded their own sales offices. Direct sales are expected to become the trend in the future as the market becomes more competitive. (Liu 2004, 38)

It is difficult for Finnish SMEs to establish their own sales offices or subsidiaries for the first time of entering the Chinese market, so they have to select local distributors or agents selling the products in China. In the process of choosing agents and/or distributors, the SMEs may meet unreliable distributors and/or have lack of control over sub-distributors. The quality of after-sales service is difficult to guarantee by Finnish manufacturers due to the chain of distributors and from region to region. The business could also be affected by the local distributors. Under these situations, the SMEs should conduct due diligence when selecting local partners to avoid immoral agents and/or distributors (Wong 2009), and other negative influences from the partners. However, when the Finnish SMEs are opting for Chinese agents and/or distributors, local agents and/or distributors are also selecting foreign enterprises. In general, local agents and/or distributors prefer acting as agent for those enterprises abroad, who have SFDA registration certificate (Lansen pharmaceutical holding limited... 2010, 4-5). That is because there are complicated steps of SFDA registration application (SFDA 2008), the local agents and/or distributors do not want to be involved in. Therefore, the Finnish SMEs should receive the registration certificates of their medical devices as soon as possible. In addition, the Finnish SMEs should be familiar with relevant regulations for medical devices in China.

#### **2.3.4 Regulations for medical devices**

China needs a more complete regulatory framework for medical devices to ensure product safety. Some of these regulations may significantly affect the industry, and enterprises may need to change some of their processes and procedures. Since June 2006, the

SFDA and Provincial Food and Drug Administrations have conducted authenticity audits of the materials submitted by domestic enterprises to give device market approvals. (Ministry of Health of the People's Republic of China 2006) Chinese medical device industry is being cleaned up by new rules and modified regulations since the year of 2007. The reason is that the safety and quality of medical products are being emphasized more and medical management system need to be improved (Chen 2008). In the last quarter of 2007, the SFDA expanded the audits to include imported devices. In order to guarantee qualities of imported medical products, the SFDA has issued that all imported medical products to be sold in China must be registered with the SFDA (SFDA 2008).

According to the Regulations on Supervision and Administration of Medical Devices, the SFDA regulates the manufacturers and distributions of medical devices in China, both of them require a license, and register all imported medical devices. The SFDA registers and tests medical devices, sets quality standards and conducts inspections, issues product registration certificates and production licenses, develops legal standards for medical devices, and categorizes medical devices. Foreign investment in medical devices manufacturing is restricted or encouraged depending on the nature of the devices to be manufactured. (Dudek, Chen & Zhang 2004, 21; SFDA 2008) This means that a medical device manufacturer in China must register for trial production before obtaining a manufacturing license. A shorter process applies if the manufacturer can show that the device is the same as, or similar to, a device already on the market. The Regulations on Supervision and Administration of Medical Devices classifies medical devices into three types according to risk-level: I means low-risk, II means medium-risk and III means high-risk. The durations of regulatory reviews for the three categories are as follows: 30 working days to obtain a manufacturing registration certificate from a municipal SFDA branch for a type I device; 60 working days to obtain a manufacturing registration certificate from a provincial-level SFDA branch for a type II device (including testing devices); and 90 working days to obtain a manufacturing registration certificate from SFDA for a type III device and medical devices manufactured overseas (including the submission of clinical trial reports and inspection of manufacturing facilities). (Dudek et al. 2004, 19-20; SFDA 2008) As a result, all foreign manufacturers have to wait at least 90 working days for their registration certificates of products. The SFDA has been administrated under the Chinese Ministry of Health since March 2008. A few new device-related regulations will be issued, for example, a registration certificate takes 45 working days after inspecting a sample of the device. Furthermore, the SFDA only reviews foreign inspection reports when domestic inspectors lack the relevant expertise. (SFDA 2008)

As claimed in the WTO agreement, China is required to ensure that all taxes and charges on imports and exports are in conformity with the 1994 General Agreement on

Tariffs and Trade. Zapiain (2003, 52) said: '*all taxes and tariffs will be applied uniformly to both domestic and foreign products*'. Tariffs on most medical devices were lowered from the original 9.9% to 4.7% by January 2005, and 90% of these reductions were completed by January 2003. Manufacturers of 132 product categories<sup>16</sup> are required to obtain the China Compulsory Certification mark from the General Administration of Quality Supervision, Inspection and Quarantine before exporting to or selling in the Chinese market. Seven categories of medical devices are affected by this change in regulation. The categories of medical devices are diagnostic X-ray equipment, haemodialysis equipment, hollow fibredialysers, extra-corporeal blood circuits for blood-purification equipment, electrocardiographs, and implantable cardiac pacemakers and artificial heart - lung machines. (Liu 2004, 38) It implicates the transaction cost for sales from Finland to China. From the angle of transaction cost, the most important determinant of market failures is tradable assets in foreign markets (Dunning 1988, 1-3; Hill & Kim 1988, 93). The exchange rate, fixed costs, tariffs and transport costs can be considered as transaction cost (Meixell & Gargeya 2005, 540-545). According to Collins & Rodrik (1991), tariffs and transport cost factors are important in the decision to export or invest.

IPR can be seen as a private right. It includes unregistered IPR and registered IPR. Unregistered IPR involves copyright, trade secrets and confidential information, printed circuit layout designs and unregistered trade marks; and registered IPR refers as patents, trade marks, design rights and plant variety rights. Enterprises should understand the different types, and then they could opt for the IPR protection required by their business. As a kind of IPR, brand protection is offered at the national level, the regional level, the international level respectively. The brand protection is according to the national legislation of China. (cf. Albaum et al. 2002, 423) The Finnish enterprises should protect their brands or technologies of products using the services of qualified local counsel, or discuss with the embassies and consulate officials of their own countries. An overall IPRs protection strategy should be developed by the enterprises. (Wong 2009) '*Technology innovations must be held proprietary*' Bharadwaj et al. (1993, 85) said. IPR of a new product, an innovated production process and a new technology, should be registered when a firm abroad decides to export its products into China, since intellectual property can be a vital and valuable asset for any enterprises. Protecting intellectual property in new markets creates a significant barrier to competitors, builds credibility, adds value and sustainable competitive advantage, and helps prevent other enterprises from copying products in the local market (Ekeledo & Sivakumar 2004, 76). Currently, China is obligated to comply with the internationally accepted norms for protecting

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<sup>16</sup>For more information, see the 1994 General Agreement on Tariffs and Trade.

IPRs (Zapiain 2003, 52), and granting patents was started in China in 1993. Enterprises overseas may apply for a Certificate for Administrative Protection for their own products or technologies, etc. The administrative protection is valid for seven years and six months (Dudek et al. 2004, 23), and the Chinese statute of limitations is two years (Wong 2009). In consideration of IPR problem, the Finnish SMEs should apply IPR protection for their products in China since Chinese IPR system differs from in the Scandinavian countries, and in the other regions of EU. Therefore, the Finnish SMEs should carefully deal with IPR businesses in China, and all relative laws and regulations also should be read. (cf. Jiao 2009)

## **2.4 Resources of Finnish SMEs**

The Finnish SMEs should formulate systematical strategies in consideration of resources (cf. Foss 1997, 53). Resources can be seen as a micro environment of the enterprises, i.e. internal factors. There are specific tangible and intangible resources and assets in the Finnish enterprises (cf. Ekeledo & Sivakumar 2004, 75; Osland et al. 2001, 154). Tangible resources and assets indicate the Finnish SMEs' machines, money, products and property. Product is the core content of export business as tangible resources. (cf. Chang & Rosenzweig 2001, 756) Intangible resources are the enterprises' capabilities, technology, organizational culture, reputation and business experience. The enterprises' capabilities are involved in managing and manipulating the environment (Forlani et al. 2008, 293). The Finnish SMEs face the resource disadvantage against bigger firms in China. One of their main resource disadvantages is cost. (cf. Lee, Lim & Tan 1999, 301 & 308) Normally, the Finnish SMEs lack the resources and capabilities to develop their Chinese markets. Their small size leads that the enterprises are difficult to reap the benefits arising from the economies of scale and scope, and the experience curve. (cf. Nooteboom 1993, 283-285) Therefore, resource shortage is an important issue for the Finnish SMEs, and it is seen as one of the major obstacles faced by the SMEs (cf. Weinrauch et al. 1991, 52).

However, many larger firms are usually slow to respond to sharp environmental changes due to organizational inertia (Hill & Jones 1998, 93-95). Conversely, the Finnish SMEs can rapidly respond to sharp environmental changes due to their flexible and change-adaptive capability. This unique capability is usually embedded in their managerial routines. Thus the capability is one of the most important ownership-specific advantages in internalizing. (cf. Cheng 2008, 211) According to Madhok (1997, 169), the enterprises face to less risk of ownership when they have high capability. For example, a Finnish SME may find out target markets quickly while it has good market know-

ledge<sup>17</sup>. The enterprises' value-creating activities are supported by capabilities in accordance with organizational capability perspective. (cf. Madhok 1997, 170-172)

## 2.5 Synthesis

This chapter discusses the first sub-objective: *to describe main factors influencing Finnish medical device SMEs on the selection of entry modes to China*. The figure 2 shows the summaries of Chapter 2. Macro factors imply some favorable conditions for exporting medical devices to China, but, there are barriers for foreign exporters. On the side of micro factor, the Finnish SMEs' internal resources are presented.

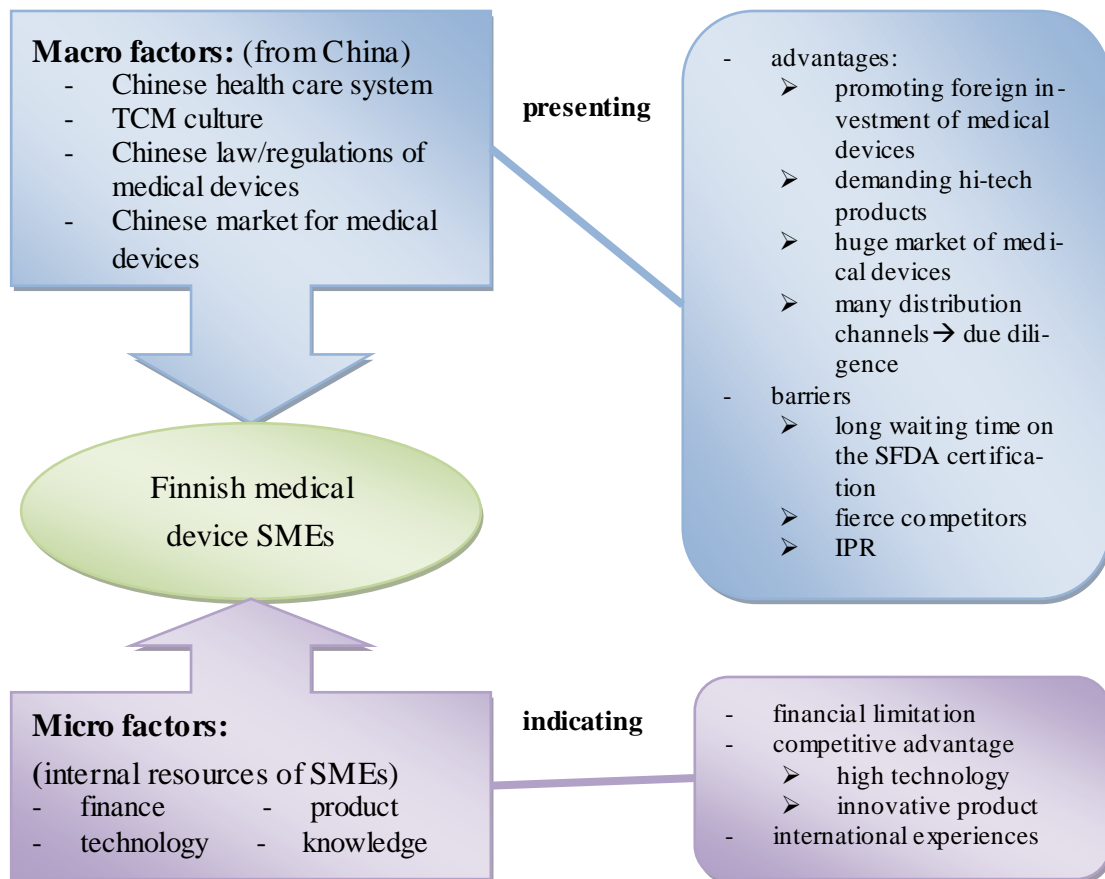


Figure 2: Synthesis of main factors influencing Finnish SMEs on the selection of entry modes to China

<sup>17</sup> Market knowledge is a kind of informational resource. It has been used to explain that the enterprises have market information. (Park & Sternquist 2008, 292)

Through analyses of main factors, the Finnish SMEs could estimate whether to enter the Chinese market. As shown in the figure 2, there are more advantages than barriers. These main factors as mentioned before lead to different entry modes. In the next chapter, international market entry modes are discussed.

### 3 INTERNATIONAL MARKET ENTRY MODES FOR FINNISH MEDICAL DEVICE SMES

*‘An entry mode is as a structural agreement that allows a firm to implement its product market strategy in a host country either by carrying out only the marketing operations (i.e., via export modes), or both production and marketing operations there by itself or in partnership with others (contractual modes, joint venture, wholly owned operations).’ (Sharma & Erramilli 2004, 2)*

In this chapter, on the basis of discussions of main factors influencing on the selection of entry modes in the chapter 2, the suitable entry modes to China for Finnish SMEs are discussed. Different entry modes can be chosen by different SMEs. However, before the enterprises decide the final international entry mode, they need to understand the nature and characteristics of each of entry modes. An inappropriate mode causes slower entry, higher cost risk, lower rate of return, unchangeable long-term contracts or large resource commitments, and sometimes even investment failure (Osland et al. 2001, 153).

International business literature (e.g. Sun 1999, 642; Hill et al. 1990, 118) indicates that international market entry modes generally have four major alternatives: exporting, licensing (or franchising), joint ventures and wholly-owned subsidiaries. Albaum, Strandkov & Duerr (2002, 311) conclude that there are two large categories of entry modes: export entry modes and non-export entry modes. The modes of licensing, joint ventures and wholly-owned are categorized into non-export entry modes.

#### 3.1 Export modes

The export entry modes are divided into indirect export and direct export on the basis of the production country (Albaum et al. 2002, 249; Osland, Taylor & Zou 2001, 154). The basic distinctions between these two exporting methods are carrying out the transactions flow between domestic agents/distributors and foreign agents/ distributors. When enterprises decide to use export modes, transaction cost in all processes of an export business should be considered from the beginning. (Albaum & Duerr 2008, 305)

##### 3.1.1 Indirect exporting

Indirect exporting is to export products through an independent third party (also called intermediary or middlemen) that is located in the export enterprises premises in home



country (Albaum et al. 2002, 275). When selling by intermediary in home country, the export enterprises are normally not responsible for collecting payment from the overseas customer, or for coordinating the shipping logistics (Delaney 1998, 68), and the intermediary is responsible for all commercial operations, for example, the shipment and market of products (Osland et al. 2001, 154). An intermediary is a relatively inexpensive and straightforward way to enter a new market, and also a quick way to get products to end customers (Delaney 1998, 68).

Indirect exporting can also involve selling to intermediaries in the Chinese market, who have in-market experience, reputation and contacts with distribution and other sales channels. Finnish SMEs' products could be then sold directly to customers or to other importing distributors or wholesalers in China. (cf. Delaney 1998, 68; Osland et al. 2001, 154) When the Finnish enterprises use the indirect exporting mode by Chinese intermediaries, they are normally responsible for collecting payment from the overseas customer and for coordinating the shipping logistics (cf. Delaney 1998, 68).

The Finnish SMEs could use home or host country based agents or merchants to export their products to China. At the moment, there is one business consulting firm supported by Finnish government located in China. The Finnish SMEs can consult this Finnish firm in China firstly before acquiring more information on the Chinese market, and then sell their products through local agents or distributors in the Chinese market. Generally, most large and medium-sized enterprises have their own export departments. For some small enterprises, it means there is high capital investment on establishing export department. Hence, in the SMEs there may be an equivalent department, or a designated manager, who is specially in charge of exporting business. The purpose is to coordinate export projects with the intermediary. (cf. Albaum et al. 2002, 275)

### ***3.1.2 Direct exporting***

Direct exporting means an enterprise exports directly to a customer interested in buying the enterprise's product. The enterprise is responsible for handling the logistics of shipment and for collecting payment. (Delaney 1998, 67) Moreover, the export enterprise is in charge of international sales activities and it may coordinate export projects with the target country's intermediaries (Albaum et al. 2002, 293).

The utilization of local agents and/or distributors is welcome to the medical device enterprises, especially for the SMEs because of low costs and versatile selling channels. Setting up a sales branch or sales subsidiary is more expensive for the SMEs than having a distribution partner. Not all Finnish SMEs are familiar with Chinese market environment so the overseas distributors or agents seem to be the quickest and the most convenient export mode for many of them. Normally if a Finnish SME wants to export

its products to China for the first time, one and more agents/distributors may be a better choice. Agents/distributors usually represent the Finnish enterprise in the Chinese market. Many well-established agents have their own customers, and some wholesalers may only buy through a certain agent. Comparing to agents, distributors are to buy products and sell again to their customers with adding a margin or setting their own price. Distributors may buy a number of products in order to hold stock, and they provide after sales service for customers. They tend to concentrate on products that are the easiest to sell with the highest margins. Therefore, if distributors handle a large range of products, part of products may not be paid attention to. (cf. Liu 2004, 38)

However, currently many agents/distributors, especially the smaller ones in China, are unreliable (Liu 2004, 38). It leads to the situation where some foreign brands may be superior in quality, but their business could be adversely affected by the agents/distributors that do not provide good services. Another bad situation may occur that bad agents or distributors replace the export company's products with those of competitors'. Based on this reason, the Finnish SMEs should take the time to select the right agents/ distributors. Word of mouth referrals are often the best way to choose a distributor as trust and a good rapport are essential. Moreover, Albaum et al. (2002, 301) list six points for the selection standard for the target's distributors or agents: *'1) a distributor's level of commitment to both product and market; 2) a distributor's financial strength; 3) a distributor's marketing skills and market knowledge; 4) product-related factors such as the distributor's product line and its compatibility, complementary nature, and quality; 5) planning abilities; 6) facilitating factors, such as political ties of a distributor, language capability'*. The Finnish SMEs should carry out a due diligence to ensure distributors are financially sound with good references and local market knowledge. According to Zacharakis (1997, 23-29), local agents often could provide foreign enterprises with complementary skills, such as market specific sales expertise, a good network of distribution channels or easy access to local authorities. That is to say Chinese agents/distributors can provide the Finnish medical device SMEs with necessary information and assist them entering the Chinese market in the shortest time. When aiming at the Chinese market, a good relationship should be formed between Chinese agents/distributors and the Finnish SMEs as well.

Here, it is worth mentioning that E-commerce has developed rapidly during the last few decades (Albaum & Duerr 2008, 31-32). According to American e-Bay website and Chinese Taobao website, various products or services in a wide scope are mostly sold on the Internet because of convenience and efficiency. For example, products and services include from catering business to apparel industry; from ornaments to household electrical appliances; or from insurance service to ticket ordering service. But, E-commerce is not pragmatic for medical devices because of adulterant, substandard, and sales or registration certifications. Hence, the E-commerce is not discussed in this study.

In the table 5 the basic advantages and disadvantages of indirect and direct exporting are presented.

Table 5: Comparison of advantages and disadvantages between indirect and direct exporting  
(adapted from Delaney 1998, 67-68)

	Advantages	Disadvantages
<b>Indirect exporting</b>	<ul style="list-style-type: none"> <li>- centralism on domestic business</li> <li>- limited liability in the Chinese market</li> <li>- inexpensive and quick entry</li> <li>- less risky because of minimal involvement</li> <li>- field-test products for export potential</li> </ul>	<ul style="list-style-type: none"> <li>- low profits</li> <li>- low control over foreign sales and actual final transactions</li> <li>- unfamiliar with end-customers</li> <li>- difficult to contact local customers → receiving feedback too late</li> <li>- slower expansion in the Chinese market</li> </ul>
<b>Direct exporting</b>	<ul style="list-style-type: none"> <li>- greater degree of control over all aspects of the transaction</li> <li>- knowing customers and understanding of customer needs</li> <li>- maintaining a good relationship with customers</li> <li>- understanding the Chinese market better</li> <li>- ability to identify possible new market opportunities</li> <li>- greater flexibility to improve or redirect their marketing efforts</li> <li>- IPR protection</li> <li>- quick customer feedback</li> </ul>	<ul style="list-style-type: none"> <li>- lots of time, energy, staff resources and money</li> <li>- local language for after-sales services</li> <li>- slower business growth because of competitors</li> <li>- preparation for responding to technical questions (technological products of medical devices)</li> <li>- relative training or ongoing support services</li> <li>- directly in charge of all businesses of products and services in China</li> </ul>

Therefore the mode of direct exporting suits better for the Finnish SMEs. The Finnish SMEs could use the network of local agents/distributors and experiences to sell their products. In the next sub-chapters, other various modes in non-export mode are explored to find out whether these modes are suitable for the Finnish SMEs or not.

## 3.2 Non-export modes

Four main forms are involved in the non-export entry modes: assembly operations, foreign direct investment (FDI), strategic alliances, and wholly-owned subsidiary. Among these main entry modes, the method of manufacturing facilities is divided into Greenfield investment and Merger and Acquisition (M&A). Licensing, contracting and joint ventures are forms of strategic alliances. (Albaum et al. 2002, 249-357) The entry mode of assembly operation is described first.

### 3.2.1 *Assembly operations*

The assembly operations has been widely used by enterprises from different countries in the global manufacturing industry, such as motor industry (e.g. General Motor from the U.S.A.), phone industry (e.g. Nokia from Finland), or electronic products industry (e.g. Philips from Holland). Foreign manufacturers only export components or parts of products to target countries by themselves or by other suppliers who live in a country of origin or abroad, then assemble components or parts together to form the complete product. The purpose of assembly operations is to save freight charges and various foreign government fees. (Albaum et al. 2002, 340-341) Because of rich labor resource and low wages, manufacturing in target country will run cost saving. (Albaum & Duerr 2008, 371)

This kind of non-export mode suits also for medical devices or equipment. However, this mode of assembly operations may be not good for the Finnish SMEs because of limited capital. When the SMEs face high investment risk, the SMEs will select a safest entry mode to avoid capital losses. The mode of assembly operations has certain risks for the Finnish SMEs, although the mode needs less investment than establishing a manufacturing factory (cf. Albaum & Duerr 2008, 371). Hence, the Finnish SMEs rarely opt for this entry mode.

### 3.2.2 *Foreign direct investment*

**Greenfield investment** and **M & A** are the most typical modes of FDI. They may result in expansion of asset scale and production capacity. (Wang 2009, 240) Chen (2008, 24-25) proposes that more international manufacturers of medical devices are going to relocate to China or localize their manufacturing activities in China. Recently, Chinese import regulations of medical devices are rigorously enforced. It is inconvenient for foreign manufacturers (SFDA 2008). Low costs (e.g. labor costs and management costs),

large growing market potential, and tax incentives are attracting more foreign manufacturers, who choose FDI as a mode to expand to the Chinese market. (Liu & Lundin 2007, 17-28) Besides, when tariffs and transport costs are declined, the modes of direct investment are preferred (Markusen 1995, 169-172). For example, when the home currency is appreciated, is cheaper to acquire the foreign assets with the local currency. That is one of the opportunities for the Finnish SMEs entering foreign markets.

**Greenfield investment** is ‘to set up a plant in the host country to produce goods locally’ (Raff et al. 2009, 3). Chang & Rosenzweig (2001, 752-753) expound ‘When a firm has a strong home-based competitive advantage, Greenfield investment may be the most efficient mode of entry since it can build its operation in a way that will minimize the cost in transferring home-based competitive advantages (knowledge) to a foreign affiliate. ... Greenfield investment is often the best way to utilize these home-based advantages.’ Therefore, the method of Greenfield can eliminate some cost caused by market transaction (Wang 2009, 240) and transportation transactions. This kind of mode requires the greatest control over local affiliates (Chang & Rosenzweig 2001, 748). Building own factories or workshops belongs to the green investment. The green investment is used rarely if the Finnish SMEs have no such experience before.

**M & A** is another alternative FDI method of building a sizable presence in a target market and gaining the specific experience quickly (Ekeledo & Sivakumar 2004, 93). The meaning of ‘mergers’ is ‘*amalgamation of two equal companies, and based on the consent of both parties*’; and ‘acquisitions’ means ‘*the combination of two companies of different qualities*’ (Jagersman 2005, 14). M&A differs from Greenfield investment in that the acquirer does not need to set up a new factory in the target market, but rather buy a local enterprise as its foreign affiliate. However, there is the risk of overpayment, inability to fully assess the value of acquired assets, and post-acquisition challenges including cross-cultural integration. (Chang & Rosenzweig 2001, 748) Caves & Mehra (1986, 449) say that large firms are more likely to enter foreign markets through acquisition than small enterprises.

In Finland, about 99.7% of enterprises are SMEs (EU Commission Recommendation 2003). And almost all firms of medical devices are SMEs (Finnish Life Science Organizations Listed 2008). The mode of FDI would be good for Finnish enterprises if they have competitiveness in cost and know-how. But, financial recourse may be a bigger obstacle for the Finnish SMEs (Lee, Lim & Tan 1999, 301). Majority of their funds are spent on product research and development in order to compete with rivals in the same field. Setting up a new factory or buying an existing firm in China is not a feasible option for the Finnish SMEs. Furthermore, it is definitely difficult to be proficient in Chinese culture for the Finnish SMEs. Although TCM culture does not directly influence the export of Finnish medical devices, Chinese business culture and organizational culture must be met by the Finnish SMEs. If the Finnish SMEs want to deal with problems

caused by culture distance, they have to spend more time and money in learning local culture. Hence, it could be said that the mode of FDI may be not suitable for the Finnish SMEs.

### 3.2.3 *Strategic alliances*

An international strategic alliance is a form of collaboration between two or more enterprises from different countries that combine core competencies of the partners to build a common global goal and to achieve mutual benefits and global advantages. Each partner in the alliance usually retains their independence (Akoorie & Scott-Kennel 2005, 379; Keegan & Green 2000, 324; Root 1994, 292-296). This mode can take many forms including *licensing*, *contracting*, *joint venture* and other forms, such as marketing distribution agreement, consortium and vertical alliance or supply-chain alliance (Albaum & Duerr 2008, 377-386). In this study, the first three common forms are discussed.

Osland et al. (2001, 154) say that '*licensing is a non-equity, contractual mode with one or more local partner firms*'. That means a Finnish enterprise could license its property to one or more Chinese enterprises. The property contains the name of enterprise, business methods, manufacturing, marketing knowledge, patents, processing, technical assistance or skills, technological knowledge, trademarks, and trade secrets (Albaum et al. 2002, 347-351; Osland et al. 2001, 154). Park & Sternquist (2008, 296) conclude that if the enterprise is rich in legal or relational resources, but lacks capital, informational, or managerial resources, then the enterprise is most like using a licensing mode. The property should be paid in a reasonable fee or in shares to the Finnish enterprise by the Chinese firm. Generally, Finnish medical devices may be licensed more in production and technology transformation. (cf. Osland et al. 2001, 154) Medical devices must be produced in accordance with high quality under the licensors' brand, i.e. the brand of the Finnish enterprises. If the licensees produce products of poor quality, it could affect the global reputation of the Finnish enterprises.

Moreover, the use of licensing means that the Chinese government could easily find alternative enterprises to do business with. When many foreign competitors attempt to enter a market, the government has more bargaining power in China than an individual foreign enterprise. Thus, when the Chinese government expects new businesses to be managed by different nations, or when the Chinese government prefers cooperation or collaboration, the Finnish enterprise must comply with the Chinese government's modal preferences. Besides, a local licensee contributes all of the capital to establish the business. The environment of current medical device market in China is stable. There is no political risk, and IPR law is updated. Hence, licensing is recommended to be used as a

quick and easy way for the Finnish SMEs when they lack the specific resources to do business alone in China. (cf. Osland et al. 2001, 157)

There are two forms of **contracting** including contract manufacturing and management contracting. Albaum et al. (2002, 351 & 353) define these two entry forms respectively as follows:

*‘Contract manufacturing is that a company contracts for the manufacture or assembly of its product(s) to manufacturers established in foreign markets, either targeted for sales there or elsewhere while still retaining the responsibility for marketing and distributing its products’.*

*‘Management contracting is that a local investor in a foreign market provides the capital for an enterprise, while an outside enterprise provides the necessary know-how to manage the enterprise’.*

According to definitions above, contract manufacturing emphasizes on manufacturing of a transfer of technology, and management contracting focuses on the necessary know-how management.

The form of contracting is often used for sourcing because of low cost of production. It is a low risk option for the Finnish enterprises to sign a contract with local manufacturers in China, if the local manufacturers can offer the lowest producing cost. The Finnish enterprises then provide the technical assistance and necessary know-how management to the Chinese local manufacturers. The local manufacturers produce all or only part of the products for the Finnish enterprises under the contracts. The relationship between the Finnish enterprises and the Chinese manufacturing enterprises is basically customer and supplier, i.e. the Finnish enterprises become customers, and the Chinese manufacturing enterprises are suppliers. If the products of the Finnish enterprises rely heavily on their design to be competitive, the Finnish enterprises should be careful and know who has the information of the relative product. Hence, the Finnish enterprises should consider manufacturing only certain components in China in order to protect its IPR. However, there is neither equity control nor legal responsibility for the Finnish enterprises when the Finnish enterprises manage the Chinese enterprises. (cf. Chan & Chung 2002, 113-120)

**Joint venture** is often used as a collaborative mode of entry (Albaum et al. 2002, 354). The main reasons are that joint venture can enhance an enterprise’s capabilities and develop new capabilities (Kogut 1988, 319; Ghoshal 1987, 425), and help a firm to gain new knowledge (Huber 1991, 89). Joint venture means that the enterprise joins with another enterprise from foreign country to form a new enterprise in the foreign market. Both parties share ownership, control, management, risks and rewards. The share proposition is allocated according to negotiations between two parties from different countries. Each party contributes equity that is in the form of money, plant and equipment, and technology. (Albaum et al. 2002, 354-356; Osland et al. 2001, 154)

Joint ventures can also be used to eliminate trade barriers between export and import countries.

After the Finnish SMEs decide to look for a partner or partners in China, they should consider their own strengths and weaknesses. An ideal partner offers complementary strengths assisting the Finnish enterprises to develop its business or production areas. In recent years joint venture mode has been quite popular in industries of medical devices and pharmaceuticals in China. One of the possible reasons may be the Chinese government policies and regulations on imported drugs and medical devices (SFDA 2008). Other reasons may be fierce competition, or nationalistic feelings. In China, the Finnish enterprises may take two types of joint venture to enter the Chinese market, i.e. equity joint venture (EJV) and contractual joint venture (CJV). These two types are different in legal form, capital and risk involvement, and management structure. An EJV is a new limited liability enterprise created by foreign and Chinese partners with equity and management shared in a negotiated proportion. A CJV is an arrangement whereby Chinese and foreign partners cooperate in some joint projects or activities according to the terms and conditions stipulated in a venture contract. However, it has been used less since the mid-1980s because of unclear independent legal form and less favorable policy treatment. (Sun 1999, 646 & 657)

The Chinese government plays a very important role for the Finnish SMEs in determining the mode of foreign entry. The policy orientation is one of major determinants of entry mode choice for the Finnish SMEs and can substantially influence the entry modes. Chinese government regulations, taxes and political conditions influence entry of Finnish medical devices (cf. Albaum et al. 2002, 415). If the Chinese government encourages joint ventures by using favorable policy treatments such as tax concessions, the Finnish SMEs, who have backgrounds of strong capital and resourceful investment experiences, may have incentives to choose joint venture as their entry mode. (cf. Chang & Rosenzweig 2001, 756)

In addition, the larger cultural differences between China and other countries, the higher frequency of using joint venture (Sun 1996, 647). Therefore, the Finnish SMEs may use the mode of joint venture if they have already set up a business with Chinese agents or distributors for several years, otherwise, the Finnish SMEs may select other foreign entry modes in order to reduce risks.

The table 6 shows a comparison of advantages and disadvantage of forms of licensing, contracting and joint venture.



Table 6: Comparison of advantages and disadvantages of licensing, contracting and joint venture

(adapted from Chang & Rosenzweig 2001, 748; Osland et al. 2001, 158; Sun 1999, 657)

	Advantage	Disadvantage
<b>Licensing</b>	<ul style="list-style-type: none"> <li>- low costs of manufacturing</li> <li>- accessing to local knowledge and the licensee's experience</li> </ul>	<ul style="list-style-type: none"> <li>- little control over the licensee</li> <li>- a much smaller slice of the profit</li> <li>- proprietary technology losing</li> </ul>
<b>Contracting</b>	<ul style="list-style-type: none"> <li>- simple</li> <li>- low costs</li> <li>- low risks</li> </ul>	<ul style="list-style-type: none"> <li>- IPR problems</li> <li>- no equity control and legal responsibility</li> </ul>
<b>Joint venture</b>	<ul style="list-style-type: none"> <li>- equity → sharing the risks</li> <li>- opportunities for growth</li> <li>- focusing on enterprises' own core strengths</li> <li>- lower tax rates on profits</li> <li>- less government interference</li> <li>- accessing resources:               <ul style="list-style-type: none"> <li>➤ specialized staff</li> <li>➤ finance</li> <li>➤ technology</li> </ul> </li> <li>- accessing the target market:               <ul style="list-style-type: none"> <li>➤ distribution network of partners</li> <li>➤ greater freedom on use promotional activities</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- less profit</li> <li>- longer time of return of investment</li> <li>- disputes because of:               <ul style="list-style-type: none"> <li>➤ IPR</li> <li>➤ jointly developed products</li> <li>➤ cultural difference</li> </ul> </li> <li>- high level of commitment in:               <ul style="list-style-type: none"> <li>➤ finance</li> <li>➤ management time</li> </ul> </li> <li>- overwhelmed (if larger local partners)</li> </ul>

Most foreign-invested health care enterprises are located in major urban areas in China because of increasing wealth and foreign population. These foreign enterprises operate small, fairly low-profile joint venture clinics and departments within hospitals. Currently there are about 200 foreign-invested health care institutions running in China (Liu & Yi 2004, 56), for example, United Family Hospital in Beijing, and Shanghai World Link Medical and Dental Center. According to the Interim Measures on the Administration of Sino-Foreign Equity and Joint Venture Medical Institutions, foreign investors may not operate wholly foreign-owned health care institutions, but foreign investors are permitted to hold up to 70 percent of the equity shares of Sino-foreign joint

venture health care institutions. Chinese government encourages the formation of joint ventures by allowing foreign investors to set their own prices for medical services, exempting them from business tax on income from medical services for the first three years of operation. (cf. Garcia-Castro 2009, 7-12) In 2006 China changed the joint venture laws (Park & Sternquist 2008, 293), and it directly lead to more and more foreign investors to enter China.

#### **3.2.4 *Wholly-owned subsidiary***

In a rapidly growing industry of medical devices, time consuming entry modes lead to high opportunity costs (Chang & Rosenzweig 2001, 756). The mode of wholly-owned subsidiary requires significant resources of capital, informational and managerial resources. When an enterprise has sufficient internal resources for a new daughter-enterprise in a foreign market, the mode of wholly-owned subsidiary must be considered as the first selection, or is chosen; but if the enterprise lacks these resources, it may rely on licensing mode. (Park & Sternquist 2008, 293)

The wholly-owned subsidiary is warmly welcome for the multinational corporations' expansion abroad because of advantages in financial control, technological knowledge and market knowledge (Park & Sternquist 2008, 295). High technology industries largely adopt the form of wholly-owned subsidiary, since this entry mode enables foreign investors to exercise a sufficient control over the operation of the business and to minimize management costs associated with joint ventures. There is one pre-condition for operating the mode of wholly-owned subsidiary successfully, that is foreign investors need to have enough knowledge of Chinese legal system, market structure, business practice and economic and policy conditions. (Sun 1999, 649 & 657) If the foreign enterprises want to set up subsidiaries in China, or have already their own subsidiaries in China, hiring and retaining good staff for local operations are necessary and important (Boyd 2009). The table 7 concludes advantages and disadvantages of wholly-owned subsidiary.

Table 7: Advantages and disadvantages of wholly-owned subsidiary

	Advantages	Disadvantages
Wholly-owned subsidiary	<ul style="list-style-type: none"> <li>- high profits</li> <li>- greater control over business activities overseas</li> <li>- can be used as importer or distributor</li> <li>- direct communication with local customers</li> <li>- high credibility</li> <li>- low risk in culture knowledge</li> <li>- easier expansion of local business and market</li> </ul>	<ul style="list-style-type: none"> <li>- high operation cost</li> <li>- high investment cost</li> <li>- understanding local tax, contract, employment laws and relative regulations e.g. a written agreement in Chinese</li> <li>- repatriating profit from the subsidiary abroad</li> </ul>

When compared to large multinational corporations, SMEs often lack the knowledge and financial resources. Normally, the Finnish SMEs have difficulties to handle most of the costs and risks of international expansion through wholly-owned subsidiaries. Consequently, if the Finnish SMEs that have entered the Chinese market for several years ago, want to expand their business in China, it is better that they rely on collaborative modes of operation in China, i.e. joint venture, not the form of wholly-owned subsidiary. (cf. Ekeledo & Sivakumar 2004, 79; Zacharakis 1997, 27) Moreover, some researchers say that the firm should use a completely-controlled entry mode to protect its proprietary knowledge. But the completely-controlled entry mode does not suit all enterprises, especially for the SMEs.

To sum up, the Finnish SMEs enter the Chinese market by four international entry modes of exporting, licensing, contracting, and joint venturing. The table 8 illustrates the relationships between characteristics and the related entry modes.

Table 8: Characteristics of alternative four entry modes

(Blythe & Zimmerman 2005, 111-112; Ekeledo & Sivakumar 2004, 75; Osland et al. 2001, 155; Sun 1999, 642-650)

Characteristics	Entry Mode			
	Exporting	Licensing	Contracting	Joint venture
Involvement / Control (level)	Low	Low	High	Moderate/ High
Knowledge Dissemination Risk (level)	High	High	Low	Moderate
Resource Commitment (degree)	Low	Low	Low	Moderate
Relational Friction	High	High	High/ Moderate	Moderate
Technology Risk (level)	Low	Low	Low/ Moderate	Moderate
Investment Cost	Low	Low	Low/ Moderate	Moderate
Investment Returns	Low/ Moderate	High	Moderate	Moderate/ High

According to Table 8, one criterion of choosing entry mode is *control*. The ‘control’ factor determines both of risks and returns, the amount of relational friction between buyers and sellers, and the ultimate performance of the firms’ investment abroad (Blomstermo et al. 2006, 212). Involvement is used interchangeably with control because of the strong correlation between the Finnish enterprises’ level of involvement and control in their Chinese partners (cf. Erramilli & Rao 1990, 135-137; Anderson & Gatignon 1986, 5-10). Involvement/control is seen as the level of market-specific managerial and financial resources committed to the Chinese partners by the Finnish enterprises. Vernon (1983, 191) indicates that different entry modes require different resource commitments. As shown in the table 8, low control entry modes require a limited or low resource commitment, thus the uncertainty in the Finnish SMEs will be reduced (cf. Blomstermo et al. 2006, 214). In other words, if the Finnish SMEs opted for the exporting mode with low-controlled and low resource commitment, they would face

lower risk and low uncertainty. Klein & Leffler (1981, 625) propose that high control entry modes are preferred when brand name value is high. In order to control own brands, the Finnish SMEs could use contracting or joint venture due to relatively low investment cost.

High-controlled entry modes tend to build up closed relationships with the foreign customers and markets (Hastings & Perry 2000, 207-210), that is, the relational friction is the lowest under the highest control. If the interaction between the Finnish SMEs and Chinese customers occurs through a local agent/distributor, the loss of control may result in bigger relational friction. Relational friction may develop due to divergent interests of enterprises, differences in business and organizational culture, and misunderstanding or misinterpretations (cf. Blomstermo et al. 2006, 216). Moreover, when a Finnish enterprise has high levels of tradable assets, it may like to select the high-controlled entry mode to reduce the opportunistic behaviors from its cooperative partners (cf. Agarwal & Ramaswami 1992, 1-27; Anderson & Gatignon 1986, 1-26). Thus, a high-controlled entry mode may reduce the relational friction generated by dissimilar partners (Barkema & Vermeulen 1998, 7-10; Barkema et al. 1996, 151-153).

Besides, Zahra et al. (2000, 926) report that high-controlled international entry modes are more conducive to fast technology transferring although the high risk leads to losing control of technology. Williamson (1979, 233) points out that new technologies are usually handled by the mode of wholly-owned subsidiary with high control; old technology is often handled by a licensing or a joint venture with low or medium control. If foreign enterprises have standardized technology, equity joint venture is the most suitable mode to invest. For Finnish SMEs, the mode of wholly-owned subsidiary is not the most suitable as mentioned before, so that they may choose the mode of licensing or the mode of joint venture to manage their technologies. Joint venture mechanism could help the Finnish SMEs to reduce the external business uncertainty associated with the cultural distance (cf. Sun 1999, 646, 653 & 657).

Selecting the exporting mode, the Finnish SMEs receive low or moderate investment returns due to low involvement/control, low resource commitment, low technology risk, and low investment cost. The licensing mode may lead to high investment returns under the similar situations. But it may make the Finnish SMEs losing control of technologies. Thus, the mode of exporting would be preferred for those Finnish SMEs that have not entered the Chinese market before. Nevertheless, Lee, Lim & Tan (1999, 308) state the SMEs may not be able to retain the market developed in the face of the large competitors later, even if the SMEs succeed in their market entry and development efforts. Hence, in order to receive more returns or benefits from the markets, the Finnish SMEs should change their entry mode and try to seek out alliances with local large firms to commercialize their inventions or products (cf. Gomes-Casseres 1997, 33), for example, many biotechnology firms have collaborated with large pharmaceutical firms. The entry

modes of contracting and joint venture may be suitable choices. Comparing to the mode of contracting, the mode of joint venture leads to higher investment return benefits.

### 3.3 Synthesis

This chapter discusses the second sub-objective in this study: *to discuss main entry modes for Finnish medical device SMEs entering the Chinese market*. Four entry modes that are most suitable for the Finnish SMEs are summed up in the figure 3.

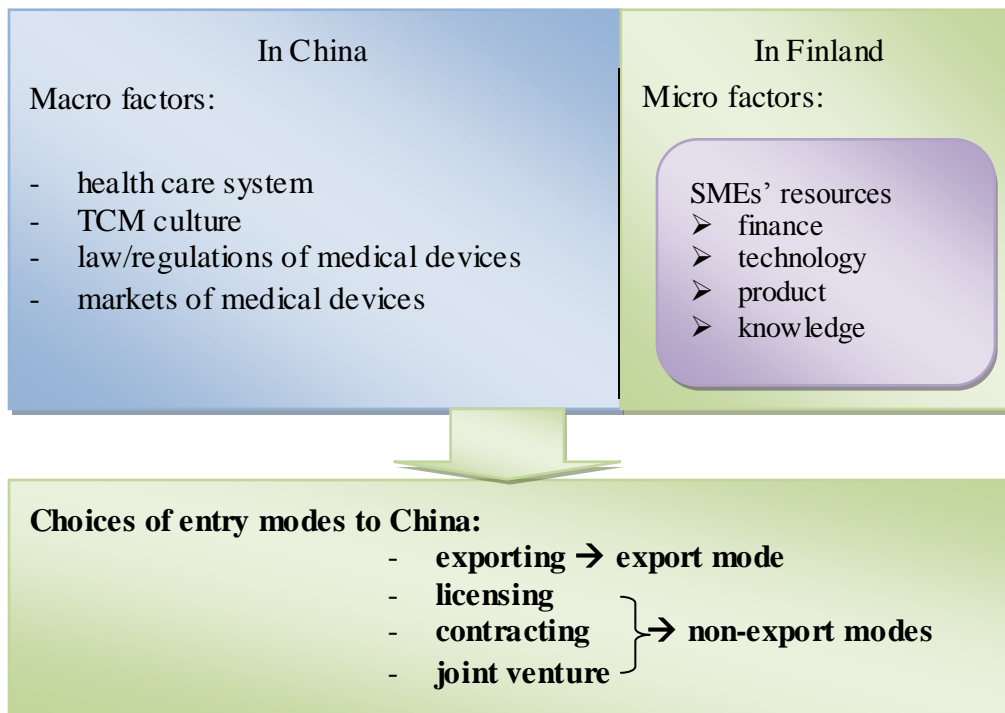


Figure 3: Synthesis of choices of entry modes based on influencing factors

As presented in the figure 3, the export mode of exporting and the non-export modes of licensing, contracting, and joint venture are best for the Finnish SMEs. Among them, the mode of exporting is best for those Finnish SMEs that enter the Chinese market for the first time. The next chapter analyzes the adaptation of marketing mix of the Finnish SMEs after entering China.

## 4 ADAPTATION OF MARKETING MIX FOR MEDICAL DEVICES

*‘Marketing is human activity directed at satisfying needs and wants through an exchange process.’ (Kotler & Turner 1983, 13)*

Marketing mix plays the leading role in the whole process of successful launch of products in one or more markets. This chapter analyzes adaptation of marketing mix, which builds upon main factors influencing the Finnish medical device SMEs on the selection of entry modes in Chapter 2. It also builds upon suggestions of suitable entry modes for the Finnish SMEs entering the Chinese market in Chapter 3. In following sub-chapters, business-to-business (B2B) marketing, review of marketing mix theories, and adaptation of marketing mix for Finnish medical devices are described and discussed one by one. Because in this study the customers are distributing, retailing or wholesaling enterprises of medical devices, hospitals, clinics, and medical research institutions in China, business-to-consumer marketing is ignored in the study.

### 4.1 Concept of business-to-business markets

Before the marketing mix is discussed, the concept of business-to-business (B2B) has to be introduced. According to definitions of B2B marketing, the customers of B2B marketing are retailers, wholesalers, or distributors, who buy goods or services for use in the production of other products and services, then resell, rent or supply to other institutions (Kotler & Armstrong 2001); as well as hospitals, charities and all levels of government (Blythe & Zimmerman 2005, 4). Blythe (2006, 27) said *‘B2B is actually much larger than B2C marketing in terms of size of markets because products typically pass through several firms before they reach the consumers’*. Hence, B2B marketing occupies a crucial position in the whole marketing.

The Figure 4 shows transactions originating from the collection of raw materials to final sale in China. As shown in the figure, the Finnish enterprises are assumed to be in charge of production process from selection of raw materials to assembly of final products, except part of production is done overseas.

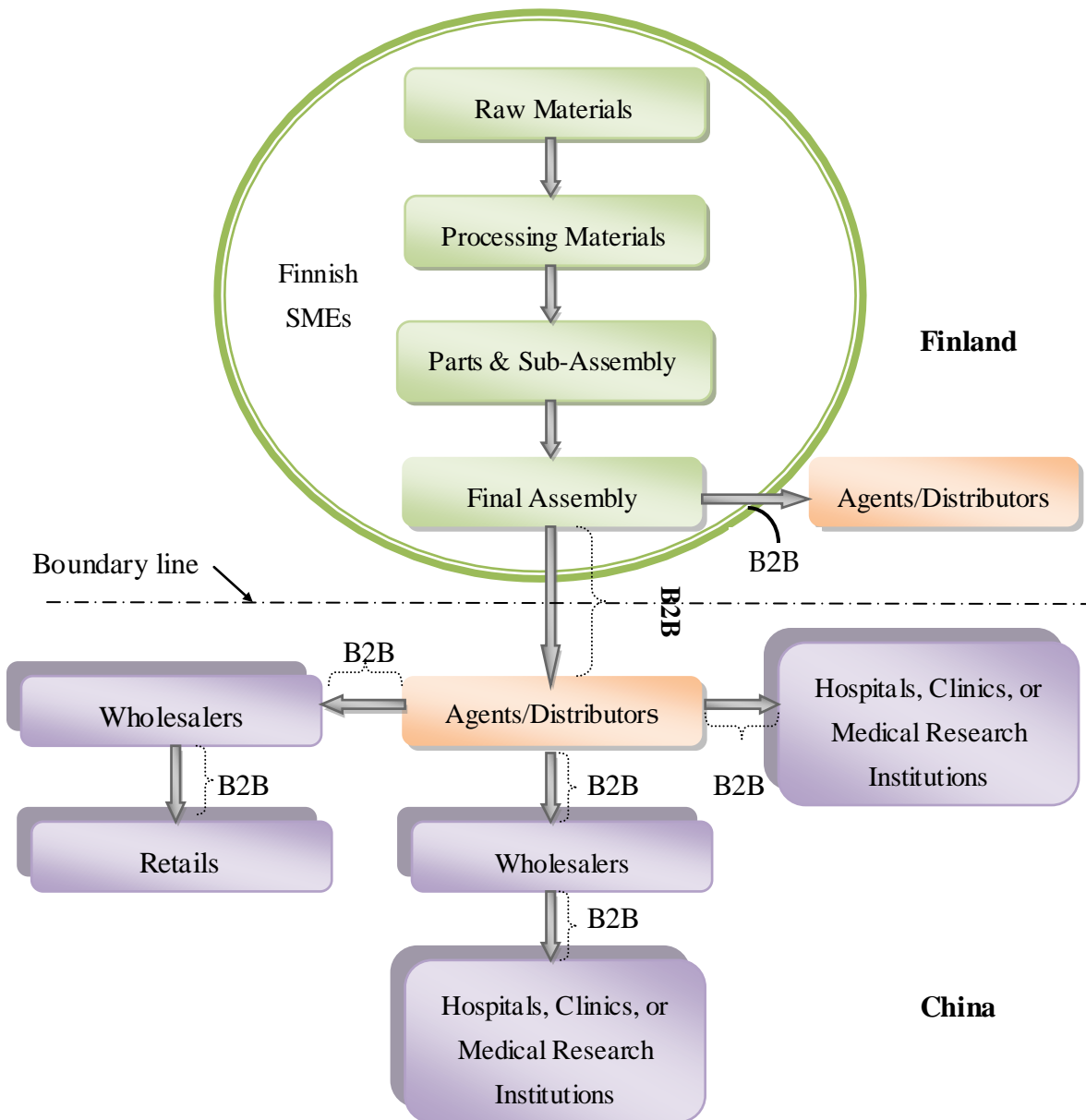


Figure 4: Transactions of medical devices between Finland and China

When the Finnish enterprises export the final assembled products to China, they may sell their medical devices to agents or distributors in Finland or in China. Then agents or distributors can resell the products to local wholesales, and/or local hospitals, clinics or medical research institutions directly. Their transactions belong to the B2B. Next, wholesalers resell the medical devices again to hospitals, clinics, or medical research institutions, and/or local retails, B2B transactions are happened one more. Certainly, B2C marketing occurs in the market of medical device too. Normally, the medical devices for B2C are small products and can be used easily, such as, fever thermometer, small electronic hematomanometer, and masseur. In consequence, after wholesalers sell the



medical devices to retailers (like as pharmacies), local citizens can buy their products at the pharmacies. Next, some schools of marketing mix theories are reviewed.

## 4.2 Review of marketing mix theories

With diversifying market during the last century, different marketing mix theories have emerged. According to Blythe (2006, 7), the marketing mix is all the activities undertaken by enterprises. The term of ‘marketing mix’ was created in 1953 by Neil Borden (Dominici 2009, 17), and the concept means that the market demand is affected by the marketing variability or the marketing elements. When enterprises want to sell their products in a new market both in their own countries and overseas, the marketing strategies have to be drawn up elaborately and precisely. Therefore, it is very important that the marketing mix theories are known well. The enterprises’ SWOT (strength, weakness, opportunity and threat) can be analyzed by the elements of marketing mix, such as 4P’s, 7P’s, 10P’s, 4C’s, or 4R’s. Since there are various marketing mix theories, and more new marketing mix theories may be proposed, one model of marketing mix cannot be suitable for all enterprises. Enterprises must find their own best marketing mix according to the enterprise’s particular essential elements. Since this study focuses on adaptation of marketing mix for Finnish SMEs in the Chinese market, the reviewing marketing mix theories is of utmost importance here.

The well-known 4P’s theory was defined by Jerome McCarthy in 1964 (Dominici 2009, 17). McCarthy & Perreault (1990, 36) defined ‘marketing mix’ consists of four elements including product, price, place and promotion. According to the 4Ps theory, there are two sides of factors which affect corporate marketing activities: one is uncontrollable factors (also called the external environment), such like political, legal, economic, cultural, environmental and geographical factors. Another is controllable factors (also called the internal environment), that a business can control, for instance, production, pricing, distribution, marketing promotion and other factors. Kotler (2001) said that if the enterprise could produce appropriate products, set appropriate prices, use appropriate distribution channels, be supported by appropriate promotions, the enterprise would be successful. The 4Ps marketing is very concise and easy to grasp so that it becomes generally an accepted model of marketing mix by marketers (Dominici 2009, 17-18). Booms & Bitner (1981, 47-51) proposed a 7Ps marketing mix theory. They added 3Ps (*participants*, *physical evidence* and *process*) on the basis of 4Ps in order to recognize the different nature of services marketing (Blythe 2006, 8).

Kotler (1986, 117) proposed an extended marketing theory, i.e. 6Ps marketing mix. 2Ps on the basis of 4Ps were added, that is, ‘*political power*’ and ‘*public relations*’. ‘*Political power*’ means that enterprises propose their own development ideas to local in-

dustry officials, legislators and government bureaucrats through using some business activities and negotiation skills. With international and domestic competition increasing, and various forms of government intervention and trade protectionism in the re-emergence of the new situation, it is necessary to use political force and public relations in order to break international and domestic trade barriers and open a way for the corporate marketing. The element of '*public relations*' effects on the public viewpoints and establishes good reputations for products and enterprises in the public through a public communication technology. (Kotler 1986, 117-124)

Kotler (1992, 50-52) introduced a strategic marketing (new 4Ps: '*probe*', '*partition*', '*priority*' and '*position*') based on the mega marketing mix. The strategic marketing mix may be considered more when a Finnish enterprise makes its marketing plan in China. In the marketing, '*probe*' is actually marketing research, it means to systematically collect, record, sort out and analyze relevant marketing information under the guidance of marketing concept in order to meet customers' demands. '*Partition*' is a process of market segmentation. Since the demands of customers are different, the whole market is divided into several customer groups. Each segment has its own characters and features. (Peck et al. 1999, 37) The following 'P' is '*priority*'. It is to select target markets on the basis of market segmentation. If Finnish enterprises want to enter the Chinese market, they must know what kind of customers are their targets in China. Moreover, the enterprises should aim at the targets and deal in certain products to meet customers' demands according to their own limited resources and customer demands. (cf. Brennan et al. 2007, 149-165) '*Position*' is the last P of the strategic marketing mix. It means market position. The Finnish enterprises need to develop unique products so that they can seize a certain market share from their strong competitors, such as the U.S.A., Germany, and Japan. (cf. Brennan et al. 2007, 166)

In short, the 4P's marketing theory is one main marketing mix approach (Grönroos 2002, 134; Kent 1986, 145-146). According to Kotler's marketing theory of 10P's, the basic marketing mix of 4P's can be developed smoothly after the strategic marketing mix is done well. In other words, enterprises should conduct research on a virtual situation in the market of Chinese medical devices and customers' demands before they apply the basic marketing mix. At the same time, the marketer may use two kinds of marketing skills 'political power and public relations' flexibly. Finally, '*people*' is added as a new factor of strategic marketing in the marketing mix.

The traditional 4P's theory faces more and more challenges from new theories of marketing mix because '*4Ps are never applicable to all markets and to all types of marketing situations*' (Grönroos 2002, 137). Moreover, there is one main argument against the 4Ps since the 4Ps model is internally oriented and lacks of customer orientation, i.e. insufficient attention to the relationship with customers (Dominici 2009, 18). The American scholar Lauterborn (1990, 26) put forward the 4C's marketing mix theory:

*customer, cost, convenience and communication.* ‘*Customer*’ refers to the customers’ wants and needs. First of all, customer value is emphasized. Enterprises must understand the customers’ demands, and then provide products according to different requirements of customers. An ideal product pricing comes from cost consideration. ‘*Cost*’ should be considered from the customer’s purchase cost. The ideal price should be lower than customers’ psychological price and let enterprises receive profit. In addition, the customer purchase cost also could be referred in customers’ currency expenditure, spending time, physical and energy consumption, as well as the purchase of risk. Next, ‘*convenience*’ means providing customers with the easiest solution of purchasing and usage. Here customers’ convenience is emphasized rather than enterprises’ own convenience. Through good pre-sale, sale and after-sales services, customers enjoy convenience when purchasing. Finally, the term of ‘*communication*’ refers to ‘promotion’ in the corresponding 4P’s theory. The 4C’s marketing theory states that through an active and effective communication with customers, enterprises build a new enterprise-customer relationship which is based on the common interests; no longer are enterprises to promote products and persuade customers. (Lauterborn 1990, 26)

However, there are still some shortages in the 4C’s theory due to the trend of the practice of corporate marketing and market development. Firstly, in contrast to the production-oriented 4P’s theory (Grönroos 1989, 52), the 4C’s theory focuses more on customers’ demands, i.e. a customer-oriented marketing theory. But, current market economy is competition-oriented. In China, the marketing of many enterprises has also turned into the phase of competition-oriented market. The essential difference between customer-oriented and competition-oriented marketing is that the former is to pay attention to new customers’ needs and demands; the latter is also to pay attention to their competitors in addition to new customers’ demands (Doyle 1995, 26-28). The enterprises analyze their own strengths and weaknesses in the competition and adopt relevant strategies. If enterprises only meet customers’ demands and ignore enterprises’ internal production cost, enterprises may receive low profits (Kotler & Armstrong 2009, 44). It will cause slow growth of enterprises. Thus, enterprises should follow the win-win principle, though customers always expect to buy products of high quality and at good price. Furthermore, according to current market development, enterprises should establish more effective relationships (for example, an interactive relationship, a win-win relationship and a co-operational relationship) with their customers, not only focusing on customer demands. (Kotler & Armstrong 2009, 46-47)

On the basis of the 4C’s marketing theory, the 4R’s marketing theory was proposed as a new marketing theory by Schuhz (2000). The 4Rs are *relevance, reaction, relationship* and *reward* respectively. The marketing theory emphasizes that enterprises should build a new active relationship with customers through more effective methods on a higher level, i.e. the significance of relations marketing. The first R is ‘*relevance*’. It

means that enterprises must contact with customers closely, so that there is a relationship of mutual aid and mutual benefit between them. ‘*Reaction*’ is the second R. The main meaning is to improve the market’s reaction speed. In an interactive market, most realistic problems for enterprises are not focusing on how to make, implement and control strategic plans, but pointing at how to listen to customers’ expectation, aspiration and demands in time. Furthermore, enterprises should respond quickly to customer demands. It benefits enterprises’ market development. The third R is ‘*relationship*’. An interactive relationship is very important between enterprises and customers. Nowadays a long-term and stable customer relationship is the key of occupying market share. Communication with customers is a crucial method of the establishment of interactive relationship. ‘*Reward*’ means return from the marketing source. The return is a necessary condition for maintaining market relations on one hand; on the other hand, the pursuit of return on sales is a driving force for marketing development. In order to pursue profits, enterprises must implement the low-cost strategy. The ultimate value of marketing is to bring the short-term or long-term revenue to enterprises. However, not all enterprises could establish the effective relationship with customers. (Schuhz 2000)

A comparison of three marketing theories (4P’s, 4C’s, and 4R’s) is concluded in the Table 9. The mentioned marketing mix of 4P’s considers marketing problems from the standpoint of enterprises. It is a basic frame of marketing. On the contrary, the marketing mix of 4C’s considers this kind of problems from the customers’ angle. In other words, the customers’ demand is emphasized. Both of these two processes of marketing mix of 4P’s and 4C’s are static. The marketing theory of 4R’s combines the marketing theory of 4P’s with the marketing theory of 4C’s. The process of marketing mix of 4R’s is dynamic, i.e. there is an interaction between enterprises and customers. Nevertheless, the marketing theories of 4P and 4C cannot be replaced by the marketing theory of 4R. Hence, if enterprises can combine these three marketing mixes according to their own actual situations, enterprises may be able to win more market shares under the situation of fierce competition at the moment. That is to say, an innovative marketing mix should be created, not by copying existing theories of marketing mix.

Table 9: Comparison of three marketing mix theories

	4P	4C	4R
Theorizer	Jerome McCarthy (1964)	Robert Lauterborn (1990)	Done Schuhz (2000)
Elements	<ul style="list-style-type: none"> <li>- product</li> <li>- price</li> <li>- place</li> <li>- promotion</li> </ul>	<ul style="list-style-type: none"> <li>- customer</li> <li>- cost</li> <li>- convenience</li> <li>- communication</li> </ul>	<ul style="list-style-type: none"> <li>- relevance</li> <li>- reaction</li> <li>- relationship</li> <li>- reward</li> </ul>
Oriented marketing	production-oriented marketing	customer-oriented marketing	competition-oriented marketing
Concern	<ul style="list-style-type: none"> <li>- products</li> </ul>	<ul style="list-style-type: none"> <li>- customers' needs and wants</li> </ul>	<ul style="list-style-type: none"> <li>- competitive advantages (interaction in enterprises &amp; customers)</li> </ul>
Shortage	<ul style="list-style-type: none"> <li>- limited resources</li> <li>- less interactive relationships with customers</li> </ul>	<ul style="list-style-type: none"> <li>- high cost</li> <li>- slow growth</li> <li>- less interactive relationships with customers</li> </ul>	<ul style="list-style-type: none"> <li>- difficult to build a good relationship of interaction in all enterprises</li> </ul>

Consequently, laying down an adaptation of marketing mix is particularly important for the Finnish SMEs when they want to develop or have launched products in foreign markets. The enterprises' sizes and resources can affect effectiveness or innovativeness of operating marketing mix. An adaptation of marketing mix for the Finnish SMEs is discussed in the next section.

### 4.3 Adaptation of marketing mix by Finnish medical device SMEs

The marketing mix of '*10Ps + 1C + 1R*' is considered as suitable adaptation of marketing mix for Finnish medical device SMEs. The '*10Ps*' marketing theory consists of the basic marketing mix of 4Ps, the strategic marketing mix of 4Ps and the marketing skills of 2Ps (Kotler 2001). '*1C*' means '*customers*', who should be focused on in the marketing mix. In this paper, the customers are mainly Chinese distributors and hospitals. Learning and satisfying customers' demands are very crucial in order to sell more products and achieve higher profits. Moreover, '*1R*' is referred as '*relationship*'. Grönroos (1990, 138) said: '*marketing is to establish, maintain and enhance relationships with customers and other partners, at a profit, so that the objectives of the parties involved*

are met. This is achieved by a mutual exchange and fulfillment of promises.’ Besides, relationship (‘guanxi’ in Chinese) is one kind of very important Chinese culture and an integral part of doing business (Vanhonacker 2004, 49). ‘Guanxi can aid a distinctive strategic positioning in China’s competitive environment, and thus it can become an important ingredient in business strategy’, Vanhonacker (2004, 50) states. It is known that the element of ‘relationship’ is necessary for developing business in China. In B2B marketing, relationships between enterprises are a complex phenomenon (Brennan et al. 2007, 62). The market-based organizational relationship is the most efficient for entering foreign markets (Forlani et al. 2008, 293). Keeping good and harmonious relationship between Finnish enterprises and Chinese customers could lead to a relatively long-term cooperation and/or collaboration. In Figure 5, the ‘relationship’ factor occupies a very important position in the marketing mix of Finnish enterprises in China. It is a bridge connecting Finnish SMEs and Chinese customers, as well as Chinese government and society.

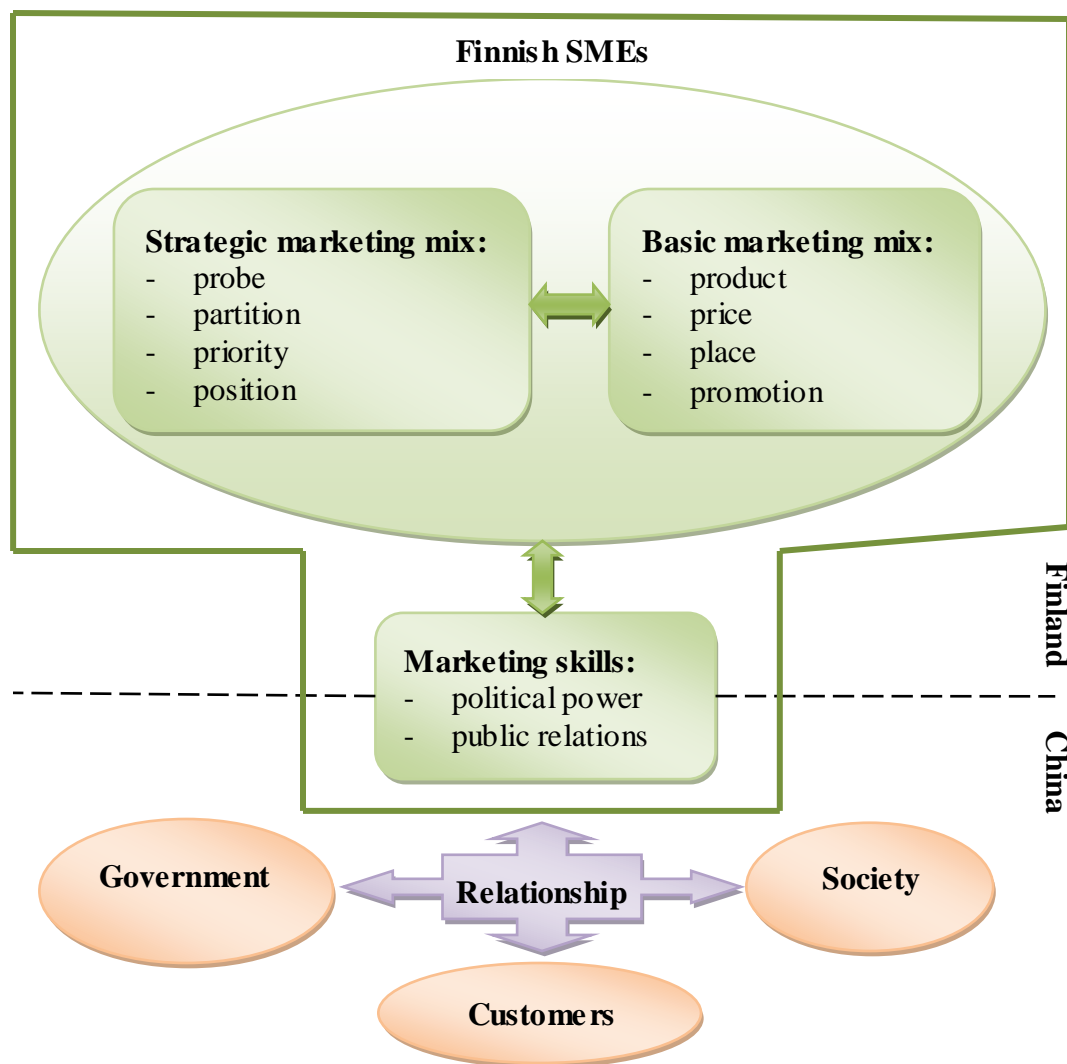


Figure 5: Marketing mix for Finnish medical device SMEs

In order to describe the adaptation of marketing mix, all the elements (10Ps + 1C + 1R) are discussed in detail in the following paragraphs.

Albaum et al. (2002, 386 & 388) said: '*the **product** is the heart of the marketing mix, and the sum of all the physical and psychological satisfactions that the buyer (or user) receives as a result of the purchase and/or use of a product*'. Chinese customers have various requirements for medical devices. Hence, multinational decisions on characteristics and packages for medical devices are necessarily quite complex (cf. Kotler & Armstrong 2009, 294). According to the actual market situation, products are defined by adaptation or standardization (Kotler & Armstrong 2009, 293), and justified by their life cycle (Brennan et al. 2007, 267-270). When the Chinese market is saturated with the same or similar medical devices, the Finnish enterprises should consider developing and improving existing products, even promoting new products in place of existing products. Exporting an uncompetitive product is not a wise decision, since it adds overhead costs and resources are often diverted from more profitable uses (Albaum et al. 2002, 402). Once a medical device has been evaluated as being uncompetitive, a decision must be made, which is about withdrawing the medical device from the Chinese market. Certainly, if there are no similar products in the Chinese market, the Finnish enterprises can launch their existing products into China directly after they have finished a feasible market research. However, many products should be adapted to the Chinese market.

A product consists of three major components in general involving in *the physical product core, the product package, and auxiliary services* (Albaum et al. 2002, 389; Kotler & Armstrong 2009, 238). As for the physical product core, medical devices are highlighted on functional features, design and style, since customers like novelty products at lower prices, with innovative function and of higher quality (cf. Brennan et al. 2007, 264). For the package of medical devices, the Finnish enterprises may use standardized packages in order to reduce the cost and generate certain benefits. At the same time, the enterprises should consider packaging material which can be recycled so that environment will not be polluted (Albaum et al. 2002, 420-421). Considering B2B marketing, the package of medical devices may be simple and convenient, but it must be safe. Moreover, products' brand names, labels and trademarks should be marked on the boxes of all packages. Brand name is important since Chinese distributors, wholesalers and retailers opt for foreign products of medical devices by brand, which indicates the origin of medical devices and is the assurance of quality (cf. Kotler & Armstrong 2009, 244). The Finnish enterprises should consult legal counsel before they plan to export medical devices to China (cf. McCarthy & Perreault 1990, 238), because there are IPR problems in China. A local brand could help Chinese customers to quickly memorize Finnish products (cf. Kotler & Armstrong 2009, 258). Generally a Finnish brand needs to have a Chinese name, which coming from its Finnish pronunciation (such as '罗氏' in 'Roche' from Switzerland) or combination of original letters and Chinese characters.

As a result, Chinese customers are familiar with the original brand of products and spread products recognition. In short, the key factors determining the success of Finnish SMEs of products underlie the quality of products and innovative technologies.

Setting a **price** in export marketing is more complex than in domestic marketing (Albaum et al. 2002, 438). In general some basic factors, including costs, market conditions and customer behavior, competition, legal and political issues, and general company policies, should be considered when an export price is being decided (Albaum et al. 2002, 440; Brennan et al. 2007, 317-318). Product manufacturers commonly prefer cost-oriented approach (McCarthy & Perreault 1990, 487), since *'costs are often a major factor in price determination'* (Albaum et al. 2002, 440). The Finnish SMEs may need to reduce their margins in order to sell to the more price-sensitive customers. Distributor margins are difficult to estimate because they can range from 0 to 100%, depending on other services that the agent provides to the customer. (Liu 2004, 38) Superior supply chain management brings competitive advantages, for example, a lower-cost business model is primarily attributable to direct sourcing and inventory management. The ability to take costs out of the supply chain creates the opportunity for gross profit margin improvement and/or pricing advantages. Pricing advantage, along with the appeal of a distinctive brand that is clearly focused on the target market, tends to lead to market share gains for the retailer. (Park & Sternquist 2008, 286) The Finnish enterprises can set up the pricing of medical devices on the basis of the brand strategy. As claimed by Liu (2004), recently foreign-branded products are preferred above local product in higher tier hospitals, and local products continue to dominate the lower-cost segments.

**Place** means *'making products available in the right quantities and locations when customers want them'* (McCarthy & Perreault 1990, 274). Chinese local distributors and sales networks are relatively important to the Finnish SMEs. They can help the Finnish SMEs enter the Chinese market quickly and precisely, and create greater efficiency in making goods available to target markets in China (Kotler & Armstrong 2009, 340). For certain aspect, an appropriate distribution channel can enhance high sales for Finnish products in China. Hence, a good distribution chain must be built by the Finnish SMEs.

**Promotion** is a very important method of communication to convey information from seller to potential buyers, and influence attitudes and behaviors of potential buyers (McCarthy & Perreault 1990, 365). It also could be said promotion is an artistic artifice in the 4P's marketing mix. In business-to-consumer marketing, enterprises normally need to create excellent and attractive advertisements to catch consumers' eyes to sell more products. For example, using 'buy two get one free' in business-to-consumer marketing. B2B marketing is about promoting sales growth and attracting customers of other brands, and early promotion is essential, especially for a non-famous brand. For instance, Roche is one of leaders in the field of medical devices. If the Finnish SMEs



want to compete with Roche in the congeneric products, and be successful in the sales of products at the early stage, they have to promote their products at once, as long as the products are developed and produced. (cf. Cooper 1996, 466-470) Otherwise, the Finnish SMEs should avoid direct competition with large firms, like Roche (cf. Lee, Lim & Tan 1999, 300).

When the basic marketing mix is combined with the strategic marketing mix (including **probe**, **partition**, **priority** and **position**), the sales results may be better (Kotler 2001). The four elements of strategic marketing mix are explained together here. First of all, the Finnish SMEs should make a market research of medical devices before they enter the Chinese market. The purpose is to understand current market demands and market situations in China. After the market research is done, markets should be segmented according to certain factors, which influence customer demands. The Finnish SMEs should focus on one or two particular market segments because the particular market segments are applicable to the SMEs given their limited resources (cf. Porter 1980). Then target markets are selected and products can be positioned on the basis of target markets. Finnish products have special features in order to form a certain impression in customers' minds. It is a process of establishing competitive advantages of products. Albaum et al. (2002, 398) said: *'how successfully a new product is diffused to an export market will be influenced by the product positioning strategy followed in a foreign market. When targeting specific market segments the marketer tries to develop those product attributes that generate the benefits matching the requirements of a targeted segment'*. It seems to be evident that the strategic marketing mix helps the basic marketing mix on a certain extent, such as aiming at the target customers and their demands, acquiring novel market data, etc. According to the data related to strategic marketing, the Finnish SMEs adjust their basic marketing mix, i.e. what kind of products should be innovated and manufactured, or how to set a reasonable price. Innovation could be presented in product technologies, materials, manufacturing, price, promotion, target markets and competition (Albaum et al. 2002, 403).

Political power and public relations are two marketing skills, which support 8P's (the basic marketing mix & the strategic marketing mix) in international marketing. Regarding the local **political power**, Chinese government influences international trade to a certain extent. In China, the particular political, institutional and business environments require the Finnish SMEs to adjust their enterprises' characteristics. With social constant development, Chinese economic environment becomes more and more liberalized. Lower business uncertainty and less risk attract more foreign investors from developed countries. (Sun 1999, 646, 653 & 657) Building harmonious relationship with local government as far as possible is relatively important, since the Finnish enterprises can rely on local government connections to build up many relevant relationships. However, it is difficult to set up this kind of relationship in a short time for the Finnish SMEs, who

enter the Chinese market for the first time. Therefore, local agents and/or distributors should be considered attentively to find out whether they have good relationships with local government or not. The Finnish SMEs may draw support from the network of local agents and/or distributors for government relations and the sales of medical devices. (cf. Kotler 1986, 117-118)

**Public relations** help enterprises establishing favorable image, and eliminating the negative image (Brennan et al. 2008, 195; Blythe 2006, 85; Kotler 1986, 118-119). Generally public relations activities include press releases, press conferences, events, corporate advertising, annual reports, internal newsletters and magazines, seminars, staff briefings, and sponsorship (Brennan et al. 2008, 195; Blythe 2006, 85-86). The purposes of public relations are *'to attract and keep good employees; to handle issues and overcome misconceptions relating to an organization; to build goodwill amongst publics such as governments, local communities, suppliers, distributors and customers; to build an organization's prestige and reputation; and to promote products'* (Brennan et al. 2008, 195). Many Finnish SMEs often manage the image of enterprises by attending medical device seminars and fairs in China or other countries and publishing products' articles on medical device magazines and newspapers. In B2B marketing the SMEs and customers can find out both parties under the previous platforms. In addition, since some used medical devices (for example, injector syringes and reagent tubes) may generate hazardous pollutants to the environment, Finnish manufacturers must warn customers in writing about consequences, which will cause negative image (cf. Breton & Boxall 2003, 400-402).

It is worth noting that attention needs to be paid on **customers'** behavior in the marketing mix. *'The nature of customer needs and wants in each relevant market affect the effectiveness of any marketing effort'*, Albaum et al. (2002, 407) say. The three categories of buying situation are straight rebuy, modified rebuy, and new task<sup>18</sup> respectively. (Brennan et al. 2007, 36; Blythe 2006, 28; Blythe & Zimmerman 2005, 24) For a manufacturing medical device enterprise, all of these three buying situations may happen. For example, the sphygmomanometer was widely produced by enterprises after it was invented. Each hospital orders this product regularly because most wards at hospitals need it. Therefore, this buying situation is straight rebuy. When time passes, many doctors find their ears are not comfortable when they wear the stethoscope, so they give feedback to the purchasing department at hospitals. The purchasing department informs the enterprises about this circumstance. After the enterprises receive the feedback, the en-

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<sup>18</sup>Straight rebuy normally means that products are purchased regularly with a simple repeating order; modified rebuy is that there is parts of change to the usual order in quantity or in specification, such as design, function and materials; new task means that one product is totally new to a buyer enterprise (Blythe 2006, 28-29; Blythe & Zimmerman 2005, 24).

enterprises make modification in the design of earphone. When the hospitals order the modified sphygmomanometer, it is modified rebuy. Hospitals no longer order sphygmomanometers with old function or design, but start to order the kind of innovative new sphygmomanometer. This kind of purchase is new task. It directly influences the composition of the decision-making unit, the length of the decision process, and the negotiation lever (Blythe 2006, 29). The enterprise should know customers' behavior and predict customers' possible purchasing intentions to keep original customers and acquire new customers.

Furthermore, customers' purchasing methods need to be known by the Finnish enterprises. Normally the methods include just-in-time purchasing, centralized purchasing, reverse marketing, and leasing. The enterprises may provide relative selling services depending on customers' requirements. For medical devices, centralized purchasing may be selected usually because customers can specialize in buying particular types of medical device products. On the contrary, the leasing method is rarely used for medical devices. Since the end-buyers are hospitals, clinics, or medical research institutions, in consideration of hygiene and repeated usage, leasing medical device is rarely happened, although this method can save capital. (cf. Blythe 2006, 29)

#### 4.4 Synthesis

The last sub-objective of this study is discussed in this chapter: *to analyze the adaptation of marketing mix for Finnish medical device SMEs on the Chinese market*. According to different theories of marketing mix, the marketing mix of '10P + 1R + 1C' is an adaptation model for the Finnish SMEs (see Figure 6). Certainly, the model may be changed or adjusted in accordance with the selected international entry mode. However, the elements of '4Ps (product, price, place and promotion)', '1R (relationship)' and '1C (customers)' are still kept in the marketing mix.

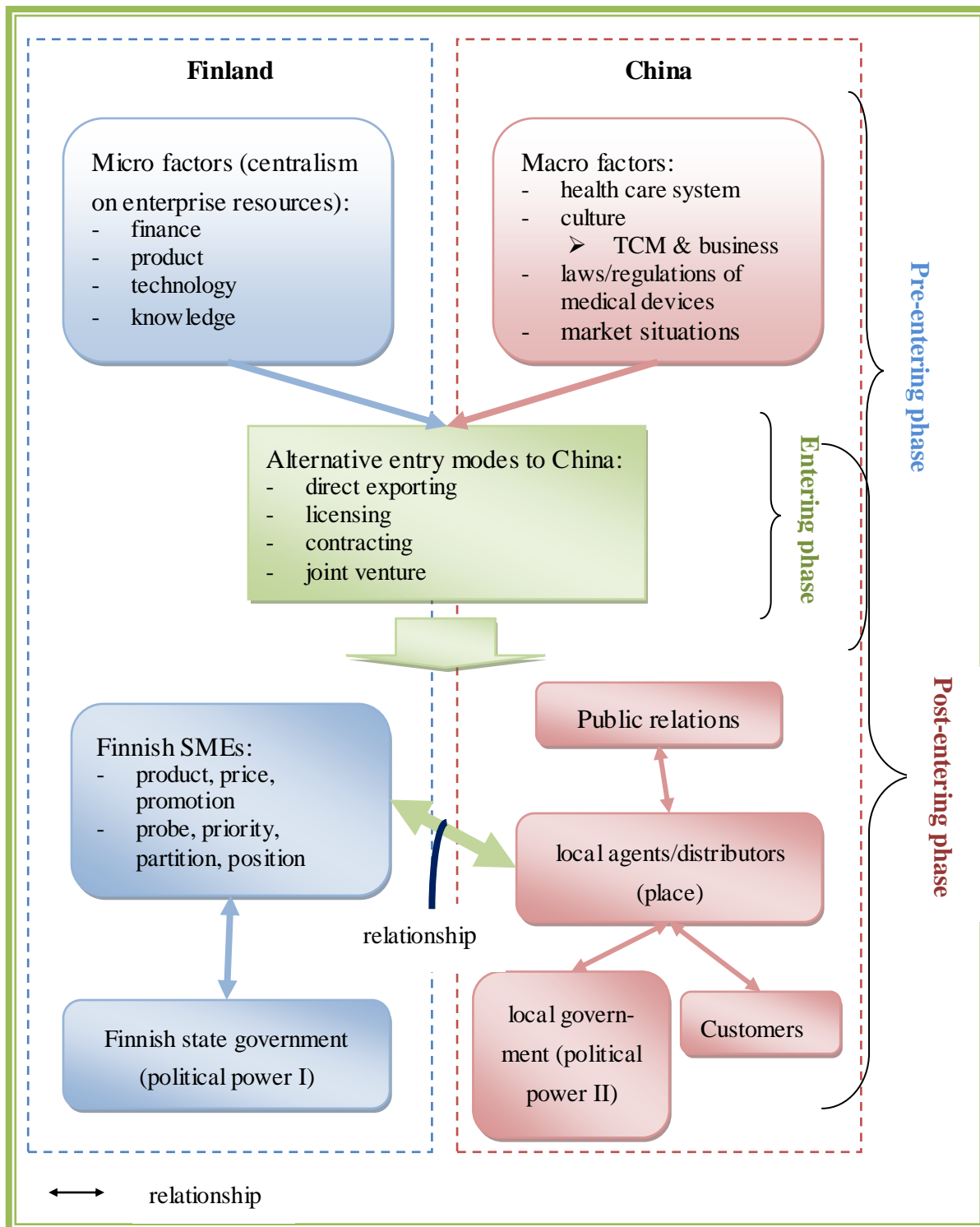


Figure 6: Synthesis of international entry modes with main factors and adaptation of marketing mix in China

As shown in the Figure 6, there are three main phases in the whole process of entry from Finland to China: pre-entering phase, entering phase, and post-entering phase. The following chapters present the empirical study of this research.

## 5 METHODOLOGY

In this chapter the research methodology is presented. At first, the chosen research approach is explained. After data collection by interviews and a case study of a Finnish SME are described, the method of data analysis is presented. Finally the reliability and trustworthiness of this study are evaluated.

### 5.1 Research approach

As the main research purpose of this study concentrates on *studying how to export medical devices from Finland to China*, a qualitative research approach is managed in this study. One reason for choosing qualitative research approach is that the research purpose is difficult to be explained by quantification. Bryman & Bell (2007, 28) state that qualitative research emphasizes the view of reality such as what kind/which, but quantitative research emphasizes quantification such as how many/how much in the data collection and analysis. Moreover, some sensitive information, subconscious feelings, complex phenomena, and the holistic dimension need to be inquired in this study. The qualitative research approach enables informants to reflect upon and express their views, or to observe their behavior. The behavior, experiences and feelings of informants are summarized in their own terms and context. Qualitative research has had a profound effect upon marketing and the market research as a whole. (Malhotra & Birks 2006, 133-135)

Malhotra & Birks (2006, 135) said: *‘the objective of taking a holistic outlook in qualitative research is to gain a comprehensive and complete picture of the whole context in which the phenomena of interest occur’*. A holistic outlook could describe and understand as much as possible about the whole situation of medical device export from Finland to China. Interrelationships could be discovered among the various components of the phenomena under this study. In evaluating different modes of international entry, the relationship of different contextual environments should be understood upon international entry. Finnish SMEs should set up suitable marketing mix in China according to their actual background and experience. Building up an understanding of the interrelationship of the international entry mode and the marketing mix leads to building up this holistic view through the qualitative approach.

A case study approach is used in this study. Yin (2003, 1) said: *‘case studies are the preferred strategy when how or why questions are being posed’*. The case study approach is associated with descriptive research, that is ‘what’, ‘who’, ‘where’ and ‘when’ (Yin 2003, 6; Bonoma 1985, 200); and exploratory research, that is ‘how’ and ‘why’ (Ghauri & Gronhaug 2002, 46; Yin 2003, 6). The unique strength of the case study is

able to deal with a full variety of evidence (Yin 2003, 8). In business studies, case studies are particularly useful when the phenomenon under investigation is difficult to study outside its natural setting and also when the presumed causal links in real-life interventions are too complex for the experimental strategies (Yin 2003, 15; Bonoma 1985, 201). Case studies represent a methodology that is ideally suited to creating managerially relevant knowledge (Gibbert, Ruigrok & Wicki 2008, 1465). Schramm (1971) defined the case study as *'the essence of a case study, the central tendency among all types of case study, is that it tries to illuminate a decision or set of decisions: why they were taken, how they were implemented, and with what result'*. Case study research includes both single- and multiple-case studies, and it can be based on any mix of quantitative and qualitative evidence (Yin 2003, 14-15). The single-case study is an appropriate method under several circumstances (Yin 2003, 39). In this study a single-case is developed because the case could be seen as a representative and gives readers a realistic view which integrates the theoretical works with the practical business operation (cf. Yin 2003, 40-41). Besides, the case study report in this study could be a significant communication device to other researchers (cf. Yin 2003, 144). The case selection is described in detail next.

## 5.2 Case selection

The emphasis of this study is on the process of exporting medical devices from Finland to China successfully. The original intention was to study at least two case studies in this aspect because a single-case design is vulnerable (Yin 2003, 53). But after all web pages of all Finnish life science organizations were checked on the list of Catalogue BioFinland 2008-2009, only approximately twelve Finnish SMEs have international business with China. Moreover, because some enterprises are reluctant to participate in this study, the amount of cases has to be reduced. Only one case study was eventually selected. The chosen SME is from the field of in-vitro device (IVD).

The case enterprise was chosen based on a recommendation in 2008, and it was also checked on the list of Catalogue BioFinland 2008-2009. At that time, the researcher learnt that this enterprise would like to develop business in China, and have done lot of preparation tasks in order to launch its products into the Chinese market. It could be seen as a typical case of a Finnish SME concerning exporting medical devices to China during the growth period of business. That is to say this case explains how to opt for a suitable international entry under certain influencing factors before the enterprise's products enter China; and how and why to adapt marketing mix after entering the Chinese market. This enterprise was contacted, and a positive reply was received from the CEO of the enterprise. The CEO was willing to take part in this study. In order to en-

hance data availability of the case enterprise, one partner enterprise of the case enterprise and another Finnish SME were contacted. Both of them agreed to be interviewed. The case enterprise and another Finnish SME<sup>19</sup> provide a significant amount of information on the enterprises' products and strategies and therefore no names are mentioned, neither the enterprises' nor the people involved. This was a prerequisite for the accessibility of data collection in the case enterprise. It also was the prerequisite for accepting the interviews by the other Finnish SME. Furthermore, the titles of the people interviewed provide better insight to the situation than names. Before the data collection process is described in detail in the next section, the background of selected case enterprise is introduced briefly.

This case enterprise was founded in 1987 and located in the central Finland. The enterprise employs about 20 people. According to the definition of SMEs by EU Commission Recommendation (2003, 39), which defined a small enterprise as '*an enterprise which employs fewer than 50 persons and whose annual turnover and/or balance sheet total does not exceed 10 million*', the case enterprise belongs to the category of small enterprise. The businesses are being operated in the traditional diagnostic field and new technology field. Currently, the main customers are in the field of life sciences in Europe, especially in the Scandinavian countries. The main products are numerous reagents and test kits to be used in the health care, research and industrial laboratories. The characteristics of a novel diagnostic system are: easy-to-use, hand-held, requiring minimum training and maintenance-free, fast protocol and PC port by quantitative and qualitative measurements. The innovative diagnostic technology is applied for small health care units, wards in hospitals, emergency laboratories and so on. Most of the products have been exported to about 30 countries. The novel diagnostic product has already been sold in Lebanon, Singapore, the United States and Turkey. However, the market shares in these mentioned countries are small due to fierce competitions. China was chosen as a next export market in summer 2006 because there is a huge market for IVD products. China will be the 3<sup>rd</sup> largest IVD market in 2015 (Scherago International Agent for the Americas and Europe 2009). In the following section, the process of data collection is presented.

### 5.3 Data collection

Yin (2003, 57) said '*preparing for data collection can be complex and difficult*'. In order to improve data collection efficiently, a protocol of case study is developed. Data

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<sup>19</sup> This Finnish SME was not another case enterprise in this study because of special circumstances such as business secret.

collection about a case study could take six forms. They are: documents, archival records, interviews, direct observation, participant-observation, and physical artifacts (Yin 2003, 83). In this study, three main methods of data collection were used: a combination of documents, direct observation, and interviews in the case enterprise. Yin (2003, 85) mentioned: *'the various sources are highly complementary, and a good case study will therefore want to use as many sources as possible'*. Inferred results will enhance objectiveness in the case study, if data are collected by more than one method.

As mentioned above, collection of primary data is mainly through documentation and direct observation in the case enterprise, as well as one interview from the case enterprise, two interviews from the case enterprise's stakeholder, and one interview from another Finnish medical device enterprise. As claimed by Yin (2003, 77), documentation is a crucial part of the database for a case study. In general, the forms of documentation are letters, memoranda, agendas, reports, and internal records (Yin 2003, 85-86). For this study, emails, written reports of events, and some articles published in community newsletters are referred. Before the collection process of relevant data was started, some key words of this research purpose had been written out firstly in order to avoid reading lots of unrelated data and time consuming on data collection. Observational information is often useful in providing additional information focusing on three sub-purposes (see Chapter 1.3). When the researcher had an internship working in the case enterprise, some barriers which restricted the products entering the Chinese market in the short term were observed. Although observational diary were not written every day, relevant notes, such as key words and chats focusing on the process of international entry on meetings, were recorded in the notebook. Malhotra & Birks (2006, 207) said: *'keeping field notes aids the researcher's memory when it comes to the formal process of data analysis and helps enormously in categorizing and interpreting collected data.'* The recorded key words and chats on meetings are crucial field notes and provide evidence for data analysis.

*'Interviews are essential sources of case study information'*, Yin (2003, 89). In some cases, interviews may also be a more economical way of collecting detailed data which are more broadly representative (Sapsford & Jupp 1996, 60). In this qualitative study, the interviewees' points of views are of much greater interest and more detailed answers are expected. Hence, semi-structured interviews were conducted, since the questions were decided in advance (see Appendix 6 & 7). A list of questions was used for an interview guide. Other relevant questions that were not included in the list of questions were also asked as the interviewer picked up on things said by interviewees. (cf. Bryman & Bell 2007, 474) During the interviews, the interviewees responded questions freely. New questions emerged under the method of Microsoft Service Network (MSN) according to the interviewees' answers. Using interviews for data collection could focus directly on the topic of case study and provide perceived causal inferences (Yin 2003,



86). The purpose of these interviews was to seek relative influence factors of international entry, selection of entry modes and adaptation marketing mix in the field of medical devices. Four qualitative semi-structured interviews were conducted with two Finnish medical device enterprises in Finland, one Finnish consult enterprise in Hong Kong and its daughter firm in Beijing, China. All interviewees had direct responsibility of export operations.

According to three sub-objectives (see Chapter 1.3), many designed questions (see appendix 6 & 7) in interviews relate to the Finnish enterprises' products, strategies, performance and future development plan, which belong to commercially sensitive issues. In regard to these kinds of questions and questions concerning some complex phenomena in the international entry, interviewees maybe are willing to answer certain questions or providing non-essential answers for certain questions. For example, interviewees may answer the entry mode they used, but not answer the reason of choosing such entry mode. Therefore, building up rapport and trust are necessary with interviewees before sensitive data can be collected (Malhotra & Birks 2006, 135).

All interviews were operated through emails and MSN messages in this study. Using emails and MSN as the interview ways is because some interviewees were not in Finland, as they were in Beijing, Shanghai, and Hong Kong respectively. Hence, the travel cost is saved (Malhotra & Birks 2006, 197). On the other hand, the interviewees prefer interviews online such as emails and MSN because there is no time limitation of answering questions and they can finalize the interviews after work. The transcripts are a vital data source in qualitative data analysis. Email or MSN interviews also enable elimination of time-consuming on transcripts. (Malhotra & Birks 2006, 208) Bryman & Bell (2007, 674) state that replies are often more detailed and considered, further information or reflections could be gone back to the interviewees, and the interview could keep sending messages to interviewees to reassure their helpful and significant written utterances. On the basis of these reasons, the interview questions were sent to interviewees by email, and they were answered in the type of Word document, or they answered directly by MSN.

However, the non-verbal communication was lost by the email and MSN interviews, such as subtle changes in facial expression and body language. The non-verbal expression is also important to the analysis of data. Moreover, a rapport between interviewer and respondent can be developed through the non-verbal communication. (Malhotra & Birks 2006, 197) In addition, the email and MSN interviews cannot develop very detailed long information comparing with face to face interviews. Generally, face to face interviews can develop a great richness of dialogue and understanding with respondents, whereas only main information or key words are written down in Word document by respondents (cf. Malhotra & Birks 2006, 197).

The summary of the main features concerning the interviews conducted for this study is presented in the following table.

Table 10: Overview of the five interviews

	Interview A	Interview B	Interview C	Interview D
<b>Position</b>	CEO	Project Manager	CEO	Project Manager
<b>Code name in Chapter 6</b>	CEO A	Project Manager A	CEO B	Project Manager B
<b>Enterprise type</b>	an IVD enterprise in Finland (case study)	an enterprise of therapeutic devices in Finland	a Finnish state consult firm in Hong Kong	(one branch belongs to Interview C's firm in Beijing)
<b>Interview's time</b>	April 2009	January 2010	April 2009	April 2009
<b>Answers methods</b>	Word document by email	- Word document by MSN - more details on MSN	Word document by email	- Word document by Email - more details on MSN
<b>Language</b>	English	English	English	English

The secondary data also plays an important role throughout the study. Official statistics can present the accurate statistics on the health care industry and the current situation of the Chinese marketing from macro viewpoint. The professional unpublished materials, such as competitors and distribution channel in China, make a great contribution to this study. After collecting the data, data analysis was done. The next section describes the process of data analysis.

## 5.4 Data analysis

Collected data should be filtered for data analysis because the data is rarely obtained in an immediately analyzable form (Sapsford & Jupp 1996, 286). Generally a process of data analysis could be divided into data assembly, reduction, display and verification (Malhotra & Birks 2006, 206). However, data assembly refers to the gathering of data from a variety of sources (Malhotra & Birks 2006, 206), so this step of data assembly

could be involved in the process of data collection. Concrete details about data collection were presented in the previous section.

Data reduction includes a major process of coding data, which identifies main categories and sets the stage to draw conclusions and interpret the meaning. Coding is a vital part in the qualitative data analysis, especially in the context of developing theory with a grounded theory approach. Throughout the process of coding, collected data could be addressed. (Bryman & Bell 2007, 584-594; Malhotra & Birks 2006, 208-212) In other words, collected data should be reorganized and restructured, and eventually broken into different categories. All data had been printed firstly before starting the data analysis. Sapsford & Jupp (1996, 290) said: '*an essential first step is a close reading of the data*'. The printed data was read carefully and marked according to main identifying categories such as factors in macro environment, international entry modes, and the marketing mix. Under main categories sub-categories were assigned in the form of words and phrases during the study. Concerning the contents of the interviews, relevant important answers were assigned in the form of sentences and whole paragraphs in order to quote the interviewees' opinions. The perspectives of coding are used to simplify or reduce the mass of data on one hand, and to expand, transform and reconceptualise data on the other hand (Bryman & Bell 2007, 594; Malhotra & Birks 2006, 210). Then all key items of data were compared and contrasted to the same categories (cf. Sapsford & Jupp 1996, 290). Some data segments under the categories were developed and re-assigned as a result in the process. They were marked in different colors on the papers. A network of relationships was formed due to categories' integration. (cf. Sapsford & Jupp 1996, 292)

Data display involves summarizing and presenting the structure for the collected data (Malhotra & Birks 2006, 212). Formats of charts and tables are used in this study. They display very basic structure of the issues or major categories and sub-categories of collected data. The synthesis figures with boxes summarize the sub-purposes of research, which are connected by arrows in order to show the interconnection between issues in each sub-purpose, and between sub-purposes. An overall figure of results of the case enterprise is presented in Chapter 6 to show the general meaning of the collected data. The case study of a Finnish SME exporting medical devices was well discussed and analyzed. Verbatim quotes are also used to illustrate and prove the issues.

Once the collected data are displayed, a valid explanation of the data needs to be demonstrated trustworthily, with no bias (Malhotra & Birks 2006, 214). This is data verification. Malhotra & Birks (2006, 214) said that '*data verification involves seeking alternative explanations through other data sources and theories*'. The use of theory as secondary data can guide and prove what may be reasonably expected as results. The data verification can also be through seeking 'similar' research findings and explana-

tions. The similar research findings from other researchers could represent a valid view in the same field of qualitative research. (Malhotra & Birks 2006, 214)

## 5.5 Research evaluation

Comparing with reliability and validity of a quantitative research's criteria (Bryman & Bell 2007, 410), there are also two primary criteria for assessing a qualitative study: trustworthiness and authenticity (Bryman & Bell 2007, 411). Among of trustworthiness, four sub-criteria are involved in. They are *credibility*, *transferability*, *dependability*, and *confirmability* (Bryman & Bell 2007, 411; Lincoln & Guba 1985, 290). These terms in the qualitative research are the corresponding criteria of internal validity, external validity, reliability, and objectivity in the quantitative research (Bryman & Bell 2007, 411). A case study is one approach in the qualitative research (Yin 2003, 34), so this study is assessed according to four sub-criteria as followed.

The establishment of the *credibility* is to reflect the reality for the constructed study. This criteria measures credible findings, results and interpretations; available information; and referential adequacy. (Lincoln & Guba 1985, 301) For improving the credibility of this study, the interconnections and logical linkages were emphasized between the main research purpose, the theoretical parts and the empirical part of the study (cf. Lincoln & Guba 1985, 312). That is, referred theories were integrated into the case study with operationalization tables (see Appendix 6 & 7) and interviewees' knowledge from China in order to justify the credibility of performed study. The operationalization tables supported an interaction between the relevant theories and the findings of the study. Thus, the improved credibility of this study was based on the theoretical framework concerning selecting suitable entry modes and deciding suitable marketing mix after entering the Chinese market. Moreover, the data analysis of the case study assisted for the development of theories.

However, some major issues reduce the credibility of this study. Firstly, there were only four available interviews. It causes the limitation of data collection. Secondly, the interviews available were concentrated on the side of Finnish firms, i.e. two Finnish SMEs and one consultation firm of Finnish government in China. Though two Chinese project managers accepted the interviews and expressed their opinions on the Chinese market due to their backgrounds and past experiences, the whole viewpoint was still on the Finnish firms' side. For all that, four interviewees have the best knowledge about processes of international entry modes and marketing mix due to working experiences in the field of medical device. The minimum period is 6 years, and the maximum is at least 15 years. Moreover, all interviews were paper-recorded because of the way of conducting them online. In order to better understand parts of responses, the interview-

wees were contacted again and they were inquired to check details. Hence, the credibility of this study has been improved in this respect. Furthermore, after the chapter of case study was finalized, the results were sent to the CEO of the case enterprise. The CEO was asked to check the relevant data and the results. Lincoln & Guba (1985, 314) indicated that member check is an important tool of evaluating the credibility in the research study.

**Transferability** is a method which describes applicability. It is as a concern of the future researcher who wants to transfer the findings to a different situation than that of initial researcher. If the initial researcher presents thick description and experiential accounts to allow comparisons, transferability has been addressed. In other words, transferability is responsibility of readers, not researchers. (Lincoln & Guba 1985, 316) Krefting (1991, 217-222) described: '*transferability in qualitative research can be achieved by the ensuing actions: using a nominated sample, time sampling, dense descriptions of the research methodology and working contextually*'. This study mainly adopted the first criterion of transferability, which is a nominated sample, i.e. the case study of a Finnish SME. To address transferability, the data analysis of the case study was analyzed in details. There are two charts about the Finnish SME in the field of medical device, especially in the IVD, which conclude the process of entering Chinese market and operating in the Chinese market. The charts are used to generate the answers to the research purpose of this research study. The complete set of data analysis of charts is available upon requests. Other readers or researchers could transfer the conclusions of the charts to other similar cases.

The third criterion is **dependability**. It emphasizes the extent to which the study can be replicated in a similar context or with similar informants and can lead to the same results (Lincoln & Guba 1985, 316-317). Bryman & Bell (2007, 414) presents that '*dependability entails ensuring that complete records are kept of all phases of the research process including problem formulation, selection of research participants, fieldwork notes, interview transcripts, data analysis decisions, and so on*'. In order to address dependability, several methods are concluded by some researchers, such as a inquiry audit, a dense description of the research method, stepwise replication, triangulation (or overlap methods), peer examination and code decoder procedures (e.g. Gibbert et al. 2008, 1468; Bryman & Bell 2007, 414; Yin 2003, 97; Krefting 1991, 216; Lincoln & Guba 1985, 317-318). For ensuring dependability in this study, a dense description and triangulation of the research methodology were used. Concerning the dense description of the research methodology, the collected data were coded and analyzed. The purpose of using triangulation is to justify credibility of the study. Krefting (1991, 219) says: '*triangulation is the comparison of multiple perspectives by using different methods of data collection, diverse or competing theoretical frameworks and/or different researchers*'. According to Yin (2003, 97-99), looking at the same phenomenon from different angles

gives different data collection strategies and different data sources. Triangulation was applied in this study by utilizing different methods of data collection, which were direct observation in the case enterprise, available interviews with four experts of three different enterprises, and internal materials of the case enterprise, as well as documents of China Medical Equipment Fair. During the literature check up, theoretical frameworks from diverse areas of knowledge were used to compare and contrast with the research findings.

*Conformability* is seen to ‘*dovetail with the audit process and hence are no longer discussed independently*’ (Lincoln & Guba 1985, 319). In other words, if the same topic of this study will be conducted or audited by other researchers, there may be no other different results, which need to be discussed. Personal values or theoretical inclinations cannot sway the conduct of the study and findings (Bryman & Bell 2007, 414). Conformability could be the strategy to achieve neutrality with conformability audit, triangulation and the keeping of a reflexive journal (Lincoln & Guba 1985, 318-319). As claimed by Lincoln & Guba (1985, 323), the findings were grounded in the data collection; and the results were based on the logical data with analytic techniques used, appropriateness of categories, and quality of interpretations. For example, the careful selection of quotations used, and the precise description of the data collection and analysis in this study.

In conclusion, for ensuring the trustworthiness of this study, there was a good interconnectedness between the main purpose of the study, the theoretical frame of reference, and the empirical part of a case study. Due to the member checking in the chapter of the case study, the interpretations are more accurate. Triangulation was one of important strategies improving the dependability of the study. However, only Finnish SMEs were interviewed. The results of interview may only represent opinions of Finnish firms, although the interviewed people have knowledge about international entry modes and the marketing mix. In the following chapter, the research findings of the case study are analyzed and discussed.

## 6 CASE STUDY OF A FINNISH SME EXPORTING MEDICAL DEVICES

There are different sorts of medical devices for various functions of diagnosis and treatment (see classifications of medical devices in Chapter 2.3.1). In this study, the case enterprise is a Finnish SME producing IVD<sup>20</sup>. Through analyzing the collected data, the detailed findings of the study are discussed in this chapter, i.e. a suitable market entry mode and marketing mix after entering the Chinese market for Finnish SMEs. All quotes in this chapter are straight quotations taken from the interviews of the study. Moreover, the interviewees' opinions are specially noted in the chapter if they are not quoted. The names of the interviewees are coded for their titles due to anonymity.

### 6.1 Main factors influencing export of case enterprise's products

According to the case enterprise's internal materials, lots of tasks had been prepared before CEO A decided to carry out the strategy of entering the Chinese market. It could be said these tasks were quite complex and time- and money-consuming. For instance, the case enterprise has visited China for several times during the past ten years. However, the case enterprise only has some exports for trial products since 2003. CEO A (2009) thought that analyses of main factors influencing export of the case enterprise's products were especially important among all tasks because large numbers of information must be collected before researching main factors.

Information collection is to gather all information influencing on the strategic decision of entry mode through diversified channels, for example, by Internet, on academic magazines, and in professional research reports (cf. Bhushan 1989, 183-190). CEO A (2009) said that information in every respect had been gathered by the case enterprise in order to enter the Chinese market, such as a market research concerning Chinese current medical device market, a network of medical device distributors and agents, medical device regulatory affairs, and differences between Western medicine and TCM. Some collected documents by the case enterprise showed that there are lots of competitors the current market situation of IVD devices in China. The competitors mainly are Chinese local manufacturers of devices and reagents and come from other developed countries (involving in one or two firms from Finland). After reading all collected information,

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<sup>20</sup> This kind of IVD devices is to exam the human body's specimens including blood and tissue donations; to provide information concerning a physiological/ pathological state, or a congenital abnormality; to determine the safety and compatibility with potential recipients; or to monitor therapeutic measures (Sale and supply of in vitro diagnostic... 2006, 2-3).

CEO A (2009) represented that the case enterprise learnt necessary entry conditions, and started to consider entering the Chinese market.

But not all collected information was suitable for the case enterprise due to a great variety of medical devices available on the market. The case enterprise had filtered the collected information so that information became valuable. Therefore, the market information about IVD device must be selected in this study (see Figure 7), since the case enterprise needs to know the market situation and trend of medical devices, and to pay more attention to the IVD devices globally.

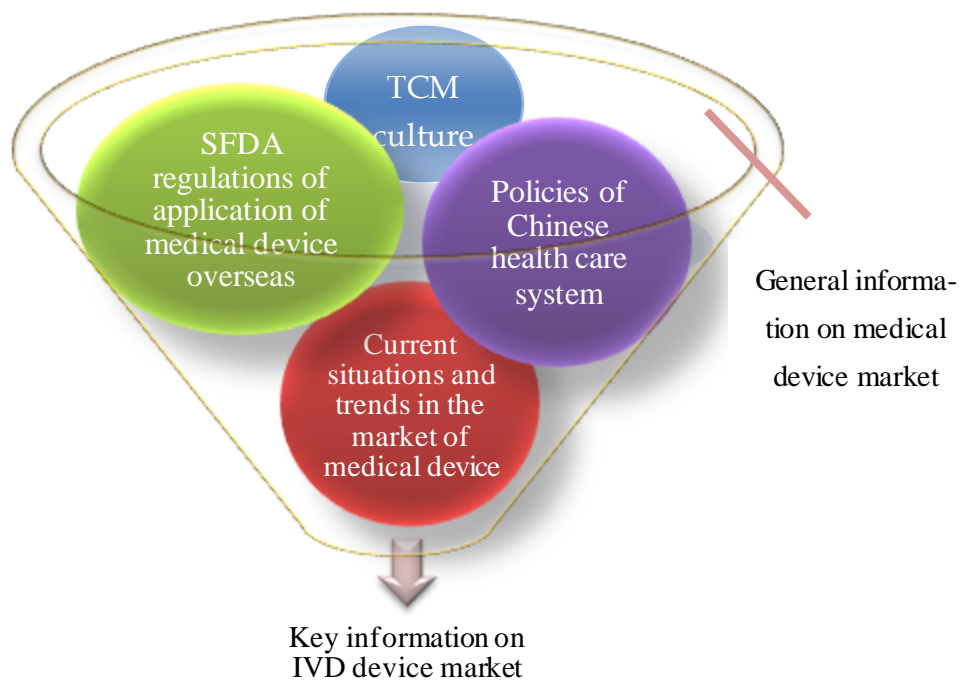


Figure 7: Information filtration in the case enterprise

Through information scanning, the case enterprise found that there were some prior conditions for its product development in the Chinese market. CEO A (2009) of the case enterprise said:

*‘China is a large and still growing market compared to some other established areas. We believe there is opportunity for success.’*

Project Manager A (2009) also expressed:

*‘China is now being a very promising country for oversea companies, not only for the huge potential market in China, but for the low labor cost there also.’*

Therefore, the preliminary determination was made to launch products into China. The next step is to consider main factors influencing the selection of international entry mode. The case enterprise classified filtrated information into macro and micro factors at first (cf. Miller 1988, 280).



*Macro factors* are seen as external factors for enterprises generally. In this study, macro factors are mainly health care system, medicine culture, and current market situation in China. Chinese health care system and medicine culture are the two important macro factors directly and/or indirectly influencing the case enterprise's decision on entry modes to the Chinese market.

CEO A (2009) believed that Chinese health care system was considered when the case enterprise planned to export its products into China. Moreover, Project Manager B (2009) said: *'it is quite important to influence the market in China'*. Since Chinese health care system is supervised by Chinese central government, Chinese government's expectations for foreign investment of medical device are expressed to a certain extent. Besides, annual new positive policies under health care system may attract and stimulate foreign investments of medical device. CEO A (2009) stated:

*'the Chinese government is encouraging western companies exports of medical devices to China to fulfill the targets of the new 5-year plan.'*

CEO B (2009) also expressed:

*'it is very good long term market for advanced products and services.'*

The Chinese government provides a stable political and economic environment for foreign investors in the medical device market, although some regulations of health care system are still being modified and updated, which leads to changing uncertainty. As foreign investors, the Finnish SMEs should learn about the updated direction of regulations and policies of Chinese health care system in order to avoid sales stagnation. Project Manager B (2009) presented an example of a Finnish enterprise, which does not produce IVD products.

*'I just was informed by one agent of Finnish SME in Shanghai for a new regulation issued by Shanghai Municipal government, that all disposal consumption materials are restricted to be used in hospitals according to the new 'social health care system'. It means maybe the Finnish SME's product will be restricted to be used.'*

Similar situation also occurred in the case enterprise, not in the process of sales, but in the process of application of SFDA registration. Changing regulations impede the optimal timing of IVD products entering the Chinese market. If the case enterprise had sold its products in China two years ago, the enterprise would have gained high profit due to its innovative products. However, at the moment, some virus tests have been surmounted by Chinese domestic IVD manufacturers, like Roche. This kind of multinational corporate has a relatively big market share. The case enterprise can only look for diagnosing different virus, which cannot be tested by existing IVD products in China. Perhaps the case enterprise may grab a small part of market share from competitors. It is not easy to succeed. After all, other IVD devices have existed in the Chinese market, and Chinese customers are familiar with these products. How to overcome this imped-

ment as far as possible? It will be discussed in the adaptation of marketing mix in China. Besides health care system, Chinese culture also should be considered as a vital macro factor influencing international entry modes according to CEO A (2009).

Cultural differences affect how businesses operate in international market (Hofstede 1980, 23), and are important obstacles to the entry mode choice in international operations (Kogut & Singh 1988, 411). Medicine culture is totally different between TCM and WM. The case enterprise produces IVD devices. These products help WM doctors to diagnose cause of disease through testing blood. In TCM, doctors diagnose disease through four main methods (see Appendix 2). So the time for waiting results is shorter in WM than in TCM. It could be said that WM impacts TCM on a certain extent, at least on the speed of blood diagnosis. Project Manager B (2009) said:

*‘Yes, I feel western medical devices have greatly impacted the traditional Chinese medicine. Western medical devices are advanced in diagnostic point of view, as well as in the surgery operation field.’*

However, TCM has its own strengths. Project Manager B (2009) also stated:

*‘Chinese medicine still has its advantages in some fields. Chinese traditional medicine can help your body to recover slowly and tenderly. Also for some illnesses, as cold, fever, sometimes, you can find Chinese traditional medicine is more side-effects than Western medicine, and the most important thing, it comes from nature.’*

TCM culture will not be replaced by WM culture, although TCM has been influenced more and more by WM. On the contrary, TCM and WM can be integrated well. TCM culture can benefit from the western evidence based medicine and the WM culture can benefit of the still largely unknown Chinese medicines (CEO A 2009). CEO B (2009) proposed that TCM did not influence import of western medical devices much, and TCM based products could also be exported to Europe. Before the case enterprise’s products entered China, CEO A (2009) had found information about Chinese medicine culture. He thought:

*‘Chinese are seeking also western products to support the balance between the traditional Chinese medical culture and the western medical science. This would give a possibility to Western innovative products and solutions benefiting the Chinese government 5 year targets.’*

Due to advanced medical devices in diagnosis, IVD devices are welcome in the Chinese market.

Recently Chinese IVD market is ranking 6<sup>th</sup> globally in the size of the market, and estimating 15% annual growth in the volume, and forecasting US1.5 billion in the value by 2014. The main IVD market is concentrated on the Eastern China. Over 20,000 hospitals require products of IVD. (Boyd 2009) Hence, the purchasing power for IVD device is huge in China. The previous positive information promoted the case enterprise

exporting its products to the Chinese market. In order to enter the Chinese market quickly and conveniently, CEO A (2009) said that the case enterprise built a friendly relationship with a consulting firm, who is on behalf of Finnish government and has headquarter in Hong Kong and subsidiary in Beijing. Therefore, the consulting firm is acting as a bridge to bring Finnish products into Chinese market, and also does direct marketing and sales for the Finnish enterprises.

As the partner of the case enterprise, CEO B (2009) presented that the consulting firm had provided advice and information to the Finnish medical device enterprises concerning market strategies, distribution systems, SFDA approval, technology transfer, manufacturing and joint ventures. Due to the rapidly growing global market (Chen 2008), the supervision of medical devices is more and more serious, and SFDA regulations are still being updated (SFDA 2008). Since 2002 IVD products in China have been regulated either as drugs or as devices by SFDA. Until 2007 only state-mandated of IVD reagents were regulated as drugs, others have been categorized as devices. (Chen 2008) In accordance with SFDA (2008), medical device registration of is unavoidable to all medical devices sales in China. All Chinese enterprises and foreign enterprises can make market survey while the procedure of SFDA registration (see Appendix 4). SFDA registration is required for selling products on the Chinese market. It normally takes one year to complete registration. (SFDA 2008) However, there were new regulations coming in 2007 causing longer timing of registration (Project Manager B 2009). It takes long time for the whole progress registration. On the basis of the internal materials of the case enterprise, the case enterprise started at the beginning of 2007 for the first products, and received registration certificate in April 2010.

There are many significant medical device regulations for IVD products have been issued by the SFDA since April 2007, for example, Application Process for Setting up for IVD Distributing Enterprises (Wholesale); Inspection Criteria for IVD Distributors (Wholesale); and Technical Guidelines for Clinical Research of IVD reagents<sup>21</sup> (SFDA 2008). These regulations should be familiar by Finnish SMEs before they decide developing their virgin market in China.

Along with the being familiar with SFDA registration, the Finnish SMEs should also work on market survey. Project Manager B (2009) declared:

*‘often before the Finnish companies join our Medical Group, our company must provide them a detailed market survey report that will contain current market volume, competitors’ information, pricing level, the business partners and resources.’*

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<sup>21</sup>More standards, regulations and law for in vitro diagnostic products, can be found from SFDA website at: [www.sfda.gov.cn](http://www.sfda.gov.cn).

The current market of IVD products is dynamic in China. The number of hospitals is still increasing. Rural hospitals and clinics are expecting to have high growth. Private and commercial laboratories are emerging though there is a very limited segment for IVD devices. Wide range of market segments of IVD is being expanded at the levels of high, middle, and low technologies. (Boyd 2009) So the extensive market segments lead to the case enterprise's effective options on distribution channels. As mentioned in Chapter 2.3.3, there are over 140,000 registered medical device distributors in China. One detailed report concerning Chinese local distributors and/or agents is important for Finnish SMEs. For seeking good and reliable partners such as distributors, Project Manager B (2009) suggested:

*'better to find a partner who has a good distribution network and can provide a total solution as Import/Export, supply chain management, sales networks, after-sales service..., better to cooperate with a State-owned Group in China. Such kind of information can be gotten via attending professional exhibitions and seminars.'*

Through learning the situation of Chinese distribution of IVD device, the case enterprise can drive profitability because distribution directly affects cost and the customer experience. Low cost can be achieved by accurate choice of distribution network (Chopra & Meindl 2010, 22-23).

On basis of analyses above concerning main macro factors in China, foreign high-tech medical devices are encouraged to enter the Chinese market because of shortage in the heterogenous medical devices or in the homogeneous high-tech medical devices.

Besides, CEO A (2009) stated that the case enterprise also considered micro factors influencing on the selection of entry modes. *Micro factors* from the enterprise itself are also taken into account, such as enterprise's size, resources, and competitive advantages. An enterprise's size is one of the most important determinants of entry mode choice (Gatignon & Anderson 1988, 305; Agarwal & Ramaswami 1992, 2-3). The size of case enterprise is small. The managerial and financial resources are limited compared to large multinationals such as Roche and GE Healthcare. The enterprise's size and financial resource make the case enterprise deliberated for entry mode selection. In addition, in comparison with large corporations, the case enterprise has a relatively lower bargaining power in negotiating to enter the Chinese market (cf. Bacharach & Lawler 1981, 219).

There is fierce competition in the market of IVD. Competitive advantages for the case enterprise are critical precondition, if the enterprise wants to enter the Chinese market quickly and gather a certain profit in a relatively short term. Competitive advantages could be presented on innovative products (i.e. high technology, novel design, or special materials used), affordable prices, and good partners. CEO A (2009) explained that the key feature of their product is high inspection speed. It means that the required

testing time is very short (only circa 10 seconds) for receiving results of testing serum and blood. Furthermore, the current price of this product may be higher than homogeneous products which are produced by Chinese domestic manufacturers. It is a weakness of the case enterprise. However, the case enterprise has had some outsourced production in Shanghai for the past two years. That is to say, part of test production has been done by its one partner in China. The production cost decreased. The price of the product can be adjusted due to reduction in production cost. Hence, through the partners' strategy, the case enterprise may have a strong China-base. More IVD information in the Chinese market can be learnt from its partners, including local outsourcing production firms and consulting firms.

Besides, CEO A (2009) believed that previous international experience of the case enterprise also affected modes' selection when entering the IVD market in China. Although the main market of the case enterprise still is in Finland, it also exports to EU countries involving the UK, Ireland, Sweden, Estonia, Greece, Lithuania, and Latvia, and to non-EU countries like Norway. The local distribution channels are used as the main entry mode. (CEO A 2009) The case enterprise has learnt and developed its knowledge along incremental internationalization process (cf. Johanson & Wiedersheim-Paul 1975, 319). Consequently, the knowledge helps the case enterprise dealing with different international entry process. While the case enterprise might face similar situation on the Chinese market as on other markets, it could use the knowledge for selecting the suitable entry mode.

SMEs usually have less competitive advantages when competition in their industry becomes global and complex (Doz & Prahalad 1980, 149). In such situation, it is difficult for Finnish SMEs to negotiate a high ownership arrangement; unless they can provide the unique advantages that the Chinese government cannot easily acquire (cf. Cheng 2008, 212; Doz & Prahalad 1980, 150).

## **6.2 Market entry modes to China**

In general, SMEs prefer exporting mode when they want to enter the foreign markets for the first time. They change to joint venture after being familiar with local culture, market and government's policies. (Eicher & Kang 2005, 209) Sarkar & Cavusgil (1996, 845) propose joint-venture as the entry mode. The reason is that joint-venture can assist for the enterprise entering the Chinese market with local skills and resources (cf. Barkema & Vermeulen 1998, 10; Madhok 1997, 45-49). When SMEs have more international experience, they will also prefer high ownership entry mode (Shraderet al. 2000, 5-7). The SMEs make the decision on entry modes after considering alternative entry modes.

CEO A (2009) expressed that the case enterprise was seeking the most effective and economical solution of entry mode, and three considerable entry modes were discussed when his enterprise prepared to do business in China:

*‘through a local dedicated partner as importer and distributor through his network; later perhaps a joint venture; or a person hired by the enterprise working for us.’*

As claimed by Albaum et al. (2002, 249), the local partner belongs to ‘direct exporting’ export mode; a joint venture belongs to ‘strategic alliances’ non-export mode; and hiring a person belongs to ‘direct exporting’ export mode. If the case enterprise preferred direct exporting, it would have a high degree of control on the transaction cost, maintain a good relationship with its customers, investigate end users’ demands, and possibility to get feedback on the products quickly from customers. Chinese local distributors also would provide the case enterprise valuable market information involving current demands, trends, and shares. However, the case enterprise would spend lots of time, energy, and money in understanding local distributors. The cost of exporting mode is lower than joint-venture mode. The profit return of exporting mode is also lower than joint-venture mode.

For less experienced SMEs, the mode of joint venture may reduce uncertainty and risk, for example, fierce competition, and acquisition of resources and the support from their partners in China. As mentioned in macro factor consideration, some policies under the Chinese health care system are to encourage foreign investment in the field of medical devices; and TCM culture does not influence import of medical devices to a certain extend, especially for IVD devices. But competition of medical devices is fierce due to lots of manufacturers from many OECD countries and local cities, and updating regulations by SFDA publication, factors of uncertainty and risk. If the case enterprise would built a collaborative relationship with Chinese local manufacturer with good reputation, it would only provide technology guidance to local manufacturer and use local raw materials with relatively lower cost than in Finland, and utilize local distribution networks. Project Manager B (2009) said:

*‘for small and middle-sized enterprises, the key point is to find a right partner.’*

Moreover, CEO B (2009) stated:

*‘SME companies need government support for market entry.’*

CEO A (2009) also indicated that the case enterprise could acquire the support of domestic government and tried to look for the support of Chinese local government, which would make easier entry to the Chinese market.

Finally, the case enterprise adopted an entry strategy. According to Johanson & Wiedersheim-Paul (1975, 305), the foreign market entry mode in manufacturing industries may be identified by using exporting at the beginning years. The reason is to avoid high

risks and some uncertainties and limited funding. In comparison with exporting mode, the mode of joint venture has higher investment cost and higher risk, corresponding investment returns is also higher. In this case study, CEO A has similarly decided to export the enterprise's products through local distributors or agents at the initial stage. In addition, CEO A has also planned to hire an employee, who is mainly responsible for businesses in the Chinese market, such as seeking local potential distributors or agents, negotiating with selecting distributors or agents, and developing markets in the different cities in China. The employee may be a Chinese person, or also a Finnish person. It is much better if this employee has good background in comprehension of Chinese business.

CEO A (2009) stated that the case enterprise entered the Chinese market with a good beginning. The case enterprise was familiar with Chinese IVD market and Chinese policies and regulations of IVD, as well as building a harmonious relationship with local governments and local partners (i.e. a good business network in China). The exporting mode may be considered being changed to the joint-venture to make a higher profit at the following stage. Thereby, if the result of entering the Chinese market is unfavorable, the case enterprise will keep the exporting mode, or even withdrawing from the Chinese market. At the moment, the case enterprise is still in the beginning of entering the Chinese market. It is difficult to say whether the exporting mode is a suitable entry mode or not for the case enterprise. However, the mode is feasible according to the current trend of development in the Chinese market of IVD. The figure 8 presents the whole process of selecting an entry mode at the case enterprise.

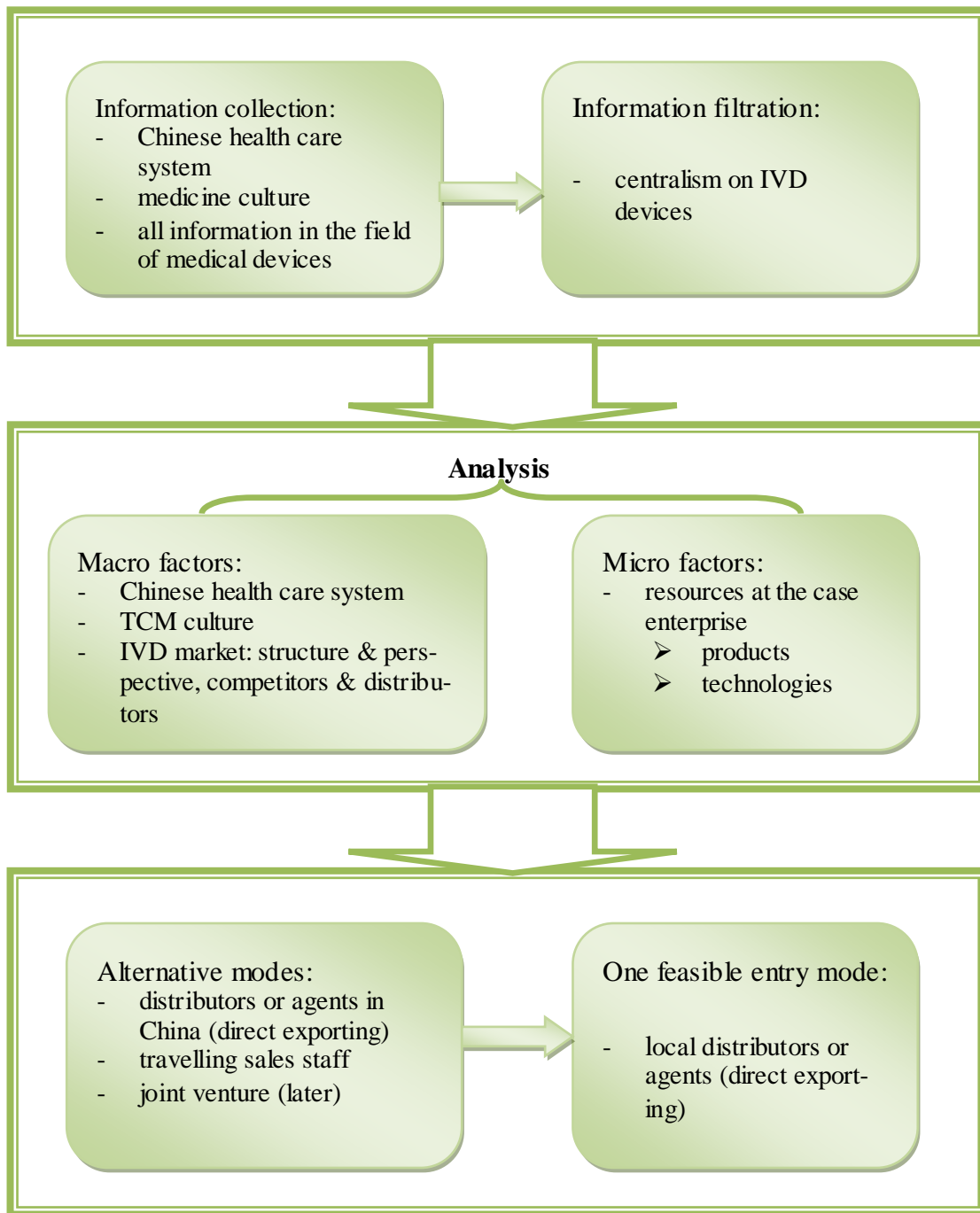


Figure 8: A process of selecting an entry mode in the case enterprise

Provided the exporting mode is defined as a feasible entry mode by the case enterprise, the process of making an adaptation of marketing mix follows next. If the marketing mix is well established, the case enterprise's business could develop steadily, and products could be infiltrated into the Chinese market of IVD.



### 6.3 Marketing mix in China

The marketing mix was mainly designed by the case enterprise on the basis of the 4Ps marketing mix at the moment. Due to the Chinese special ‘relationship’ culture, relationship was a necessary element added into the marketing mix. (CEO A 2009)

For the enterprises, relationships with different parties are requisite. Project Manager B (2009) said:

*‘to balance the relationship among all parties who will be related to your business. They can help you but they can also destroy you.’*

The case enterprise faces an entirely new Chinese medical device market, so that the personal relationship is needed to start the case enterprise’s business in China according to CEO A’s opinion. Following relationships are built with the distributors or agents based on business development. The products of the case enterprise will be sold to the customers through distributors. Moreover, the relationship with customers is also important for the case enterprise. But at the present stage, the partners, such as product agents, are usually in charge of a good relationship with the sales channel. Currently, the case enterprise has only an indirect relationship with the customers. (CEO A 2009)

Product is core element of the marketing mix. *‘Product means the need-satisfying offering of a firm. The idea of product as potential customer satisfaction or benefits is very important.’* (McCarthy & Perreault 1990, 218) For the case enterprise, if its products have demand in the Chinese market, it would mean that the products are worth exporting to China. Recently there are many competitors in the IVD market in China. Customers’ requirements for IVD products are high. The demand trend of products is concentrated on novel style, portability, testing speed, degree of accuracy, high technology and high quality. Project Manager B (2009) suggested to Finnish SMEs:

*‘one more thing is the high quality. In China, you can find almost all advanced products from all over the world, and if your product is out of date, please give up your intention.’*

In other words, products must have high quality, and their selling point must be attractive, so that the products have competitive advantage in homogeneous IVD products. CEO A (2009) described their product advantages:

*‘our unique selling points are mobile wireless technology with fast analysis times, technology usability also in small health units [because] analytics seems in China be done in big analyzers in big laboratories rather than in small units.’*

Therefore, in high competition environment, the products of the case enterprise are positioned to be sold to small units in China, for example, to street health stations in the urban sector, village stations in the rural sector, or small laboratories. Most large hospitals use IVD products of Roche corporate (Project Manager B 2009). It is quite difficult

to the case enterprise to sell its products to the same hospitals as Roche as does. On the angle of marketing strategy, the case enterprise's products should avoid to be at the same hospitals or research institutions with Roche's products at the same time (cf. Lee, Lim & Tan 1999, 300). Comparing to Roche's IVD products, Chinese distributors/agents and customers are not familiar with the products' functions and how to use them. Before the products of the case enterprise are accepted by Chinese customers, the products could be sold to the customers at the bottom of pyramid, mainly in the rural sector at first, but the quality of the product must be guaranteed.

Due to consideration of issues of costs and fierce competitions, CEO A said that the case enterprise has to seek an innovative method of setting its products' price. Prices of health care services and products in China are set according to a two-track approach (see Chapter 2.1.1). Except for basic health services on the basis of historical fees established by the government, service fee of using medical devices could be charged by each hospital. Foreign manufacturers may set the price by considering competitors' price and provincial price. Medical device price could be set according to provincial level in China (Boyd 2009). CEO A thought the price should be set lower than competitors:

*'the price level in China has been cut by the government although there are differences in and between provinces. We have to find innovative solutions to cut our exports prices in order to be competitive.'*

Hence, the enterprise sets prices of its exporting products to China by the method of pricing inversion. It means that the enterprise refers about the unit price and usage times from similar IVD products in Chinese hospitals first, and then calculates intermediate parties' service, the enterprise's cost and a potential profit. The final price of exporting products is calculated as the assumed formula below.

$$\text{Final price} = \text{unit price} * \text{usage times}^{22} + \text{intermediate parties' service fees} + \text{the case enterprise's cost} + \text{profit}$$

The final price may be changed according to the variable number of intermediate parties (CEO A 2009). In other words, if the number of intermediate parties is low, the case enterprise can earn more marginal profit. On the contrary, if there are three or more levels of intermediate party between the case enterprise and the end-customers, the marginal profit would be decreased. Concerning total cost's calculation, the change in total variable cost will directly affect total cost (McCarthy & Perreault 1990, 489). In accordance with the formula above, the case enterprise works out the prices of exporting products. After the computed prices are compared with the other prices of congeneric

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<sup>22</sup> Usage times are predicted according to operational life span of product.

IVD products in the Chinese market, the case enterprise properly adjusts the prices of products, and sets ultimate prices (CEO A 2009).

As mentioned before, CEO A said cutting export price will make export products more competitive. However, this situation of cutting price is only suitable for products that are at the stage of maturity or decline of product life cycle in a saturated market. If the export products of the case enterprise were one kind of novel and innovative products, or the Chinese market was not saturated with this kind of products, or the kind of products had their own special technology which could not be copied, the prices would be set a little higher on the basis of high quality. Project Manager B (2009) presented her work experience:

*‘here the people often accept that the import device should be more expensive than locally made.’*

Thus, the price of export products of the case enterprise must not be set too low though there is a fierce competition in China. An average pricing level is suitable for the case enterprise.

*‘People won’t buy your product if they have never heard of it’*, McCarthy & Perreault (1990, 365) said. Since the case enterprise’s products were approved by Chinese SFDA in April 2010 according to the internal document of the case enterprise, most Chinese distributors and end-customers have not yet been familiar with the case enterprise’s brand of IVD products, excluding minor agents. However, the internal document also recorded that the case enterprise participated in various international medical device fairs in different regions several times, collected lots of information concerning demand development and trends of Chinese market, and promoted its own products and looked for collaborative partners on the fairs. Moreover, through participations of the international medical device fairs, public relations could be set up. CEO A (2009) said:

*‘scientific articles together with participation of the medical fairs will be the most potent tool for us to build public relations.’*

Scientific articles could affirm and prove innovative functions and quality of the enterprise’s products, and enhance products’ persuasion in front of public. That is, scientific articles may be seen as a tool of advertisement. Many medical devices are not direct consumer goods because the end-customers are not consumers. It may not be possible to advertise medical devices on TV, on the radio, or in regular magazines and newspapers except for minor household products, such as thermometer. Project Manager B (2009) proposed:

*‘you should find the right way to promote your products. Otherwise, you will lose more money and gain nothing.’*

Since the end-customers are professional institutions or organizations, the product’s introduction or description should be published in the scientific articles in the professional journals by the authoritative publications, especially by the Chinese publications

in the field of medical devices. Let more customers know the products from the case enterprise, which is located in Finland. At the same time, participating international fairs can be used as a platform of building relationships with public relations, distributors, customers, even with local government.

Nevertheless, building a good relationship with Chinese local government is carried out better by the case enterprise's partners in China. CEO A (2009) thought:

*'our forthcoming partners need to have good network of relationships with local government. That is, networking through our partners.'*

Chinese business has its own culture, and it differs from Finnish business culture. The case enterprise can use Chinese partners for building relationships with Chinese government, then doing by itself. So it follows that lots of time could be saved for the case enterprise. That is because the process of building a deep relationship with local government is complex and difficult. The case enterprise has to be familiar with Chinese business culture in advance, Project Manager B (2009) emphasized:

*'do business in comply with a Chinese way, otherwise, you cannot develop the business successfully.'*

Therefore, local agents or distributors are key connections between the case enterprise and local government.

Selection of local agents or distributors is one 'P' (place) of the marketing mix (McCarthy & Perreault 1990, 274). Project Manager B (2009) also stated:

*'distribution channel is a must for you, when you select the mode to pick up a partner instead of direct sales by yourself.'*

Good distribution channel can assist the case enterprise allocating products to customers at the quickest speed, and bring new orders. The profit of the case enterprise may be ensured for a certain period. At the moment, the case enterprise is still negotiating some potential agents or distributors in China (CEO A 2009). This process runs relatively slowly in finding one or two capable agents or distributors, who can provide assistance to the case enterprise's entering the Chinese market as quick as possible, and support the enterprise developing network in China.

In sum, the marketing mix in China for the case enterprise is '6Ps + 1R + 1C'. '6Ps' are product, price, promotion, place, political power and public relations; '1R' means relationship; and '1C' is customers. Among of these elements, 'customers' are mainly communicated through the partners of the case enterprise. Figure 9 shows a current marketing mix of the case enterprise in China. The marketing mix may be changed on the based of business development in China.

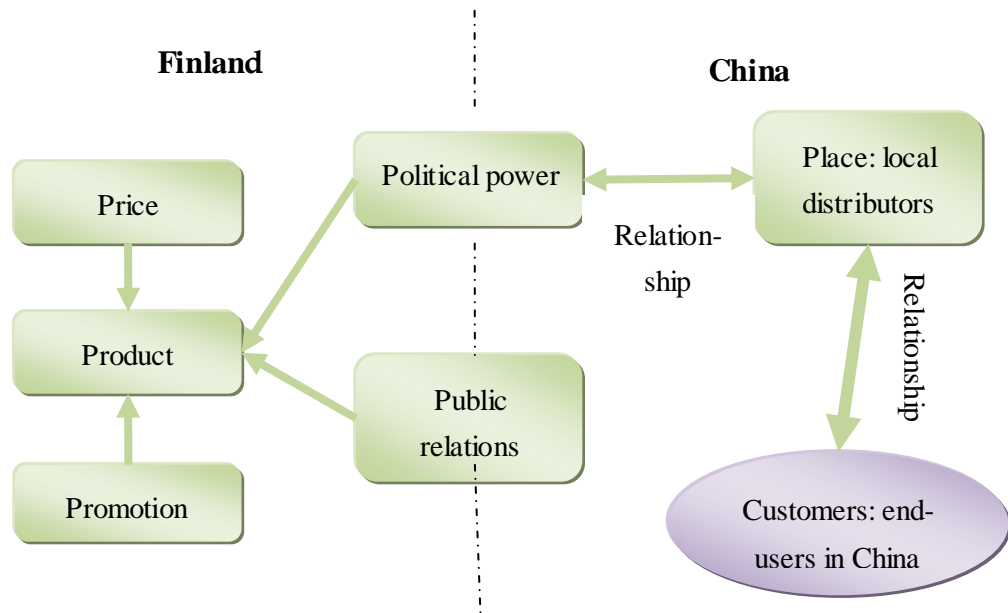


Figure 9: Case enterprise's marketing mix

The strategy of marketing mix of the case enterprise is similar to another Finnish SME which was also interviewed in January 2010 (see table 11). This Finnish SME produces therapeutic devices, and has exported its medical device to China successfully. On the table, this therapeutic device SME is named as Company X because Project Manager A asked for anonymity. The bold parts present those aspects that are important in the marketing mix of medical devices according to Company X's achievement in China.

Table 11: Comparison of the marketing mix in China between the case enterprise and Company X

	Case enterprise	Company X
<b>Product</b>	<ul style="list-style-type: none"> <li>- high technology</li> <li>- high quality</li> <li>- easy to use</li> </ul>	<ul style="list-style-type: none"> <li>- <b>high quality</b></li> <li>- good-looking shape</li> <li>- easy to use</li> </ul>
<b>Price</b>	<ul style="list-style-type: none"> <li>- referred as policies by the government</li> <li>- referred as competitors</li> <li>- an innovative method</li> </ul>	<ul style="list-style-type: none"> <li>- referred as competitors</li> </ul>
<b>Promotion</b>	<ul style="list-style-type: none"> <li>- fairs in China and in other regions</li> <li>- through partners</li> </ul>	<ul style="list-style-type: none"> <li>- exhibitions/seminars</li> </ul>
<b>Place</b>	<ul style="list-style-type: none"> <li>- local distributors</li> </ul>	<ul style="list-style-type: none"> <li>- local distributors</li> </ul>
<b>Political power</b>	<ul style="list-style-type: none"> <li>- through partners</li> </ul>	<ul style="list-style-type: none"> <li>- establishing <b>relationship with government people</b></li> </ul>
<b>Public relations</b>	<ul style="list-style-type: none"> <li>- scientific articles</li> <li>- medical fairs</li> </ul>	<ul style="list-style-type: none"> <li>- at round table for having meal &amp; drink (in China)</li> <li>- at sauna room (in Finland)</li> </ul>
<b>Relationship</b>	<ul style="list-style-type: none"> <li>- personal relationship</li> <li>- with distributors and their agents</li> <li>- within the sales channel to customers</li> </ul>	<ul style="list-style-type: none"> <li>- good use of own <b>personal relationships</b></li> <li>- with different stakeholders in the <b>purchase chain</b></li> </ul>
<b>Customer</b>	<ul style="list-style-type: none"> <li>- through partners</li> </ul>	<ul style="list-style-type: none"> <li>- through partners</li> </ul>

As showed in the table 11, the high quality of product is the core of the marketing mix. Various relationships must be set up if the Finnish SMEs want to develop their businesses in China, including with local distributors, government people, and different stakeholders in the purchase chain. Among of these relationships, the relationship with local distributor is the most important for the case enterprise. Local distributors not only assist the case enterprise performing promotional activities in China, but also keep communication among the case enterprise, government and customers. Besides, personal relationships should be used well if it is possible. That is because ‘*personal relationships are central to every aspect of Chinese society, including business*’ (Vanhonacker 2004, 49). According to comparison of the marketing mix in China of two Finnish

SMEs, the adaptation of marketing mix for Finnish medical device SMEs is proposed as ‘6 Ps (product, price, promotion, place, political power, and public relations) + 1R (relationship) + 1C (customers)’.

## 6.4 Synthesis

This chapter presents the findings of the case based on the theoretical framework and empirical study. The relatively complex process of selecting the international entry mode and the marketing mix (see Figure 10) is summarized in the following paragraphs.

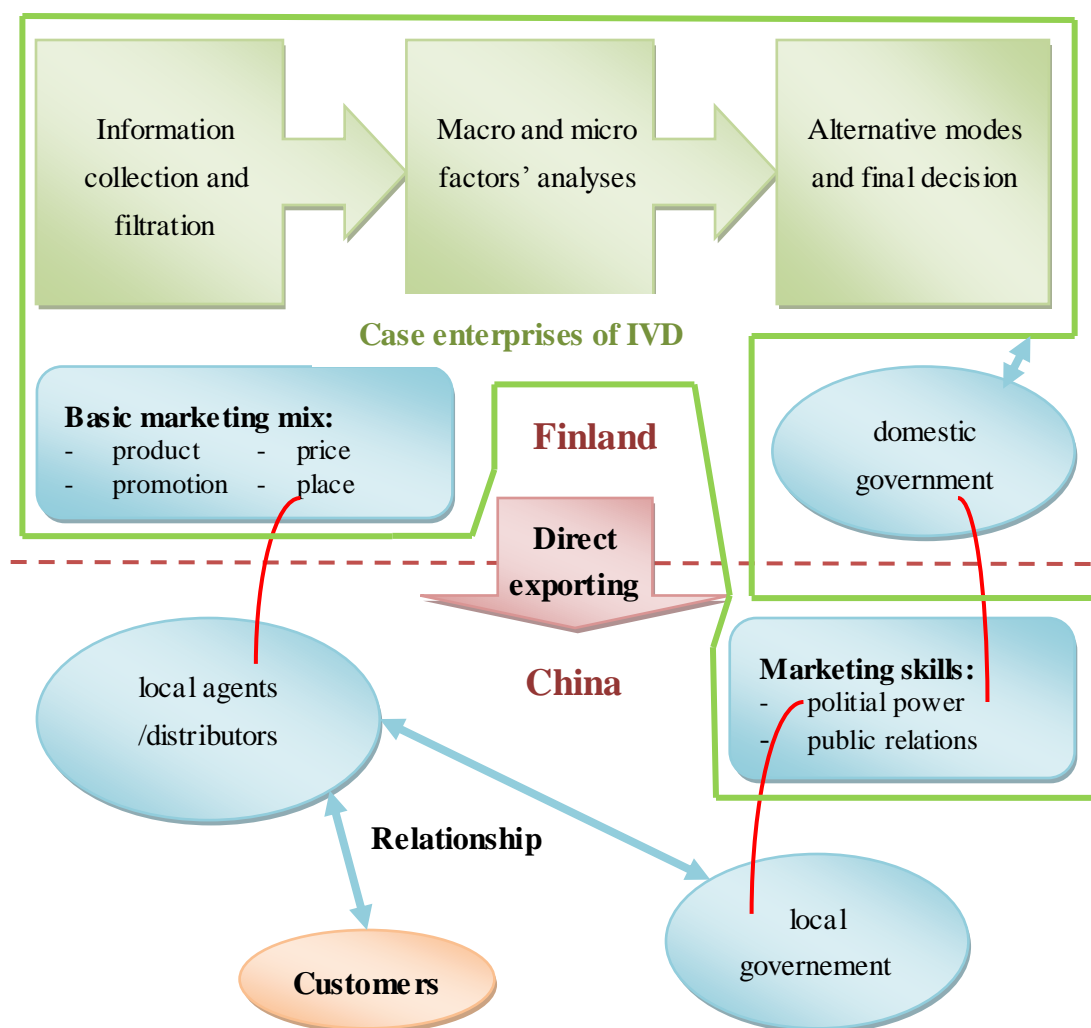


Figure 10: Synthesis of case study – a process of exporting IVD products to China

As can be seen in the figure 10, it responds to the research objective by showing how to export Finnish medical devices to China in the case enterprise. The upper part of the figure (in light green color) explains how to ultimately define one feasible entry mode in the case enterprise; and the lower part of the figure (in light blue color) suggests the

adaptation of marketing mix through the case study. The orange color indicates the customers of case enterprise in China. The customers are local organizations in health care, such as hospitals, clinics, and pharmacies. In the basic marketing mix, the case enterprise develops its competitive advantages by innovative products and setting affordable price. The promotion tool focuses on participation at various fairs of medical devices in the different regions.

Furthermore, a good relationship should be set up between the case enterprise and customers directly or be established by local agents/distributors. At the same time, the relationship with government should also be established and maintained well. In Finland, the Finnish SMEs can contact the Finnish government to receive support on entering the Chinese market; in China, the Finnish SMEs can build the relationship by their local agents/distributors. Since the case enterprise chooses exporting as its entry mode, the relationship with Chinese government and local customers are maintained by its agents/distributors. Hence, it is very important to establish a good and harmonious relationship in the beginning.



## 7 CONCLUSIONS

Conclusions are drawn on theoretical contributions at first, and then managerial implications. Finally, limitations and suggestions for future research are presented.

### 7.1 Theoretical contribution

This study has presented *how to export Finnish medical devices to China*. The literature concerns international entry modes and marketing mix. On the discussion of international entry modes, main factors influencing on the selection of international entry modes are separated from Chapter 3 and form a separate chapter, i.e. Chapter 2. The reason is to accentuate the importance of the analyses of main factors before entering the Chinese market. The main factors have important implications. For example, demands on hi-tech products on the Chinese medical device market, and huge medical device market in China. This aspect is discussed because explicit attention of main factors should be given to the Finnish SMEs. Besides, one situation is concluded on the side of marketing mix that the Finnish SMEs know the marketing mix of 4Ps well, but they are unfamiliar with other theories of marketing mix.

Generally speaking, the findings of this study are both pragmatic and theoretically justified, and these findings can further reference what and how a Finnish SME should actually consider and choose their entry modes to China. This study proposes a well-rounded theoretical framework that based on three theoretical views including main factors' consideration at the pre-entering phase, selection of entry modes at the entering phase, and marketing mix at the post-entering phase. The theoretical framework is to examine the possible choices of the Finnish SME's entry mode strategy and marketing mix strategy in the Chinese market. These three theoretical views have applied in describing the key determinants of export Finnish medical devices to China. Furthermore, this study fills a gap of the prior studies, which is lacking of international entry modes of medical devices between Finland and China; and provides a solution for selecting the marketing mix after the Finnish SMEs entering the Chinese market on a small scale.

### 7.2 Managerial implications

The findings have important managerial implications. First the study shows that relationship is very important in the marketing mix when a Finnish medical device SME enters the Chinese market, and it may influence the selection of international entry modes to a certain extent. Besides, huge potential markets for medical devices are in

China. Several Finnish SMEs consider selling their products in China because there is established relationship with a Finnish consulting company which is located in China, and they have a good relationship with Chinese local agents of SFDA registration certificates and other distributors of medical devices. These Finnish SMEs believe they can enter the Chinese market quickly under this relationship. They are probably correct, if the SFDA regulations are not always updated. The Finnish SMEs should apply for registration certificates as early as possible due to long waiting time and changing SFDA regulations.

Moreover, a 'good relationship' should be also set up and developed with local distributors. However, the Finnish SMEs have to follow the Chinese way to do business in China, such as having dinner at round table with agents/distributors with a friendly environment, and then local government people and customers will/may be introduced to the Finnish SMEs by the local agents/distributors at dinner. People sitting around the table can exchange business cards and deliver the relative information freely. Their own personal relationship may be established. As a result, the Finnish medical device SMEs should properly establish a strategy for the business relationships based on their own financial condition.

Second, the culture factor cannot be neglected in the selection of international entry mode and doing business in China. Chinese business culture influences the Finnish SMEs' business operations in China. As mentioned previously, doing business in China must follow Chinese way. It leads to that the Finnish SMEs have to consider opting for an entry mode, which can integrate into the Chinese business society as far as possible and avoid setting culture barriers. After all, learning Chinese business culture cannot be accomplished in a short period. It takes a quite long time to accumulate experience of dealing with various people, reacting in different situations, and judging real meanings from someone's words and conduct. Concerning Chinese business culture, it is quite difficult to explain since the business culture covers many aspects. Therefore, the Finnish SMEs adopt the exporting mode to launch their products into China for the first time. The risks in business culture will be decreased. Chinese local agents/distributors are responsible for most communication with local government and customers.

Third, the result of the marketing mix indicates that the element of product is the most vital. High-quality and high-tech medical devices are emphasized through a series of analysis. Nowadays, Chinese manufacturers can produce low-tech products skillfully in short time. It can be said that the Chinese medical device market is saturated with low-tech products. On the contrary, innovative products with advanced technologies are being required widely in China. Only if the Finnish SMEs produce innovative and high-quality product that can satisfy the Chinese customer, the Finnish SMEs would have own competitiveness to rival with strong competitors on the Chinese market. Product innovation can be presented in good-looking shape, easy-to-use, and high technology.

Finally, the case study of a Finnish SME in in-vitro diagnosis devices was discussed and analyzed on the suitable international entry mode and the adaptation of marketing mix, so that the combination between market entry mode and the marketing mix can be more clearly represented. The results of case study may be at some extent generalized to the application of other Finnish medical device SMEs that are going to enter, are entering, and have entered the Chinese market. Furthermore, this study also offers Chinese agents/distributors of medical devices what the expectations of Finnish SMEs are; what kind of marketing mix will be or is used in the Chinese market; and how they decide their international entry strategies.

### **7.3 Limitations and suggestions for further research**

Most researchers show a growing interest in the international entry modes and marketing mix. However, previous research about the selection of international entry modes is still limited, particularly about medical device SMEs. There are some limitations in this study. Firstly, a static picture is provided on the selection of entry modes and marketing mix of international market. How entry mode choice changes over time is not considered. This study only mentions that selected entry modes may be changed over time and the operating marketing mix of medical devices in China will be adjusted with entry modes and the SMEs' own situations.

Secondly, the amount of interviews is few, only 4 available interviews. Chosen interviewers are only in the Finnish SMEs. Information from Chinese local agents/distributors is collected much less. Thus, the research in the future should extend the quantity and the range of interviews. If possible, the quantitative research method should be applied into the study. Moreover, case study in the future research could consist of at least two cases. Yin (2003, 133) states that with a single case it is relatively difficult to analyze various phenomena under a situation, and the findings lack of persuasiveness facing different appearances. In the way of multi-cases, more aspects will be discussed in international entry modes and marketing mix of medical devices in China. By comparison of two or more cases, subtle differences and more similar opinions will be found, so that arguments are unbiased.

Thirdly, the primary data was obtained in the case enterprise, so some personal thoughts may have affected the result's credibility, transferability, dependability, and conformability. When the Chinese IVD market was analyzed, the difficulty was in finding the information of the competitors. Every competitor tends to protect data about their strategies, market share, and enterprise investment in China, therefore the information is almost impossible to find out. On the competitors' websites, they mainly refer to their general information on the sizes, products and the current events of the enterprise.

Thus, it is hard to compare the case enterprise to their competitors in the Chinese market. Besides, the case enterprise's professional technology, financial resources, plans and budgets of investment for Chinese market are not published here due to business secrets.

## 8 SUMMARY

Most of medical device enterprises in Finland are SMEs. Some of them have entered the Chinese market successfully or are entering the market, and the others may plan to launch their products into China. In order to assist the Finnish SMEs those have not entered the Chinese market yet but want to develop their business in China; or are entering the Chinese market. This study discussed the selection process of international entry modes for Finnish medical device SMEs and an adaptation of marketing mix after entering the Chinese market. The research purpose is *to study how to export Finnish medical devices to China*. It consists of three sub-objectives following:

- To describe main factors influencing Finnish medical device SMEs on the selection of entry modes to China;
- To discuss main entry modes for Finnish medical device SMEs entering the Chinese market;
- To analyze the adaptation of marketing mix for Finnish medical device SMEs on the Chinese market.

The theory of main factors has been used to analyze SMEs' macro (external) and micro (internal) factors influencing export modes of Finnish medical devices to China. On one hand, macro factors influencing the selection of international entry modes are found in Chinese policies and law/regulations of medical devices, Chinese TCM culture, fierce competitors, local distribution networks, and IPR problem by presenting Chinese health care system, Chinese medicine culture, and current situation of the medical device market in China (e.g. Haruo 2007, 1-2; Liu 2004, 38-39). On the other hand, micro factors focus on the Finnish SMEs' finance, technology, product, and knowledge on the basis of enterprise resources. Limited financial resource may lead to export entry mode (e.g. Chang & Rosenzweig 2001, 756). High technology and innovative product form the enterprises' competitive advantage to a certain extent (e.g. Ekeledo & Sivakumar 2004, 70). As well as knowledge consideration of enterprises directly affects the selection of entry modes (e.g. Park & Sternquist 2008, 292-296).

According to Albaum et al. (2002, 249-356), the international entry modes are divided into export entry modes and non-export modes. In accordance with the theories, four feasible international entry modes were suggested to Finnish SMEs. These four modes were exporting, licensing, contracting, and joint venture respectively. The Finnish SMEs could use the above mentioned entry modes entering the Chinese market depending on the enterprises' own situations. Each entry mode has its own advantages and disadvantages. In the entirety, comparing to the joint venture, the exporting, licensing, and contracting modes have low risks and low costs. However, the profits and level of control are also low. Generally, in order to reduce export risks, the SMEs incline to choose the entry modes with low risk and low cost (e.g. Ekeledo & Sivakumar 2004, 75;

Osland et al. 2001, 155). Moreover, the enterprises may face IPR problems in China. The implementation of joint venture can help the enterprises to share the risks with partners and access partners' resources. Besides, there are many opportunities for development of Finnish SMEs in China, whereas it takes longer time for the return of investment. Normally, when the Finnish SMEs enter the Chinese market for the first time, the enterprises would prefer to opt for the mode of exporting. However the mode of joint-venture can also be considered after the Finnish SMEs have already operated in China for several years. However, using a suitable entry mode cannot guarantee that the Finnish SMEs will achieve successful business operation in China for sure. The suitable entry mode is only one of two preconditions for the sales of product in China at the beginning. The other precondition of making a business success is an adaptation of marketing mix in China. These two preconditions are very important for operating businesses in China.

Based on various theories of marketing mix, i.e. McCarthy (1964)'s marketing mix of 4Ps (product, price, promotion, and place); Booms & Bitner (1981, 47-51)'s marketing mix of 7Ps (product, price, promotion, place, physical evidence, process and people); Kotler (1992)'s marketing mix of 10Ps (product, price, promotion, place, political power, public relations, probe, partition, priority and position); Lauterborn (1990, 26)'s marketing mix of 4Cs (customer, cost, convenience, and communication); and Schuhz (2000)'s marketing mix of 4Rs (relevance, reaction, relationship, and reward), an adaptation of marketing mix of medical devices in China has been analyzed in this study. As forgoing theories mentioned, 7Ps and 10Ps of marketing mix are based on McCarthy (1964)'s 4Ps of marketing mix. 4Cs and 4Rs of marketing mix are relatively new theories, which are proposed after 1990s. The elements of 'customer' in 4Cs of marketing mix and 'relationship' in 4Rs of marketing mix are paid close attention to by enterprises. Meeting customers' demands could help enterprises retaining existing customers and attracting new customers from competitors. In order to know the customers' demands, establishing a good relationship with local partners (agents/distributors) and/or with local customers is necessary. Hence, the marketing mix of '6Ps (product, price, promotion, place, political power, and public relations) + 1R (relationship) + 1C (customer)' is concluded from previous theories. Moreover, the Finnish medical device SMEs can adjust this marketing mix to marketing mixes of '4Ps + 1R + 1C' and '10Ps (product, price, promotion, place, political power, public relationship, probe, partition, priority and position) + 1R + 1C' based on own enterprises' actual conditions and situations in China, such as scale of enterprises, orientation of funding investment, and relationship with local partners.

The theories above were empirically studied. A qualitative case study approach was used in this research. One Finnish in-vitro diagnosis device SME was selected as a case enterprise for this study. By analyzing macro and micro factors, the case enterprise

found that there was a huge market of hi-tech medical devices in China. Moreover Chinese government's policies in the section of health care promote foreign investment in the field of medical devices. But, the time of waiting for the SFDA registration certificate is quite long, it lasts at least 6 months. Besides, distributors should be chosen by due diligence. In this study, the case enterprise selected exporting as its international entry mode when it initially entered the Chinese market. After the case SME enter the Chinese market, an adaptation of marketing mix is important. On the basis of the theoretical part, the marketing mix of '6Ps + 1R + 1C' was considered as a basic adaptation model for the case enterprise at the moment, i.e. basic marketing mix (4Ps: product, price, promotion and place) + marketing skills (2Ps: political power and public relations) + relationship (1R) + customers (1C).

Overall, there is fierce competition in the Chinese medical device market. This situation brings a challenge for the Finnish SMEs. In order to acquire the market share, the Finnish SMEs must have their own competitive advantages over their competitors, who are from other OECD countries and China. Moreover, as the Finnish SMEs carefully choose the international mode, they also should precisely consider the marketing mix which operates in China. The marketing mix may be affected by the international entry mode.

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## APPENDICES

### Appendix 1: Comparison of basic data between China and Finland

(adapted from World Bank 2010)

	China	Finland
Population (in 2009)	1,331,460,000 - urban: 20% - rural: 80%	5,338,000 - urban: 65% - rural: 35%
Land area	9,640,821 km <sup>2</sup>	338,145 km <sup>2</sup>
Average population density	140/km <sup>2</sup>	17/km <sup>2</sup>
Provinces	23	12
Autonomous regions	5	---
Municipalities	4	---
Special administrative regions	2	---
Official language	Chinese	Finnish & Swedish
GDP (in 2009)	US\$ 4,909,280	US\$ 237,512
GDP per capita (in 2008)	US\$ 3,267	US\$ 51,323
Public health expenditure (% of total health expenditure, in 2007)	44.7%	74.6%
Out-of-pocket health expenditure (% of private expenditure on health, in 2007)	92%	74.3%
Health expenditure per capita (in 2007)	US\$ 108	US\$ 3,809
Life expectancy, total (years, in 2008)	73	80
Exports of goods & services (% of GDP, in 2008)	36.6%	44.2%
Imports of goods & services (% of GDP, in 2008)	28.5%	40.3%

Note:

1. Health expenditure is defined as *‘the sum of public and private health expenditure.*

*It covers the provision of health services (preventive and curative), family planning activities, nutrition activities, and emergency aid designated for health but does not include provision of water and sanitation'. (World Health Organization 2010)*

2. Public health expenditure is referred as '*consisting of recurrent and capital spending from government (central and local) budgets, external borrowings and grants (including donations from international agencies and nongovernmental organizations), and social (or compulsory) health insurance funds*'. (World Health Organization 2010)
  
3. World Health Organization (2010) defines that '*out-of-pocket payment is any direct outlay by households, including gratuities and in-kind payments, to health practitioners and suppliers of pharmaceuticals, therapeutic appliances, and other goods and services whose primary intent is to contribute to the restoration or enhancement of the health status of individuals or population groups. It is a part of private health expenditure*'.



## Appendix 2: Comparison of TCM and Western medicine

(adapted from Beijing digital museum of TCM 2007; Lam 2001, 763-764; Sun 2007, 214-215; Wong et al. 1993, 283)

	Traditional Chinese Medicine	Western medicine
<b>Diagnostic theoretical basis</b>	<ul style="list-style-type: none"> <li>Chinese archaic scientific culture</li> <li>Clinical experiences</li> <li>Philosophical thinking &amp; discrimination</li> </ul>	<ul style="list-style-type: none"> <li>European traditional ideational culture               <ul style="list-style-type: none"> <li>- Atomism &amp; reductionism</li> </ul> </li> <li>Anatomy</li> <li>Biochemistry</li> </ul>
<b>Diagnostic methods</b>	<ul style="list-style-type: none"> <li>Four main methods: looking; listening &amp; smelling; asking; and pulse-taking &amp; palpation</li> <li>Other methods: auricular examination, abdominal palpation, and palm examination</li> </ul>	<ul style="list-style-type: none"> <li>Three main methods:               <ul style="list-style-type: none"> <li>- Etiological diagnosis</li> <li>- Pathological diagnosis</li> <li>- Pathophysiological diagnosis</li> </ul> </li> </ul>
<b>Therapeutic methods</b>	<ul style="list-style-type: none"> <li>Medicinal herb &amp; dietary</li> <li>Acupuncture &amp; cupping</li> <li>Moxibustion</li> <li>Tuina</li> <li>Qigong</li> </ul>	<ul style="list-style-type: none"> <li>Chemical-based medicines</li> <li>Injection</li> <li>Surgery</li> <li>Chemotherapy</li> </ul>
<b>Advantages</b>	<ul style="list-style-type: none"> <li>Predictable diagnosis</li> <li>Explanations in detail</li> <li>Clear diseases completely</li> <li>Weaker side effects</li> </ul>	<ul style="list-style-type: none"> <li>Cellular elements' structure</li> <li>Modern advanced medical devices</li> <li>Easily accepting &amp; studying</li> <li>Convenient &amp; shorter time in therapeutic process</li> <li>Quicker recovery</li> </ul>
<b>Disadvantages</b>	<ul style="list-style-type: none"> <li>Inconvenient &amp; longer time in therapeutic process</li> <li>Slower recovery</li> </ul>	<ul style="list-style-type: none"> <li>Strong side effects</li> <li>Curing diseases incompletely</li> </ul>

### Appendix 3: Initial registration of imported medical devices

(Direct quotations from SFDA 2008)

#### A. The Direction for the Application Form of Registration

1. All the contents filled in shall be in both Chinese and English;
2. Upon the application, the form shall be printed;
3. All the items must be completely filled in, and as for the vacant items, “/” shall be used to show inapplicability;
4. The Name of Devices and Model, Name and Address of Manufacturer must be unanimously the same as the contents carried in the documents approved by the government of the Country (Region) of Origin, and must be consistent with the contents concerned carried in the test reports, operation manual of the product, and so on;
5. Any enterprise shall not set up the format for the Application Form for Registration without authorization. The Application Form may be downloaded from the website: <http://www.sda.gov.cn/ylqjzc/setup.exe>.

#### B. About the Application Documents

1. The certificate of the legal production qualification of the Manufacturer:
  - 1) The certificate issued by the government agency of the Country (Region) of Origin to authorize the Manufacturer to engage in the production and distribution of medical devices (equivalent to the business certificate or manufacturing enterprise license) .
  - 2) The certificates may be submitted in the form of the copy thereof, subject to the seal by the original issuing agency or the notarization by the local notarization agency.
2. The qualification certificate of the applicant:
  - 1) Business certificate of the Applicant;
  - 2) The certificate of commission given by the Manufacturer to the agent for registration.
3. The certificate recognized or approved by the government of the Country (Region) of Origin to authorize the products as medical devices to enter into the market of the country:
  - 1) The certificate recognized or approved by the government of the Country (Region) of Origin to authorize the products as medical devices to enter into the market of the country.
    - a) In case of any special authorization documents specified by the government of Country (Region) of Origin for medical devices to be put into the market of the Country (Region) of Origin, such formal authorization doc-

uments as 510 K or PMA of the U.S. FDA, and the CE certificate of the EU shall be submitted.

- b) In case of one of the following circumstances:
  - 1) That no special authorization documents are required to handle by the government of the Country of Origin;
  - 2) That in case of any change to the Products on the basis of the Products specified in the original special authorization documents, due to the difference in the partition of registration elements, no re-application is required by the government of the Country of Origin, the enterprise shall give a statement, and provide the following certificates:
    - the free sale certificate issued by the government; or
    - the certificate to the foreign government; and
    - the enterprise self-guarantee declaration in conformance with the provisions concerned of local regulations.
- 2) In case of no document issued by the government of Country of Origin to authorize the medical devices to be put into market.
  - a) If the products shall be regulated as medical devices in the Country of Origin, but they have not been authorized by the government of Country of Origin to be put into market, the Standards of the Products to be Registered authorized by the competent department shall be submitted; in case of Products of Class II or Class III, the full-performance test report, Clinical Trial Reports, risk analysis reports within the territory of China and other documents necessary for the registration of import products shall be submitted, subject to which, the application may be accepted and after the acceptance, the on-site inspection of the production quality system will be arranged.
  - b) If the products shall be regulated as medical devices in the Country of Origin, but need not be authorized by the government of Country of Origin to put in the market because they are produced specifically for China, the first paragraph of this Article shall be applied.
  - c) If the products fail to be regulated as medical devices in the Country of Origin but the Products are defined as medical devices in China in accordance with the definition of medical devices, the first paragraph of this Article shall be applied.
- 3) The certificates may be submitted in the form of the copy thereof, subject to the seal by the original issuing agency or the notarization by the local notarization agency.
4. The Standards of the Products to be registered shall apply the Provisions for the Management of the Medical Devices Standards:

- 1) The methods for the implementation of “Only the Original of the Standards Sealed or Signed by the Legal Representative may be submitted”:
    - a) Standards of the Products to be Registered may be sealed through the following three methods: (a) to be sealed by the Manufacturer; (b) to be sealed by the office or representative office of the Manufacturer in China; (c) to be sealed by the unit in charge of the conclusion, arrangement, drafting of the Standards of the Products to be Registered commissioned by the Manufacturer. And in the certificate of commission, it shall be clearly indicated that “the ××× Unit is commissioned to be responsible for the completion of the Standards of the Products to be registered in China, and the Manufacturer shall be responsible for the quality of the Products”.
    - b) The Definition of the Legal Representative: in accordance with the international practices, " the signature and seal of the Legal Representative" of the Manufacturer abroad may be signed and sealed by the senior official in charge of the corresponding business activities.
  - 2) The Standards of the Products to be registered reviewed, codified, and recorded by SDA Standard and Technical Committee;
  - 3) As for the Products with national standard and industrial standards, the manufacturer shall, with the implementation of the standards mentioned above, based on its own specialties, supplement and add corresponding requirements, formulate the Standards of the Products to be Registered, and assure the safety and effectiveness of the operation of the Products; if the enterprise thinks that no requirements on safety need to be added, and that the direct adoption of national standard and industrial standards as the manufacturer Standards of the Products to be Registered is sufficient for the assurance of the safety and effectiveness of the products, the manufacturer shall submit a statement justifying that without any increase and improvement in the standard index on the basis of national standard and industrial standards, the safety and effectiveness of the products for application can be assured, declaring to bear the quality liabilities after the launching of the products and carrying the model, specification of the Products. As for the products with ISO or IEC standards, the manufacturer shall convert the standards to the Standards for the Products to be registered.
5. Operation Manual of the Products:
- 1) The methods for the implementation of “Only the Original of the Operation Manual Sealed or Signed by the Legal Representative may be submitted”:
    - a) The Operation Manual of the Products of Class II or Class III shall be sealed by the Manufacturer; the Operation manual of the Products of Class I shall not be sealed.

- b) (2) The Definition of the Legal Representative: in accordance with the international practices, " the signature and seal of the Legal Representative" of the Manufacturer abroad may be signed and sealed by the person in charge of the corresponding business activities.
- 2) Implementation of the "Administrative Provisions on the Operation Manual of Medical Devices". The operation manual of medical devices shall implement the national standards provided in "Operation Manual for Industrial Products-General provisions". In accordance with the specialty of the medical devices , the following contents shall be included:
  - a. Name of Product, Name, Address, Postal Code and Tel. of the Manufacturer;
  - b. Registration number of the products;
  - c. Applied product standards;
  - d. The main structure, performance, specification of the Products; the usage, scope of application, contraindication, precautions, cautions and suggestions of the Products;
  - e. Interpretation of the figures, logos, abbreviations, etc. of the labels and marks;
  - f. Illustration and graphic expression of the Installation and Operation;
  - g. The Maintenance methods, special storage methods and length of life of the Products;
  - h. Other necessary contents specified in the Product Standards.
- 6. The Type test Report presented by the medical devices quality test agency recognized by the State Drug Administration within the recent one year (Applied to the Products of Class II and Class III):
  - 1) About Test-after-Registration of import products: the following import products may apply to Test-after-Registration.
    - a) X-Ray Computerized Topography (CT);
    - b) Positron Emission Computerized Topography (PET);
    - c) Single Photon Emission Computerized Topography (SPECT);
    - d) Extraneous Shock Wave Crusher;
    - e) Color Ultrasonic Diagnostic Scanner;
    - f) Large Laser Therapy Apparatus;
    - g) Large X-Ray Diagnostic Equipment;
    - h) Automatic Biochemical Analyzer;
    - i) Cobalt 60 Therapy Unit;
    - j) Gamma Knife;
    - k) Medico- electronic Linear Accelerator;
    - l) Simulated Positioner;

m) Magnetic Resonance Imaging System.

To apply Test-after-Registration of import products, the Manufacturer shall submit an application for the Test and that the Products shall commit to complete the Test at first, as the product gets into the Chinese market. If the product fails to pass the following test, the registration certificate shall be cancelled by the original issuing agency.

- 2) About the Scope of Acceptance for Examination of the Examination Center:  
The test on placing the Products under the competent unit shall be determined in accordance with the “government certified Scope of Acceptance for Examination of the Examination Center”. The enterprise may at its option select one among the qualified examination centers. In case of any ambiguity on the catalog of the Scope of Acceptance for Examination of the Examination Center, a written report shall be submitted to the office of acceptance, and the office will deliver the case to the competent department to designate one center for test.
- 3) Under the following Circumstances, no test is required:
  - a) Among the laboratory equipment, the electrophoresis apparatus 、centrifuge、 Ultra Low temperature refrigerator, paraffin slicing machine, paraffin embedding machine, cell centrifuge smearing machine, and full automatic dying machine no clinical trial reports and Product Type Test Reports issued by the medical devices quality test agency and recognized by the State Drug Administration are required to be provided .
  - b) The Products of Class I in accordance with catalog of classification of the medical devices Products of China.
- 4) As for the medical devices in conformance with both of the following conditions the application for exemption from test may be made:
  - a) The domestic enterprise has received the authentication certificate of GB/T19001+YY/T0287 or GB/T19002+YY/T0288 issued by the quality system authentication agency recognized by the State Drug Administration, and the quality system concerned has covered the Products for application.
  - b) The Products abroad has received the authorization of launching from the competent department of the Country of Origin, and the certificate is still valid, and the enterprise has been authenticated in accordance with the ISO 9000 Serial Standards (or equivalent).
  - c) The difference between the structure and performance of the Products for application and those of the registered products of a kind is insignificant in terms of safety and effectiveness.
  - d) The Products for application are not implantable device.

- e) No radioactive sources exist in the Products for application.
  - f) In case of any malfunction, no grave injury accidents such as death of and body injury of the user or operator will be caused.
7. The clinical trial report of medical devices, the methods on the provisions of the report should be applied in accordance with the “Provisions for the ‘Sub item of Clinical Reports’ for the Registration of Medical Devices”. The clinical trial shall be implemented in accordance with the “Provisions for the Clinical Trial Management of Medical Devices”.

- 1) Prior to the promulgation of the new Clinical Trial Management Methods, the quantity and trial period of the Clinical Trial shall be implemented in accordance with the “Interim Provisions for the Clinical Verifications of Medical Devices” issued by the State Drug Administration in 1997.

If in accordance with the requirements for sub-item concerned, the provisions for Clinical Reports are not necessary, the enterprise may make a statement upon the application.

- 2) Clinical Reports of Import Products in the Country of Origin may be provided through the following two methods.
  - a) In case those clinical reports are required to submit upon the authorization of launching by the Country of Origin, the clinical reports upon the authorization of launching by the Country of Origin shall be provided;
  - b) In case that no clinical reports are required to submit upon the authorization of launching by the Country of Origin, the Manufacturer shall make a statement that no clinical reports are required to submit upon the authorization of launching by the Country of Origin, and guarantee the authenticity thereof. In the event, the enterprise may submit the Clinical Trial Reports and documents after the launching of the Products.
- 3) Under the following Circumstances, no clinical reports are required.
  - a) In accordance with the clear division of work in the State Drug Administration, Among the IVD reagent approved and registered by Department of Medical Devices, in case of those for the diagnosis of hepatitis and AIDS, the Clinical Trials shall be carried out in designated medical institutions (quantity and statistical methods undetermined); as for other types of IVD reagent, generally no Clinical Reports are required to be provided.
  - b) As for condom Products, no Clinical Reports are required to be provided.
  - c) Among the laboratory equipment, the electrophoresis apparatus, centrifuge, Ultra Low temperature refrigerator, paraffin slicing machine, paraffin embedding machine, cell centrifuge smearing machine, and full automatic dying machine no clinical trial reports and Product Type Test Re-

ports issued by the medical devices quality test agency and recognized by the State Drug Administration are required to be provided.

- d) The Products of Class I in accordance with the catalog of classification of the medical devices Products of China.
8. The Product Quality Guaranty presented by the Manufacturer, to promise that the quality of the products registered and sold in China are unanimously the same as that of the identical products put into market in the Country (Region) of Origin.
  9. The certificate of commission for the After-Sale Service Agency designated in China, the letter of commitment and business certificate of the commissioned agency.
    - 1) Certificate of commission of After-Sale Services:
      - a) Presented by the Manufacturer;
      - b) The name of the Products shall be indicated clearly in the certificate of commission;
      - c) In case of multilevel commissioning, the consignor at every level shall provide the certified documents of the Manufacturer.
    - 2) The letter of commitment:
      - a) The contents promised in the letter of commitment shall be consistent with the matters consigned in the certificate of commission;
      - b) The letter of commitment shall also contain:
        - a. Liabilities for reporting the Product quality accidents;
        - b. Liabilities for actively contacting with the State competent department in charge of the registration of medical devices.
    - 3) The qualification certificate of after-sale service units: Business certificate (the scope of business shall contain corresponding technical service items) or the registration certificate of the representative agency in China of the manufacture.
  10. The Self-Guarantee Declaration on the authenticity of the materials submitted: shall be presented by the manufacturer.
    - 1) Presented by the manufacturer or the office thereof in China;
    - 2) A list of the materials submitted;
    - 3) Commitment on the Liabilities.



## Appendix 4: Registration requirements for IVD products

- SFDA registration application form
- Legal documents:
  - Legal production qualification
  - Authorization of registration in China
  - Marketing approval from foreign government
  - Quality management system certification
  - Quality guarantee letter
  - Authorization letter to a Chinese Agent
  - Self-guarantee declaration letter
- Research summary:
  - Intended use & product description
  - Biological safety evaluation information
  - Summary of key research and evaluation results
  - Global registration status overview
- Product insert & quality specification
- Sample testing report:
  - Class II IVD products: one batch sample
  - Class III IVD products: three consecutive batches

(Testing should be conducted at SFDA certified testing centers)
- Research information of key raw materials
- Research information on manufacturing process or reaction system
- Analytical performance evaluation data:
  - Sensitivity, specificity, diagnostic range, accuracy and deviation
- Reference value (reference range) determination data
- Stability data
- Clinical research data:
  - Conducted in foreign countries: submission
  - Conducted in China:
    - ✓ Class II products: 2 or more hospitals, at least 200 cases
    - ✓ Class III products: 3 or more hospitals, at least 1000 cases
- Production records and quality control release report
- Product package and label artwork
- Quality management system inspection report

(Source: SFDA 2008)

## **Appendix 5: Re-registration of imported products of medical devices**

(Direct quotation from SFDA 2008)

1. The Direction for the Application Form for Registration:
  - 1) All the contents shall be in both Chinese and English;
  - 2) All the contents must be printed;
  - 3) All the items must be completely filled in, and as for the vacant items, “/” shall be used to show inapplicability;
  - 4) The Name of Devices and Model, Name and Address of Manufacture must be unanimously the same as the contents carried in the documents approved by the government of the Country (Region) of Origin, and must be consistent with the contents concerned carried in the test reports, operation instructions of the product, and so on;
  - 5) Any enterprise shall not set up the format for the Application Form for Registration without authorization.
2. As for the medical devices products manufactured by enterprises abroad, they shall be re-registered 6 months prior to the date of expiry of the registration certificates. Upon the application for re-registration, the following materials shall be submitted:
  - 1) The qualification certificate of the Applicant.
  - 2) Copy of the original registration certificate.
  - 3) The certificate recognized by the government of the Country (Region) of Origin to authorize the products as medical devices to enter into the market of the country.
  - 4) Technical Standards of Products: Requirements of Safety and Technical Performance of Products, and the corresponding experimental measures (the standards of the products to be registered).
  - 5) Operation manual of Products.
  - 6) Type test Reports issued by the Medical Devices Quality Detection Agency authorized by the State Drug Administration within the recent one year(applied to Products of Class II and Class III).
  - 7) Product Quality Follow-up Reports: The Product Quality Follow-UP Reports presented by the Manufacturer or after-sale service agencyafter the application in the medical units of China.
  - 8) The Product Quality Guaranty presented by the Manufacturer, to guarantee that the quality of the products registered and sold in China are unanimously the same as that of the identical products put into market in the Country (Region) of Origin.

- 9) The certificate of commission for the After-Sale Service Agency designated in China, the letter of commitment and business certificate of the commissioned agency.
- 10) The Self-Guarantee Declaration on the authenticity of the materials submitted.

*Note: The requirements for the documents listed in Items (1), (3), (4), (5), (6), (8), (9) and (10) shall be consistent with those carried in “the Initial Registration of Import Products”.*

## Appendix 6: Interview questions for Finnish medical device SMEs

Operationalization Table

Research Objective	Sub-Objectives	Theory	Interview Questions
To explore how to export Finnish medical devices to China	To explain main factors influencing Finnish medical device SMEs on the selection of entry modes to China	Chapter 2	Q4 - 12
	To discuss main entry modes for Finnish medical device SMEs entering the Chinese market	Chapter 3	Q13 - 15
	To analyze the adaptation of marketing mix for Finnish medical device SMEs in the Chinese market	Chapter 4	Q16 - 24

1. Could you introduce yourself briefly?
2. When did your enterprise start your business in China? (When is your enterprise going to develop your business in the Chinese market?)
3. Why did your enterprise choose China as a target?
4. What did you know concerning Chinese health care system before your products enter into China? And how?
5. How do you think what role Chinese health care system plays on your decision of exporting products to China?
6. Comparing with Finnish health care system, do you find any differences or gaps with Chinese health care system?
7. What did you know about Chinese medicine culture before your products enter China?
8. Do you think Chinese medicine culture is crashed by Western medicine culture? Or could Chinese medicine culture be integrated of Western medicine culture?
9. How has this knowledge of Chinese medicine culture influenced on your decision of exporting products to China?
10. Was your enterprise familiar with Chinese market for medical devices before entering the Chinese market? What information do you need?

11. Until now, Chinese medical device regulations are updated continuously. How have these regulations influenced on your decision of exporting products to China?
12. After your enterprise decided starting the business in China, what other factors has your enterprise considered? Which one is the most important? Why?
13. What kind of entry modes did you consider when your enterprise is operating business in China? Why?
14. Based on your experiences today, how has this entry mode gone in the Chinese market?
15. Your products also have been exported to other countries, has your enterprise chosen different entry modes comparing to the entry mode in China? If yes, could you explain what is different and why?
16. How do you see your product placement? Is there any selling point of your products in China, e.g. function, quality and style, etc?
17. How do you set the price for your products in China? Is the pricing done differently in China compared to your other market areas? If yes, could you explain briefly?
18. How do you develop your promotion actions in China? Is the promotion done in China same as in your other market areas?
19. How do you think political power influencing your business in China? How do you think that you should build a good relationship with Chinese local government?
20. How do you build public relations for your business in China? Is it same way as in your other market areas?
21. At the moment, how do you position your products in China? Is there any difference with your other market areas? If yes, could you explain briefly?
22. 'Relationship' (*Guan Xi*) is very important in China. How do you think personal relationships on your business network in China?
23. Do you want to mention any other issues what need to be considered in the Chinese market?
24. To sum up, based on your experiences, what kind of advices or comments would you give to a Finnish medical device SME, who is planning to enter the Chinese market?

## Appendix 7: Interview questions for the case enterprise's partners

Operationalization Table

Research Objective	Sub-Objectives	Theory	Interview Questions
To explore how to export Finnish medical devices to China	To explain main factors influencing Finnish medical device SMEs on the selection of entry modes to China	Chapter 2	Q4 - 10
	To discuss main entry modes for Finnish medical device SMEs entering the Chinese market	Chapter 3	Q11, 12
	To analyze the adaptation of marketing mix for Finnish medical device SMEs in the Chinese market	Chapter 4	Q13 - 15

1. Could you introduce yourself briefly?
2. What kind of business does your enterprise do in China?
3. How many Finnish enterprises through your services have started their business in China so far? And how many Finnish enterprises have contacted your enterprise and are going to develop the business in China? What kind of Finnish enterprises were there?<sup>23</sup>
4. What kind of advice or information has been provided to the Finnish medical device enterprises before entering the Chinese market? In general, who has provided this kind information and how this kind information was provided?
5. How do you think what role 'Chinese health care system' plays on exporting western medical devices to China?
6. Is there any impact or influence to Traditional Chinese Medicine, when western medical devices or equipment have been brought into China?<sup>24</sup>

<sup>23</sup>Please skip this question if you do not want to answer it.

<sup>24</sup>This question is only for Chinese interviewees. However, if they could answer this question, Finnish interviewees are warmly welcomed to answer the question.

7. Based on your experience these years, which factors influence exporting western medical devices to China? Could you give any examples of these factors? How would you describe them?
8. How has Traditional Chinese Medicine influenced on exporting western medical devices to China?
9. Does your enterprise provide any survey about Chinese market for medical devices to your customers, i.e. Finnish medical device enterprises?
10. Until now, Chinese medical device regulations are updated continuously. How have these regulations influenced on importing western medical devices?
11. In your opinion, which entry modes should Finnish enterprises choose when these enterprises decided to enter Chinese market?
12. Is there any difference in recommended entry modes for Finnish SMEs and for Finnish large enterprises? Could you explain the difference, please?
13. What should Finnish enterprises operating in China pay more attention to (e.g. product innovation, selling price, distribution channel and promotion, etc.)? Why and how?
14. Anything else that should be focused on? Why and how?
15. Do you have any recommendations to give for those Finnish enterprises, which are going to develop business in China?