

New Trends in Japan's Medical Device Market

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I. Update on the Japanese Economy

Overview of the Japanese Economy

Japan's economy boomed in the 1980s, but since the early 1990s the country has found itself in deep recession. Centralized control of industry, excessive bank credit during the late 1980s and the government's fiscal contraction (especially in social spending) to cover the resulting excesses of the stock and real estate markets caused Japan's financial bubble to burst in 1990. Eight years later, in late 1998, Japan is still suffering from an inefficient financial sector and an entrenched bureaucracy: banks are burdened with over \$500 billion in bad loans, consumer demand is low, and business confidence is eroding. GDP shrank 5.3% during first quarter 1998 and unemployment reached a new high of 4.1% in April 1998. Along with the rapid depreciation in the yen, these trends have caused many foreign companies, including medical device companies, to worry that their sales and exports to Japan will stagnate.

However, Japan has reached a turning point in its economic policy. Efforts to reform the sickly banking system are underway, as well as a comprehensive deregulation program introduced over the past year. Interestingly enough, the impetus for *some* of these reforms was the Asian financial crisis, which caused the yen's value to fall over 20% and export growth to slip by 3.8% since January 1997. To stem the effects of the crisis, the Japanese government passed a ¥30 trillion (US\$217 billion) package in February 1998 to support the banking system, and a ¥16 trillion (US\$116 billion) fiscal stimulus package in April 1998 that included ¥6 trillion (US\$43 billion) in tax cuts to stimulate demand. Japan has also made some changes in its banking structure; many banks are expanding into areas like asset management in order to recoup from unprofitable lending, and several regional banks have merged to cut the scale of Japan's banking problems.

Deregulation Measures

Over the past year, Japan has also embarked on a comprehensive deregulation program covering energy, telecommunications, housing, finance, and medical devices and pharmaceuticals. Under the new deregulation initiative, Japan is speeding up customs clearance processing by introducing new pre-arrival and clearance-upon-arrival procedures, and installing a new computerized system that links the Customs Agency with other agencies. The Japan Fair Trade Commission (JFTC) is conducting a survey for the first time of Japan's top 2,000 firms to assess their Antimonopoly Law compliance programs and increase its enforcement of antitrust laws. JFTC will also monitor Japanese manufacturers to ensure they do not restrict foreign competition by threatening retaliation against distributors who handle imported products. Restrictions on the admittance of foreign lawyers and foreign legal consultants have also been eased, and the Japanese government is trying to streamline and increase the transparency of its administrative system by simplifying and speeding the application process for licenses, permits, and other permits needed to do business in Japan.

Future of the Japanese Economy

Despite the current problems, Japan's economic future will improve. Japan still possesses the fundamentals for strong economic recovery and growth — advanced technology, strong manufacturing capacity, heavy investments in education and a disciplined workforce. Savings rates continue to be high (about 30% of after-tax income) and Japan still maintains \$207 billion in reserves, equal to about 60% of all savings held worldwide.¹ While unemployment and slow growth will continue in the short run, continued reforms — especially in deregulation — will cause growth and import demand in Japan to be stronger in future years.

II. Overview of the Japanese Healthcare Market

Japan's healthcare market is large — in 1996, Japan's healthcare expenditures totaled \$290 billion, and the market continues to grow about \$7.1 billion a year. Nevertheless, Japan still spends the least on healthcare in the OECD — in 1994, Japan's healthcare spending as a percent of GDP was only 6.9%, compared to 9.5% for Germany, 9.8% for Canada, and 14.3% for the U.S.ⁱⁱ Total healthcare spending in Japan is divided into public expenditures, social insurance payments, expenditures under the Health and Medical Service Law for the Elderly, and private consumer expenditure (see Figure 2-1 below):

Figure 2-1. Breakdown of Healthcare Expenditures in Japan, 1995

	Public Expenditure	Social Insurance Payments	Expenditures on the Elderly	Private Consumer Expenditure
Percent of Total Expenditure	4.8%	51.9%	31.5%	11.8%
Percent Change From 1994	2.7%	2.6%	8.2%	4.5%

Source: Ministry of Health and Welfare, 1996

As can be seen in Figure 2-1, the growth of “Expenditure on the Elderly” and “Private Consumer Expenditure” are dominating Japan's healthcare market. There are two possible reasons for this. First, Japan's population has been aging rapidly since 1980, causing an increasing amount of national spending to be directed towards elderly care (about \$63 billion in 1996). Second, while Japan still offers universal health insurance to its population, rising medical costs have forced the government to contract its healthcare contributions. As a result, the co-payment or deductible consumers have to pay towards their medical care is higher than it was a few years ago.

Breakdown of the Japanese Healthcare System

Japan's healthcare system is broken down into three areas: medical devices, pharmaceuticals, and healthcare services. All three medical markets have enormous potential given the country's rapidly aging population and increased demand for better medical treatment, and foreign medical companies can expect growing opportunities in these areas over the next few years.

Japan's \$21 billion market for **medical devices** is currently the second largest in the world behind the US. Market demand grew an average of 13.3% annually between 1993 and 1995, and is expected to continue to grow about 6% annually over the next few years.ⁱⁱⁱ The Asian crisis has dampened import growth slightly, but cannot overcome the large annual increases in demand for high-quality medical technology — before the crisis, real import growth was expected to

grow about 20% annually for the next few years; currently, it is still relatively high at about 5-10%.^{iv}

Japan's \$48 billion market for **pharmaceuticals** is the largest in the world behind the US, holding 19% of the global market. Ninety percent of the market, however, is dominated by domestic production. Imports account for less than 10% of the total market, and have remained at a constant value for the past several years.^v The majority of foreign pharmaceutical companies in Japan are large U.S. and European drug companies that manufacture their products locally and license compounds to Japanese drug manufacturers. Nevertheless, while Japan is one of the leading pharmaceutical markets in the world, its growth rate since 1995 has been only 1%, compared to 9% for the U.S., and 6% each for France and Germany.^{vi} Thus, as Japan deregulates, there will be great potential in this sector for foreign firms.

Finally, Japan's \$10.9 billion market for **healthcare services** is also expected to grow rapidly in coming years. The market is divided into three broad categories: hospital support businesses, which hold about a 55% share, health maintenance and promotion services with a 30% share, and home care services with a 15% share.^{vii} The fastest growing area is home care services which, with the greying of Japan's population, grew about 85% in 1993 and is expected to grow about 20% annually over the next few years.^{viii} Japan's growing market for home care will be discussed in detail later on in this report.

Increased Demand for Quality Healthcare

A growing number of Japanese, particularly the elderly, are being diagnosed with diseases common in advanced industrialized countries (see Figure 2-2 below). The number-one cause of death is now cancer, number two is heart disease, and number three is cerebrovascular disease. Demand for high-quality medical treatment in Japan is therefore accelerating, creating numerous opportunities for foreign medical companies in coming years.

Figure 2-2. Total Number of Deaths by Leading Causes of Death in Japan

<i>Year</i>	<i>Malignant Neoplasms (Cancer)</i>	<i>Cerebrovascular Disease*</i>	<i>Heart Disease</i>	<i>Pneumonia**</i>
1985	187,714	134,994	141,097	51,366
1990	217,413	121,944	135,478	74,535
1995	263,022	146,552	139,206	79,629
1996	271,094	140,298	138,044	70,922

* The kinds of cancer conditions are also changing: colo-rectal cancer, lung cancer and hepatumor are increasing, while gastric cancer, which used to be the number-one condition is decreasing.

** Before 1995: includes bronchitis.

Source: Ministry of Health and Welfare, 1996.

Advantages to the Japanese Healthcare System

Japan's healthcare system has many impressive qualities, not the least of which is its commitment to provide universal health insurance for its 130 million citizens. While the U.S., for example, is unable to insure 40 million of its citizens, Japan's healthcare system guarantees that anyone needing medical assistance will be treated. The success of Japan's healthcare system is evident in its life expectancy rates, which at 77 years for men and 83 years for women are the longest in the world. Despite some specific areas of discontent, healthcare institutions in Japan seem to generally enjoy broad acceptance. In a comparative survey of 10 nations in 1994, only 6% of Japanese respondents believed that their healthcare system needed to be "completely rebuilt," compared to 29% of Americans, 17% of British, 10% of French, and 5% of Canadians and Dutch.^{ix}

Disadvantages to the Japanese Healthcare System

Like its economy, however, Japan's healthcare system is still over-regulated and inefficient in many areas. As mentioned before, medical costs are rising at an annual rate of about \$7 billion, and Japan's rapidly aging population is creating a huge additional burden on the nation's healthcare system.

Much of the inefficiency in Japan's healthcare system is due to Japan's current fee schedule for healthcare, which encourages widespread profit-seeking among hospitals and physicians. The Japanese hospital fee structure, for example, currently rewards hospitals for keeping patients for long periods of time, making the Japanese per capita average hospital stay (about 35 days) one of the longest in the world. Furthermore, physicians reap large profits from every medical test and drug prescription, creating excessive spending on medical treatment and a suboptimal allocation of medical resources.

Inefficiency in the healthcare system is also due to the multitude of regulations and restrictions that have discouraged the sale of innovative, high-quality medical products from abroad. By doing so, Japan has not only denied its citizens access to better healthcare, but it also has denied itself the ability to stem the rise of its healthcare costs by using more efficient technologies and drugs. Ultimately, poor health planning, insufficient attention to preventative care, especially for the elderly; and obstacles to introducing innovative, money-saving technologies are all responsible for the faltering state of Japan's healthcare system today.

Differences Between Japanese and Western Healthcare Facilities

Compared to healthcare facilities in the West, Japan's medical institutions and personnel have many advantages and drawbacks. On the positive side, Japan has the highest number of hospitals and clinics per capita of any country in the world. While there is one medical facility for every 12,000 people in Japan, there is only one for every 47,000 people in the U.S., and one for every 40,000 in Germany. Thus, in some respects, the Japanese have much easier access to "general healthcare treatment" than people from other countries.

Nevertheless, there is a downside to the services Japanese healthcare facilities provide. Although Japan has a greater number of medical facilities spread out over its population, there

are only 0.79 employees per inpatient hospital bed in Japan compared to an OECD average of 2.0 and a U.S. average of 3.35.^x The relatively low number of medical professionals in Japan compared to other countries is illustrated in Figure 2-3 below:

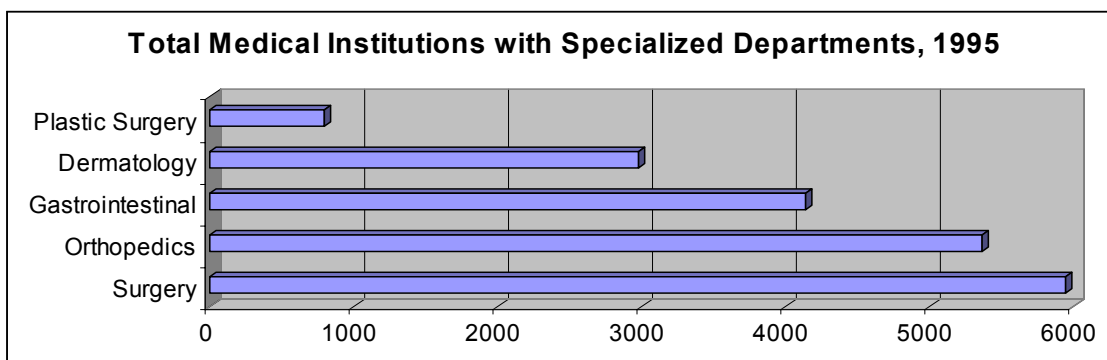
**Figure 2-3. Country-Wise Comparison of Medical Professionals
(Per 10,000 People)**

	<i>M.D.</i>	<i>Nurse</i>
Japan	16	58
USA	18	69
Sweden	22	92

Source: ADMIS, Inc.; Tokyo, Japan; 1998

Furthermore, Japanese hospitals and clinics are unable to provide the same number of specialized medical treatments at every facility as those in other countries. The typical Japanese hospital or clinic, for example, conducts only about 24 heart pacemaker implants annually (versus more than 70 in the U.S.) and engages in far fewer orthopedic implant procedures than hospitals in the U.S. and Europe.^{xi} Although Japan currently has 9,606 hospitals and/or clinics, the number of specialized departments for each facility are quite limited (see Figure 2-4 below):

Figure 2-4.



To streamline its healthcare system and increase the number of services available, Japan has decided to deregulate its medical industry and further allow the importation of more innovative, cost-effective medical products. Specific reforms Japan has made in its healthcare system will be discussed later on in this report. Ultimately, Japan's economic deregulation and healthcare reforms will offer numerous opportunities for foreign medical companies. U.S. and European medical companies, leaders in cutting-edge medical technology, will certainly benefit from the

new emphasis on innovative medical products. Greater market access will allow their operations to grow in line with the accelerating market demand for better healthcare services over the next several decades in Japan.

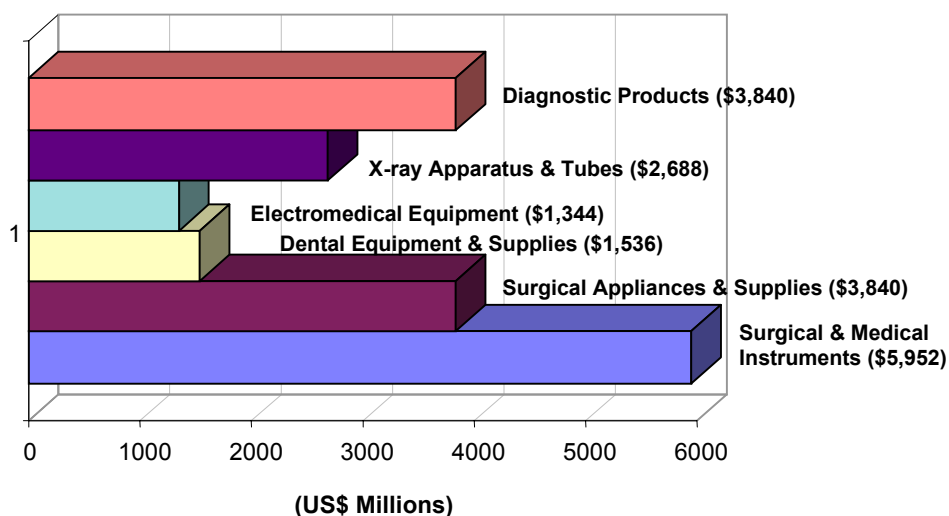
III. Overview of Japan's Medical Device Industry

Japan's \$21 billion medical device industry, the second largest in the world behind the U.S., is growing rapidly. While the Japanese economy grew by only 2.6% during 1996, the medical device and diagnostic market grew about 6% in yen terms.^{xii} Per-capita spending on medical devices has grown about 10% since 1995 to \$161. Japan's medical device market will continue to grow rapidly in coming years as the country's aging population drives demand for better medical technologies and Japan's deregulation initiatives increase competition in the device market.

Breakdown of the Medical Device Market

Japan's medical technology market is divided into six major categories: 1) Surgical and Medical Instruments, 2) Surgical Appliances and Supplies, 3) Dental Equipment and Supplies, 4) Electromedical Equipment, 5) X-ray Apparatus and Tubes, and 6) Diagnostic Products. The shares each of these categories held in Japan's medical device market in 1996 are listed below:

Figure 3-1. Composition of the Japanese Medical Device Market, 1996



Source: Health Industry Manufacturers Association (HIMA), 1997

As can be seen above, best sales prospects for U.S. and European medical companies exist in such products as surgical implants, high-resolution diagnostic imaging devices, disposable products and dental materials. Figure 3-2 below lists additional medical equipment that offer the best sales opportunities for foreign medical companies:

Figure 3-2. Best Sales Prospects in the Japanese Medical Device Market

<i>X-ray films (medical)</i>	<i>Oxygen therapy/other respiration devices</i>
<i>X-ray films (dental)</i>	<i>Artificial joints</i>
<i>Contact lenses</i>	<i>Other orthopedic implant devices</i>
<i>Intraocular lenses</i>	<i>Dental implants</i>
<i>Patient monitoring instruments</i>	<i>Dental materials</i>
<i>MRI, ultrasound and clinical lab instruments</i>	<i>Hearing aids</i>
<i>Cardiac and other catheters</i>	<i>Pacemakers and implantable defibrillators</i>
<i>Dental equipment</i>	<i>Heart valves and other artificial organs</i>
<i>Laser equipment</i>	<i>X-ray and related diagnostic equipment</i>

Source: S. Kimura, D. Gossack. Japan: Medical and Dental Equipment. Industry Sector Analysis, USFCS, 1996.

Market Demand

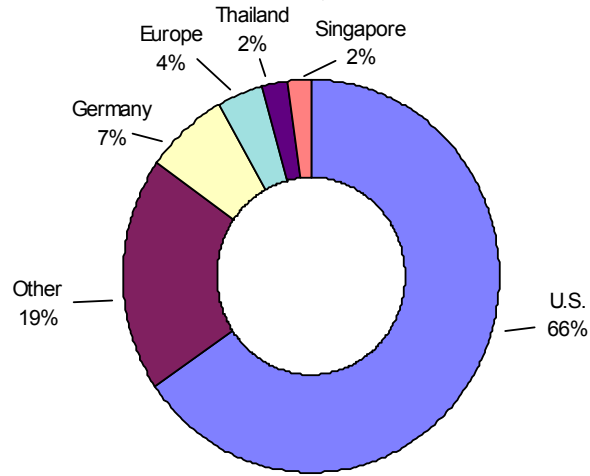
Market demand for better-quality medical technology has been increasing rapidly in Japan, and is expected to grow about 6% annually for the next few years.^{xiii} One of the main reasons for this growth is Japan's rapidly aging population. By the year 2000, about 20% of the population will be over 65, driving increased demand for high-quality medical equipment and treatment.^{xiv} And since Japan's domestically-manufactured medical equipment is also among the most expensive in the world, the country is looking increasingly to foreign medical companies that can supply innovative medical products at a much lower cost. For example, the growth in Japan's elderly alone will cause demand for cardiac pacemakers to increase by 30% to 40% over the next few years, greatly expanding opportunities for foreign medical companies.

Foreign Participation in Japan's Medical Device Market

Foreign participation in Japan's medical device market has been increasing rapidly over the past few years. Since 1996, total production of medical devices has been growing about 16% annually, while imports have been growing an annual average of 20%.^{xv} The Asian crisis has hurt import demand somewhat, but the effect will be temporary and the growth of imported devices is still expected to grow about 5-10% annually for the next few years.^{xvi}

Imports currently account for about 38% of the Japanese medical device market.^{xvii} The U.S. dominates the import market with a 65% share, and Germany is the next-largest country importer. Several other European countries, including Britain, the Netherlands, and Switzerland, are also major importers, but each as an individual importer holds less than 4% of the Japanese import market. Only two Asian countries, Thailand and Singapore, are among the top ten import sources in Japan, each with a market share of about 2.4%.^{xviii} Figure 3-3 below illustrates the shares different countries held in Japan's medical device market in 1996.

Figure 3-3. Import Shares in Japan's Medical Device Market, 1996



Source: Health Industry Manufacturers Association (HIMA), 1997

IV. Product Registration

Overview

The Japanese Ministry of Health and Welfare, (MHW), Japan's equivalent of the FDA, requires all medical products in the country to be registered. The fundamental objective of this agency is to ensure that Japanese citizens have access to the latest technology in medical devices and that products are safe and effective for this quality-conscious society. In Japan, medical device manufacturers and medical device importers are expected to be socially responsible. The MHW, therefore, enforces its directive by maintaining stringent quality standards for both medical device products and manufacturing or import facilities. Consistent with these MHW regulations, the Japanese government requires foreign medical manufacturers to maintain a physical presence (either directly or indirectly) in Japan in order to assure a prompt response to safety problems relating to the use of a medical device.

Kyoka and Shonin

A medical device manufacturer (whether domestic or foreign) must first obtain two types of consent from the MHW: *kyoka* ("license") and *shonin* ("approval"). *Kyoka* essentially grants the medical device manufacturer (or distributor) permission to market its products in Japan. *Kyoka* is required for each manufacturing plant and representative office in Japan. To be granted *kyoka*, a manufacturer must meet the requirements of Articles 6 and 18 of the Pharmaceutical Affairs Law (PAL) and must employ a "technical director" at each facility in Japan. In the case of foreign medical device manufacturers, *kyoka* will be granted either to their in-country branch or subsidiary office or to the Japanese distributor importing the product. *Kyoka* must be renewed every five years.

The second type of consent is *shonin*, which is required for each product that the medical device manufacturer is seeking to market in Japan. *Shonin* is granted once the MHW is satisfied with the safety and effectiveness of the medical device; clinical trials in Japan may be required for unique products that have or have not already undergone testing in the U.S. or Europe.

Direct versus Indirect Registration

If a foreign medical manufacturer chooses to set up an office in Japan, the manufacturer can establish a representative office, a branch office, a joint venture or subsidiary corporation. The foreign manufacturer can use its own sales force or local distributor(s), in which case medical devices can be registered *directly* by a representative of the office in the foreign medical company's name. Obviously, the high start-up costs and annual budget expenses should be taken into account before deciding to establish an office in Japan.

If a foreign medical company does *not* want to set up an office in Japan and instead decides to export its products, allowing a Japanese distributor to sell them, the manufacturer must choose whether to register its products *directly* in its own name via an In Country Caretaker (ICC), or to let the Japanese distributor register the company's products *indirectly* in the Japanese distributor's name.

Advantages of the ICC

The major advantage of direct registration via the ICC is increased control for the foreign manufacturer over its marketing strategy in Japan. Direct registration makes it possible to appoint multiple primary product distributors from day one. It also makes it easier for the foreign medical company to charge distributors, since transferring product registration can be difficult without direct *shonin*. Thus, while generally more costly than indirect registration, direct registration can lead to a more effective marketing strategy, paying significant dividends in the long term.

First, without direct registration or *shonin*, changing distributors can be a difficult, time-consuming and costly process. If the current distributor is doing a poor job or is no longer suitable as a company's distributor, and is not willing to relinquish control over the *shonin*, the foreign manufacturer may have to begin the *shonin* process again to obtain a new approval with a new distributor. A foreign manufacturer with a unique product may also be required to redo expensive and time-consuming clinical trials. In general, a *shonin* for a common or "me-too" product usually takes about five months. Registration of new or unique medical devices that require clinical trials may take 20 months or more. In many new product cases, it is difficult to predict when a new registration procedure will be completed.

The situation described above is known as an "unfriendly" transfer. During this process, product sales are likely to slump until all new parties and registration documents are in place and renewed sales efforts are well underway. In general, change occurs more slowly and is more difficult in Japan than in the West. Changing registration is no exception.

In contrast, a "friendly" *shonin* transfer minimizes sales losses during the transfer process. With a "friendly" *shonin* transfer, the current distributor willingly transfers the registration documents to the foreign medical manufacturer or the foreign medical manufacturer's *new* distributor, usually for a negotiated dollar amount. In many cases, however, negotiating the cost of a buyout is complicated and can be contentious. The parties must discuss whether the buyout amount should be based on current or future sales and must also attempt to put a monetary value on the time and energy put in by the original distributor in launching the product to the Japanese marketplace.

The best strategy for companies registering their products indirectly via their distributors is to negotiate a buyout provision or formula before consummating the initial distribution agreement so that friendly *shonin* transfers can be made as easily as possible if they become necessary in the future. Of course, divorce clauses in new contracts (between new "partners") can be a very sensitive issue, especially in Japan. During a friendly transfer, it is ideal if the documentation and related paperwork from the *original* testing and clinical trials are also available so that the foreign medical company does not have to repeat the same procedures.

With direct registration or *shonin*, a foreign medical manufacturer can change Japanese distributors easily. None of these transfer complications discussed above arises when the *shonin* is registered in the name of the foreign manufacturer via an ICC. In this scenario, the foreign manufacturer should have possession of all the documents needed — i.e., clinical trial results,

safety data, translated applications, etc. Indeed, official acknowledgment of the problems involved in the *shonin* transfer process was a key factor in the creation of the ICC system and direct registration.

Second, a major advantage of direct registration is that a foreign medical manufacturer can appoint multiple primary product distributors when signing its original distribution agreements or at a subsequent date. Without direct *shonin*, only one primary import distributor has possession of the approval. All other distributors involved in marketing need to be considered “sub-distributors” of the primary dealer.

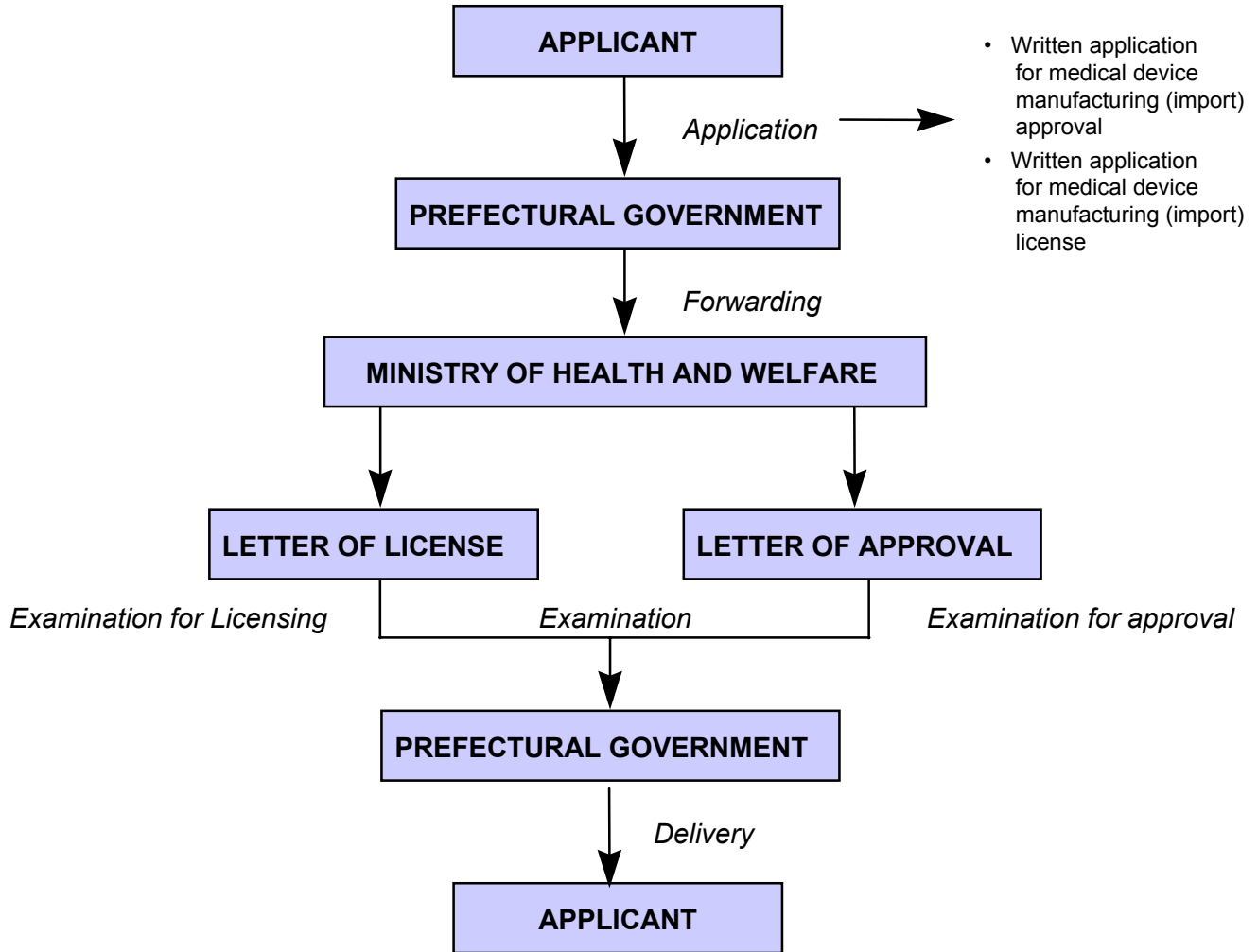
Third, with direct *shonin* the foreign manufacturer has more leverage in working with its distributors to market its products. A Japanese distributor, in most situations, is likely to be more responsive to a foreign medical device manufacturer that has possession of its own product registration approvals in its own name. When the foreign medical device manufacturer has direct *shonin*, its Japanese distributor has significantly less control and thus may have a substantial risk of losing the foreign company’s business if the medical device company is not satisfied with the distributor’s performance or thinks a new distributor can do a better job. The additional flexibility and control that direct *shonin* provides the foreign company can also lead to improved sales.

While there are three main advantages to the ICC, the major disadvantage is the additional cost borne by the foreign medical device company. The costs include at least a one-time registration fee and a yearly fee for assuming “watch-dog” or ongoing responsibilities. Without an ICC, if the foreign medical device manufacturer decides to register its products indirectly, it may not have to bear the majority of the initial registration costs, since the importer or distributor often will be willing to pay such fees in order to have products registered in its own name. In general, initial registration fees using an ICC for common or “me-too” devices average between \$10,000 and \$30,000 per product, while new medical devices that may or may not require clinical studies can cost between \$50,000 and \$250,000 per product, including clinical trial costs. In addition, after registration, an ICC is required to perform ongoing duties that can cost about \$15,000 per year for “me-too” products and about double that per year for unique products that have required clinical studies in Japan.

Thus, the major consideration in deciding whether to use an ICC, register one’s products directly, and bear the ICC’s cost, depends upon the foreign manufacturer’s best estimate of the potential size of the Japanese market for its products — versus the additional cost and increased control one has with the ICC. If the market size for a foreign manufacturer’s product is large or is expected to grow quickly in Japan, the extra costs of registering products directly with an ICC may be worthwhile. If there is no such potential, an ICC and its related costs may not be justified. Primary market research to determine the size and growth of the market for one’s medical products in Japan is probably a good first step to analyze this decision.

Figure 4-1.

***Product Application Process
Japan's MHW***

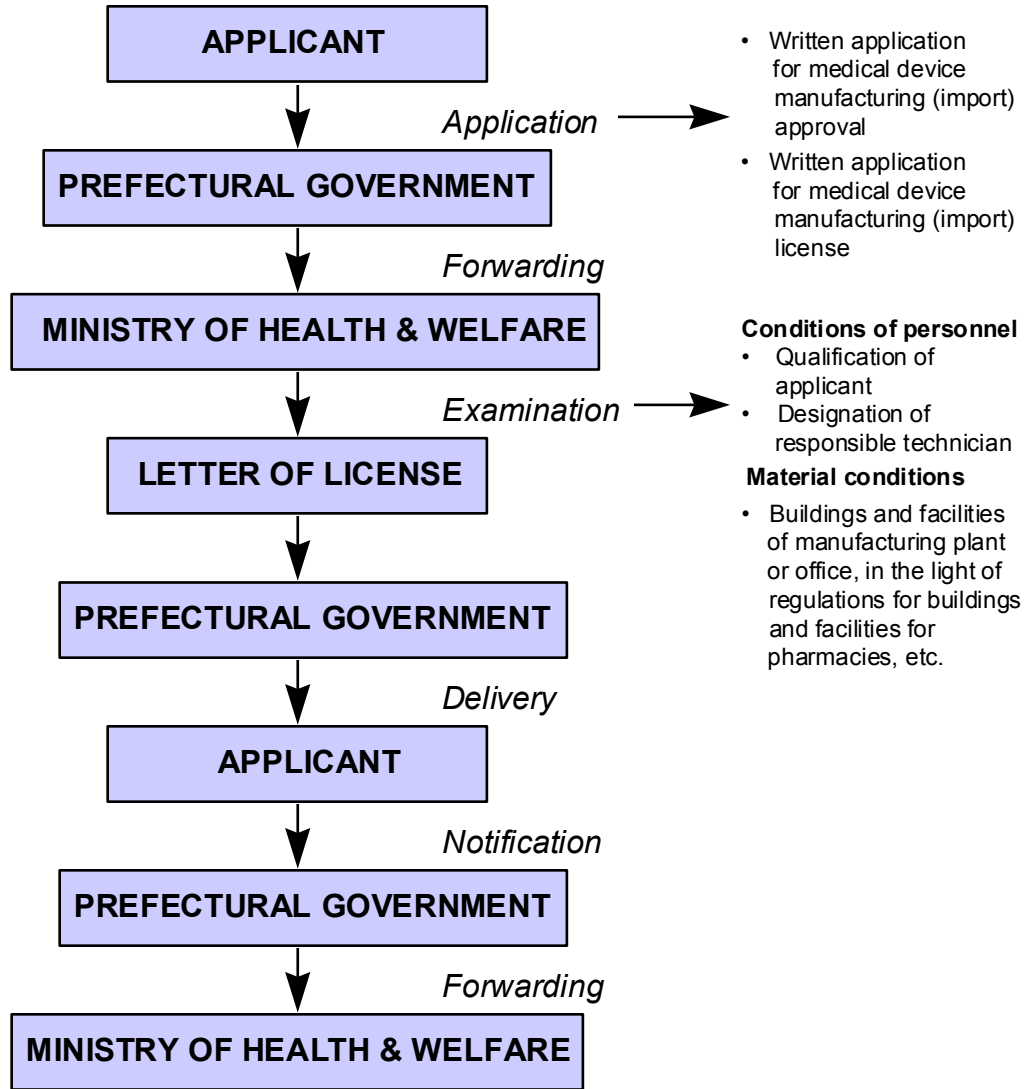


Source: *Guide to Medical Device Registration in Japan*, 5th ed. Tokyo: Yakuji Nippo, Ltd., 1994.

Figure 4-2.

Product Application Process

Products Exempted from Approval Under Article 18 of the Enforcement Regulations



Source: *Guide to Medical Device Registration in Japan*, 5th ed. Tokyo: Yakuji Nippo, Ltd., 1994.

Registration Process

In the case of “new medical devices,” defined as medical devices whose structure, usage and indications are different from those of existing approved devices, an advisory council of the MHW called the Central Pharmaceutical Affairs Council (CPAC) is charged with reviewing each case. CPAC evaluates new medical devices or new pharmaceuticals to determine their appropriateness for manufacture or importation. The CPAC Committee on Medical Devices has nine subcommittees that examine applications according to their respective sub-categories. The CPAC makes a recommendation to the MHW, which then makes the final registration decision.

Since July 1, 1995, the Japanese government has delegated to the Japanese Association for the Advancement of Medical Equipment (JAAME) the authority to examine and approve or disapprove “me-too” medical devices. While me-too devices are still officially approved by the MHW, JAAME’s role is to give *de facto* approval and a formal recommendation to the MHW. The major reason authority was delegated to the JAAME for me-too devices was to speed up the MHW examination and review time.

Executives at JAAME claim that its designation by the MHW for this role means it must protect or promote confidentiality of information to the same degree as any other part of the Japanese government and that any violation of confidentiality would be a criminal act. To make such confidentiality easier, the office in JAAME where the actual medical review takes place is physically separated from all other sections of the organization. However, since JAAME also consults for domestic medical device manufacturers on other regulatory issues (including the evaluation process and compliance with Good Manufacturing Practice (GMP) standards), effective confidentiality protection may still be a real issue.

Figure 4-3.

APPROXIMATE TIME REQUIRED FOR MEDICAL DEVICE REGISTRATION IN JAPAN				
Type of Application	ICC Preparation	MHW	Other	TOTAL
Me-too medical device	2 months without trials	3-4 months		5-6 months
New medical device	Dependent upon time for clinical trials	12 months	Prefectural Gov't: 3-4 months	At least 24 months
Partial change	1 month	2-3 months		3-4 months
<i>Kyoka</i> (manufacturing or import license)		3 months		
<i>Kyoka</i> for medical devices exempt from approval		3 months		

V. New Regulatory Trends and Issues

Introduction

Japan's regulatory environment for medical devices is changing rapidly as the government tries to lower healthcare costs and improve the quality of medical treatment. Deregulation of the medical industry is also disrupting traditional ties between the medical industry and government in Japan. In order to succeed in the Japanese medical device market, foreign medical device companies need to keep informed of these changes and understand how the new regulatory environment, as it evolves, affects their operations in Japan.

Reorganization of the MHW

One of the major changes is the reorganization and policy shift of the Japanese Ministry of Health and Welfare (MHW). The MHW has long been criticized for its inefficiency and inability to make its operations public. After a series of scandals in 1995-96 that indicted many MHW officials on bribery and safety violations, the organization was forced to revamp its structure and streamline its administration.

Increased safety monitoring and efficiency in product approval are top priorities in the MHW's new reforms. The MHW, for example, has combined its departments for drug safety measures and general medical practices to establish a new Pharmaceutical and Medical Safety Bureau. It has also established a new Pharmaceuticals and Medical Devices Evaluation Center, which will come under the National Institute of Health and Sciences as an inspection agency for new medical products. Finally, the MHW is planning to triple its pharmaceutical examination staff to 200 by 1999. All in all, the new safety measures will improve the quality of medical products, and the increased inspection staff may also reduce approval times for new medical products.

Another priority is the separation of the MHW's regulatory and industry promotion functions. Previously, the combination of these two functions produced a conflict of interest within the MHW, and may have been a major factor in the bribery scandal that plagued the organization a few years ago. As a result, the MHW is planning to move the divisions of Economic Affairs, Medical Device Development, and Research and Development, all of which were previously involved in business promotion and attached to the Pharmaceutical Affairs Bureau, to its Health Policy Bureau. Officials also hope that the organization's new streamlined structure will increase transparency and make it easier for foreign companies to voice their concerns.

Health Insurance Reimbursement

Foreign medical device companies should also pay close attention to changes in the reimbursement system in Japan. Currently, a product is technically qualified to be brought to market when a firm has its *shonin* and *kyoka*. In actuality, however, a product's sales depend upon reimbursement under the National Health Insurance System, which covers virtually 100 percent of the population. A manufacturer must seek an appropriate price listing under the system, or medical institutions cannot receive the medical remuneration for using the approved medical devices.

The insurance price listing process is separate from the rest of the approval process for the *shonin* and *kyoka*. The cost of newly purchased medical equipment will not be reimbursed until either a particular medical equipment item itself or treatment involving the equipment is listed in the insurance medical remuneration system. In the Japanese system, each medical examination or treatment is accorded points corresponding to a value chart issued by the MHW, known as the piecework payment system.

According to the piecework payment system, each medical examination or treatment is denoted by points according to a value chart (1 point = 1 yen) issued by the MHW. The payments are fixed for the entire nation, regardless of medical institution or doctor. The medical institution is subsequently reimbursed by the insurer via a screening and payment agency.

The MHW consults a committee known as the *Chuikyō* in order to gather a comprehensive range of opinions regarding the apportionment of points for reimbursement. The *Chuikyō*, or Central Social Insurance Medical Council, is the intermediary between those receiving and those paying for insurance. This council is made up of 20 members representing medical practitioners, those who pay fees and parties working on behalf of the general public welfare. After the MOSS talks in 1986, *Chuikyō* discussed for the first time new rules for assigning reimbursement based upon the health insurance system.

To determine the type of reimbursement, MHW's Health Insurance Bureau divides medical products into three categories: 1) technical fee, 2) special treatment materials (STMs), and 3) highly advanced medical technology systems (HAMTS).

In the **technical fee category**, reimbursement is paid on a per-procedure, not a per-product, basis. Thus, this category does not recognize the cost of the product being used, only the cost of the procedure itself. The problems with this type of reimbursement are evident, and are discouraging for medical device manufacturers whose products fall under this category.

Products falling under the **STM category**, on the other hand, *are* reimbursed on a per-product basis according to device function. Based on a weighted average of all brands in a functional group, as well as a price survey, reimbursement prices under this category are revised every two years. The problems with reimbursement under this category are that 1) it is hard to classify every medical device according to its function, given the rapid rate of technological innovation; and 2) price differentials between domestic and imported products make price determination difficult. Products under the STM category include guidewire angiography catheters, foley catheters, and orthopedic accessories.

Finally, the **HAMTS category** covers breakthrough technology noted for their safety, effectiveness, and high degree of social acceptance. Hospital reimbursement in this category in some respects is similar to technical fee reimbursement, since it is given only for procedures and related procedure costs, not for products. The major difficulty in setting prices for HAMTS products is that clinical trials can take a long time, and there are no set time limits for ending the HAMTS trial and approving reimbursement. Ultimately, this can discourage foreign medical device manufacturers from bringing advanced technologies to Japan since this system creates difficulty in obtaining a higher price for improved technology. In fairness to the MHW,

however, it is difficult for the government to approve devices that are expensive and used only by a limited number of patients — especially since all citizens are supposed to receive the same level of treatment in Japan.

Thus, the current medical product reimbursement system discourages new technology from being introduced into Japan's medical device market since cost over quality is emphasized and product approval for new technology is much longer. Many foreign manufacturers, exporters, and agents have experienced success (particularly those exporting less advanced medical technologies to Japan), but many have also experienced difficulty. The following are a few examples of inadequate or non-reimbursement of U.S. medical equipment and supplies as illustrations of what can happen under Japan's reimbursement system.

A major U.S. medical firm, despite having received the required *shonin* and *kyoka* in 1982 for an expensive implantable painkilling device, did not hear anything from the MHW about authority for reimbursement until 1994, when the organization actually *rejected* reimbursement for the company's product. The MHW claimed that the equipment in question would involve a large expenditure each time it was purchased and therefore went against the organization's effort to cut rising healthcare costs. MHW stressed, however, that the fact that the product was foreign-made had no bearing on the decision against reimbursement.

Japan's reimbursement system has also discouraged the use of disposable endoscopic devices, a standard product in the U.S. These devices fall under the technical fee category, and are therefore *not* reimbursed on a per-product basis. In the case of endoscopic surgery, for example, no reimbursement is authorized for the *single* use of such disposable endoscopic devices as biopsy forceps. As a result, Japanese doctors are not willing to order and use these devices, even though studies show that failing to use them puts the patient at a greater risk of secondary infection and thus increases national healthcare expenditures as a whole.

In a third case, reimbursement is not approved for a new, minimally invasive Coronary Artery Bypass Graft (CABG) method that has helped reduce treatment costs for traditional CABG procedures by about 40% in the U.S. The MHW and hospitals believe that this new technology reduces a hospital's revenue margin over costs by eliminating the reimbursement that would otherwise be received for cardiopulmonary bypass surgery. Furthermore, Japan's current hospital fee structure rewards hospitals for retaining patients for a long period of time, and the new CABG (or any new, time-saving medical technology, for that matter) would reduce the number of hospital stays for patients.

However, MHW's outlook is changing, and the organization is trying to cut healthcare costs by introducing more advanced, efficient technologies. Japan, for example, has established new healthcare standards to increase cost efficiency in hospitals, including a more careful review of high-priced medical tests and operations. Also, to shorten the number of hospital stays, the Japanese government decided in September 1997 to reward hospitals with more funding if they could get patients out in fewer than 20 days. Under the same initiative, higher rates will be applied for patients with hospital stays of more than six months, and reimbursement for daytime hospital care and rehabilitation facilities will be more strictly regulated. Finally, the time for medical product reimbursement, particularly for high-technology devices, has also been

shortened and insurance coverage under the national health insurance system has been extended to some new state-of-the-art equipment. All of these changes have increased demand for more innovative, cost-efficient technologies, and as major suppliers of such products U.S. and European medical device companies can expect growing opportunities in Japan in the future.

Medical Device Reclassification

To simplify the introduction of new medical devices in Japan and expand the range of devices not needing approval, a new classification of medical devices was also established in March 1998 by the Central Pharmaceutical Affairs Council. While the previous system, implemented in 1961, classified medical devices by functions, the new system follows the European classification of medical devices according to patient risk in usage.

The old system of classification divided medical equipment into five functional categories: 1) Medical devices, 2) Medical products, 3) Dental materials, 4) Health products, and 5) Medical products for veterinary use. Clearly, this classification was too general, and many medical products could fall under multiple categories. On the surface, the new system still divides medical devices into functional areas: 1) medical devices for home use, 2) medical devices for professional use, and 3) new medical devices. *However*, medical devices for professional use are further divided under the new system into four risk-based categories: (I) representing devices with the lowest risk and (IV) representing devices bearing the highest risk.

Category (I) devices, which include plaster, dental equipment and miscellaneous steel devices, are given the least amount of regulation. Since the risks to the patient in this category are minimal, no clinical tests or official approval are needed, even for poor-quality devices.

Category (II) devices, which are produced by “clearly established technology,” face a similar amount of regulation. If the products already meet the existing technology standard, no further approval or tests are required. Category (II) devices include the laminograph apparatus, digital blood pressure meter, condoms meeting the Japanese Industrial Standard (JIS), and massaging apparatus.

Category (III) and (IV) devices, on the other hand, require both regulatory approval and clinical tests. Category (III) devices, which include artificial organs, Gamma knives, and contact lenses, partially need committee submission for approval, and committee consultation for new products. No tracking (keeping records of the patients) is required. Category (IV) devices, which include cardiac pacemakers, prosthetic cardiac valves, and artificial cerebral lining, also need committee submission for approval, and committee consultation for new devices. Tracking for category (IV) devices, however, is partially needed. Unlike the devices in category (III), category (IV) devices are critical to a patient’s condition and extensive quality assessment for the latter is therefore imperative.

The new risk-based classification of medical devices reflects the Japanese government’s commitment to deregulating the medical industry and harmonizing its standards with those used internationally. Foreign medical device companies will benefit greatly from these measures, and should keep abreast of future changes in Japan’s regulatory environment to maximize their success in the country’s medical device market.

VI. Japan's Elderly: Driving Demand for Foreign Medical Devices

Implications of Japan's Aging Population

Japan's average life expectancy in 1935 was only about 50 years; today, it is 80 and growing at one of the fastest rates in the OECD (see Figure 6-1). Currently, the number of Japanese over 65 years accounts for about 15% of the population. And given Japan's low birth and death rates, this figure will jump to 25%, or about 33 million, by the year 2020.

**Figure 6-1. Ratio of the Elderly Population of Several Advanced Countries
And Future Projections**

Country	Ratio of Population Aged 65 and Older (%)			
	1950	1985	2000	2020
Japan	4.9	10.3	17.0	25.5
U.S.	8.1	11.9	12.3	16.3
UK	10.7	15.1	15.4	18.2
Germany	9.7	14.6	15.5	19.1
France	11.4	13.0	15.6	19.5
Sweden	10.3	17.9	16.7	20.2

Source: Ministry of Health and Welfare

The rapid growth of Japan's elderly is placing an enormous burden on the country's healthcare system. Faced with rising healthcare costs of about \$7 billion a year, the government can no longer provide adequate services for its aging population, 2.3 million of which already need full-time care.^{xix} Furthermore, the number of elderly needing expensive, full-time treatment is growing by about 100,000 annually, forcing the government to revamp its healthcare system. To keep up with the new medical requirements of its aging population, the government established a New Gold Plan in 1994 that updated its goals and criteria for the physical facilities and services needed by the elderly. Under this plan, the government reviewed and then decided whether to approve requests for subsidized funds and requests to obtain and operate new, improved facilities and services for the elderly. However, while the number of health service facilities for the elderly have been increasing steadily under this plan, they have not been growing fast enough — meeting only 30% to 50% of the MHW's goals amidst economic stagnation and the current financial crisis.^{xx}

New Insurance System for the Elderly

To remedy the situation, the government passed legislation in December 1997 establishing a national insurance system for the elderly that integrates their existing welfare and national health insurance plans into a separate, long-term program. The new system, which will be in place by April 2000, pays for nursing costs for members of the elderly population that need long-term care. It also streamlines healthcare services for the elderly by providing easier access to home care and encouraging private companies to enter the new system as providers.

Under the new system, local municipal governments, *not* the national government, will be the insurers. The national and local governments would each share half of the cost of benefits — 50% of the cost of total benefits, and the other 50% being met by premiums. Local governments will set premiums based on the availability of healthcare in their area.

The new plan concerns everyone above 40 years of age. Individuals over 65 have their premiums automatically deducted from old-age or retirement pensions, while those aged 40 to 64 are eligible for benefits only if they need long-term care arising from apoplexy or presenile dementia. In the case where persons in the 40-to-64 age group need support for other illnesses or accidents, existing welfare services for the disabled would apply.

Insured persons would pay 10% of the cost of home care facilities or services, with 90% reimbursed by the government. Based on an estimated ¥4 trillion (\$28.6 billion) needed to fund the system, insured persons would pay an average monthly premium of about ¥5,000 per couple, although the actual premium per couple or person is determined by income. Salaried employees between the ages of 40 and 64 would share the cost with employers.^{xxi}

The types of home care and institutional services provided under the new system are listed in Figure 6-2 below. By encouraging the elderly to use home care services, the MHW hopes to cut ¥340 billion (about \$2.4 billion) from the country's senior healthcare bill in fiscal 2000.^{xxii}

Figure 6-2. *Types of Services Covered by New, Long-Term Insurance System*

<i>Home Care Services</i>	<i>Institutional Services</i>
<ul style="list-style-type: none"> • Regular visits of home doctors, including dentists • 24-hour nurse visits and home care assistance • Home rehabilitation office • Day care center service • Group-home service for seniors with dementia • Mobile bathtub service • Technical aids services: wheelchairs and special beds • Minor home reconfiguration: installing handrails, etc. 	<ul style="list-style-type: none"> • Nursing homes • Geriatric care facilities

Home Care in Japan

The Japanese government's new health insurance system for the elderly reflects its resolve to improve Japan's home care and nursing facilities. Thus, as the government encourages non-acute patients to be treated at home, a growing number of foreign companies are entering the Japanese home care market with high-quality home care equipment.

Home care currently accounts for more than half of Japan's medical equipment market, with sales expected to grow 10% annually for the next several years. Specific home care products include dialyzers for kidney patients and oxygen generators for lung patients, both of which are leading products in the U.S. and Europe and are in high demand in Japan because of their quality. The hearing aid market in Japan is also very favorable for U.S. companies, who can expect increases in sales of 5% to 6% annually for the next several years.^{xxiii} The markets for pacemakers and wheelchairs, which in 1994 were valued at US\$306.9 million and US\$121.1 million, respectively, are also expected to grow at about 10% annually for the next several years.^{xxiv}

Japanese companies are also taking advantage of the growing home care market. Teijin Ltd. is promoting a sales organization that combines sales managers of at-home medical equipment and medical researchers to actively promote the expansion of the Japanese healthcare market. Teijin has been working towards combining the two staff's sales routes in order to enlarge the company's operations territory for home care. Currently, the company has over 450 medical researchers and over 250 sales people for home care products in Japan, and is continuing to develop its operations.

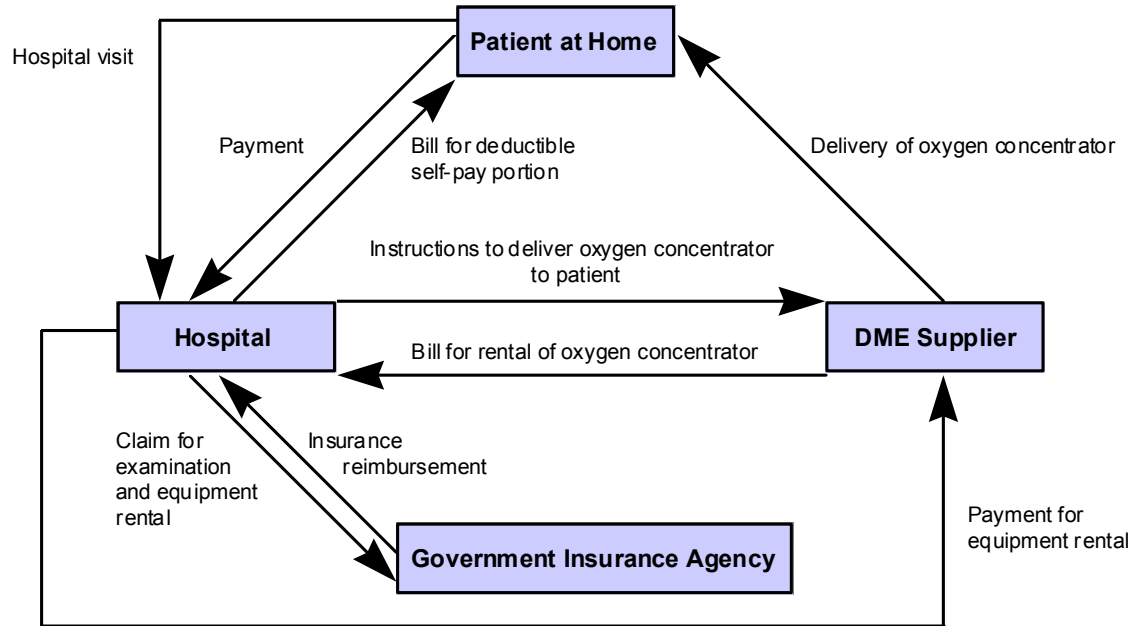
Home Care Equipment Distribution and Billing in Japan

Home health care delivery and control in Japan is still centered in the hospital. Japanese *physicians* choose which medical technologies will be used by their hospital, and the doctor is therefore the key decision maker on the specific home therapy treatment procedures and devices the patient can use at home. Similarly, nurses providing home care services are also dispatched from the hospital. Japan's home care system, originating from the hospital, is the direct result of the nation's reimbursement system. Although medical care services and supplies may be delivered in the patient's home, the national health insurance reimbursement billing is done through the hospital. In addition, billing must be sent through home healthcare support stations, which are essentially clinics managed by local city governments.

For example, a patient under home oxygen therapy and needing an oxygen concentrator must first be examined and "qualified" by a hospital physician to use the device. After receiving permission from the physician, an order is sent to a medical equipment supplier who will then deliver the oxygen concentrator to the patient's home. The patient must return to the hospital every month to requalify for coverage, and if approved will pay a deductible self-pay portion at that time. Also, the equipment supplier will bill the hospital every month for the rental of the oxygen concentrator, at which time the hospital will file a claim with the Health Insurance Agency for the oxygen concentrator and the doctor's examination fee (a.k.a. guidance fee). A

diagram of this process of control, billing and administration of home care is illustrated in Figure 6-3 below:

Figure 6-3. Home Care Equipment Distribution and Billing in Japan



VII. Market Entry Strategies in Japan's Medical Device Market

Overview of Market Entry Strategies

In order for foreign companies to decide on the best market entry strategy for Japan's medical device industry, they should first examine the size and growth rate of the possible market for their product(s). When the market is small to medium-sized and the company is only interested in exporting, it should probably market its products through a qualified distributor. Companies that see larger market possibilities should consider setting up an office or establishing some type of joint venture to manufacture their products in Japan. In order to determine the size and growth rate of the medical market for a company's products, and thus its appropriate entry strategy, extensive market research should be done in Japan.

Marketing Through a Distributor

Companies thinking of marketing their products through a distributor must first understand how the Japanese distribution system has been changing over the past few years. In the 1980s, Japan's complicated distribution system had an average number of distribution layers between the producer and customer that was much higher than in the West. This led to large mark-ups in the prices of medical devices each time they passed through another distribution layer. However, this complex distribution system is collapsing, and less layers exist today. Thus, if a foreign medical company wants to concentrate on exporting its products to Japan, marketing through a distributor will hopefully become a much more direct option.

Manufacturing in Japan

If a company sees greater market potential for its product, it should consider setting up a marketing and/or manufacturing facility or joint venture in Japan. Manufacturing directly in Japan has several advantages over simply exporting a medical product. If a company manufactures locally, for example, products can more easily be altered to meet the needs of the local market, with appropriate input from the relevant members of the medical community. This is especially important in the medical products area, where it is easier for foreign medical companies with a local presence in Japan to poll consumers, doctors, clinics, hospitals, and government officials procuring medical products and to adjust their medical products or services accordingly. As more and more foreign medical products companies are setting up manufacturing operations in Japan, those who do not follow suit will often be left with lower competitiveness and marketability. As a caveat, however, a foreign medical manufacturer may first want to launch assembly projects to test the Japanese device market before it commits to a full blown manufacturing facility in Japan.

Setting Up an Office

If a foreign medical manufacturer sees large market potential for its product(s) in Japan, but is not yet ready to start a manufacturing plant, it can choose to set up its own local office, normally for marketing purposes. There are three main options for setting up an office in Japan.

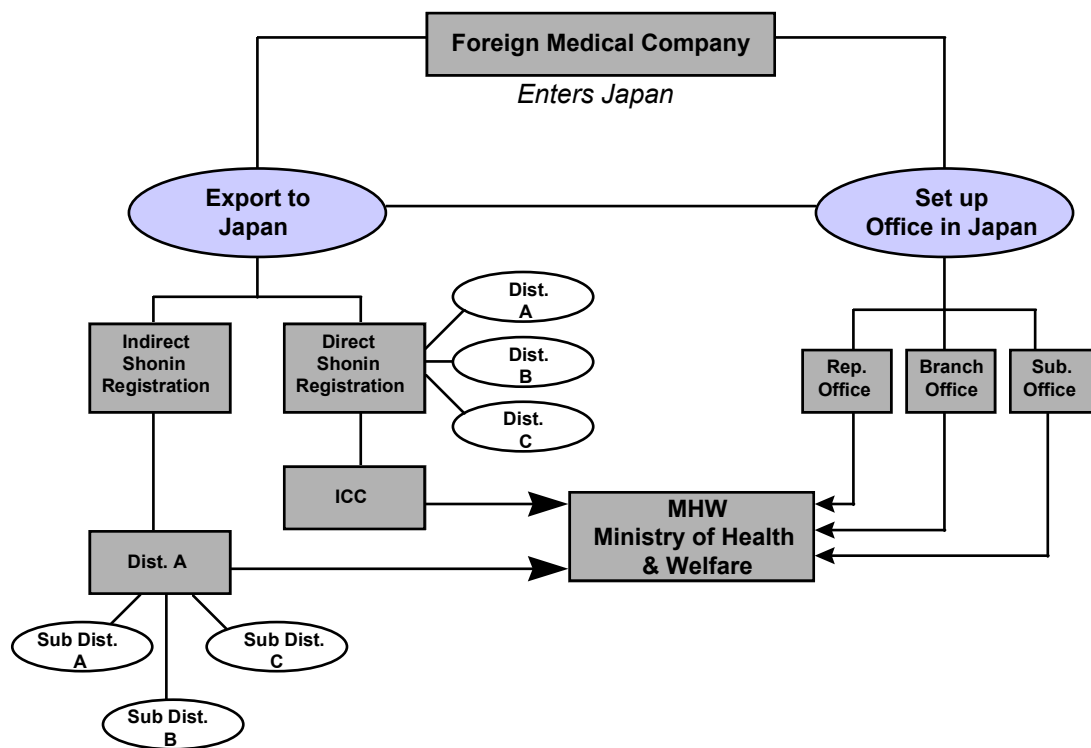
The first and easiest type of office to set up is a representative office for promoting the company's activities. To do this, only a few registration documents are required, and additional costs are minimal. However, at least in theory, representative offices are not allowed to go beyond promotional activities to perform any type of business transaction, including sales, importing, shipping, invoicing, and other activities.

A second type of office is the branch office, which is allowed to perform the business functions denied to a representative office. However, there are higher costs involved in setting up a branch office. A branch office must be registered, for example, and certain fees, procedures, and paperwork need to be submitted to obtain government approval for the company's operations to commence. Specific procedures include filing the company representative seal, registration of tax and related expense items, submission of proxy notifications, etc. Branch offices in Japan are also generally subject to corporate income tax.

The third option is a subsidiary corporation. This type of office provides additional advantages over both a representative and branch office such as accelerating the arrangement of local financing, attracting local employees, and possibly leasing office space. Subsidiaries, however, require capital investment (a minimum of about \$100,000 in the operation). The Japanese government also requires subsidiaries to maintain a full-time director in Japan.

The basic market entry strategies outlined above for foreign medical firms are illustrated below in Figure 7-1. Product registration options will also flow from a firm's market strategy.

Figure 7-1. Japan Market Entry Strategies



Recruiting in Japan

After deciding on how to enter Japan's medical device market, foreign firms must then staff their Japanese operation(s). In order to find qualified executive candidates, medical device firms must first acquaint themselves with Japan's labor laws and human resources practices.

Labor trends in Japan, for example, are different from Western labor practices in three respects. First, Japanese workers generally have lifetime employment with a single company, and mid-career hiring is *not* common. Second, although subject to change, promotions and increases in responsibility are generally based on seniority, not merit — thus, the promotion of a younger employee over more senior-level workers can create tension in the workplace. Third, all foreign companies that employ Japanese citizens must prepare a “constitution” outlining the company's personnel program, accounting procedures, and administrative rules. This document needs to be submitted in both English and Japanese, and must be submitted regardless of the legal structure of its operation in Japan.

VIII. Medical Product Distribution in Japan

Japan's Previous Distribution System

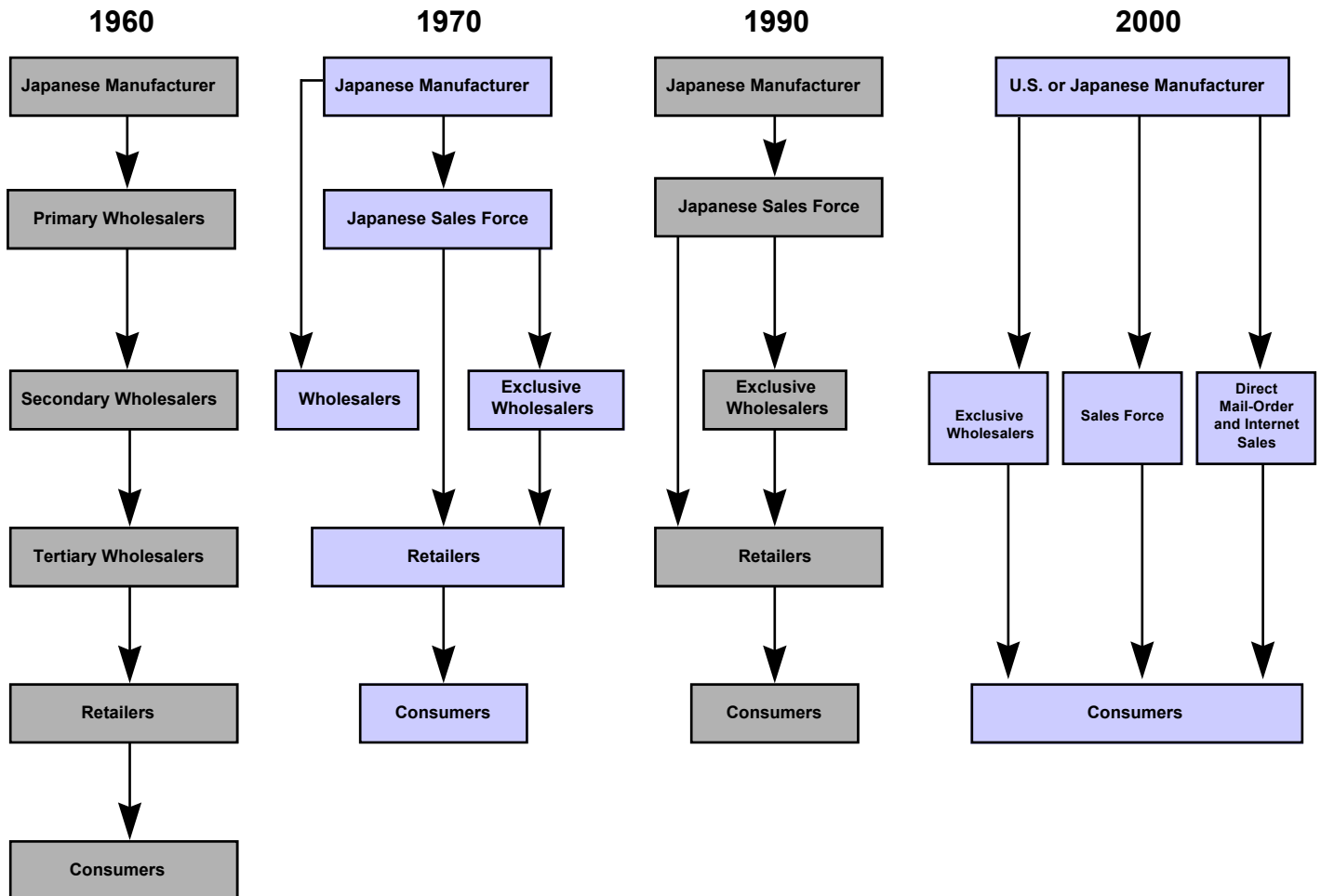
Japan's distribution system is changing. Some companies and products still follow the old distribution system, others follow the new system, and still others operate between the two systems in a "hybrid" type situation. Nevertheless, there will be a clear transition to the new Japanese distribution system over the next several years, and its streamlined structure will greatly benefit foreign medical device companies looking to enter the Japanese market.

Japan's *previous* or "old" distribution system has been a huge obstacle to foreign medical companies. The old distribution system had four main features. The first was the large number of retailers per capita — 1 retail outlet for every 69 persons in Japan, compared to 1 for every 126 in the U.S. The second was the excess of distribution channels. In the 1980s, Japan had an average of 2.2 distribution layers between producer and retailer, compared to only 1 in the U.S. and 0.73 in France. Third, Japanese manufacturers controlled the distribution system through suggested retail prices, company stores, and large rebates to ensure customer loyalty to their products *regardless of price*. And fourth, Japanese manufacturers, suppliers, and distributors often colluded with each other.

Changes in the Distribution System

To improve the pricing and efficiency of medical product distribution as well as the overall business environment for foreign medical companies, Japan's Fair Trade Commission (JFTC) is now enforcing deregulation of the distribution sector. As a result, the number of layers in Japan's distribution system has been shrinking (see Figure 8-1), causing retail prices to fall as well. Also, many of the traditional, inefficient Japanese business practices that were widespread in the 1980s (such as lifetime employment and consensus decision making) are becoming less popular, giving way to a more competitive, market-based business environment. Finally, with Japan in recession, Japanese consumers have also become more cost conscious, making it easier for foreign companies to attract Japanese consumers that were previously loyal to Japanese brands, no matter how expensive they were.

Figure 8-1. The Evolution of a Japanese Corporation's Distribution Network

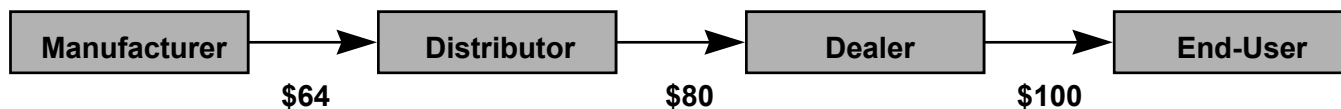


Source: Adapted from *Retail Distribution in Japan*, Tokyo, Dodwell Marketing Consultants, 1991.

Distributor Pricing

Generally, in the medical distribution system, the markup from the manufacturer to the first line of distribution is about 30% to 40% off of the list price, with an additional 20% markup imposed for each subsequent level of distribution. Because of this, when setting pricing in Japan, the list price (end-user) is the starting point. Then each layer of distribution will retain a maximum “margin” of around 20% off of their stated selling price to the next level (see Figure 8-2 below).

Figure 8-2. Distributor Pricing of Medical Devices in Japan: An Example



As mentioned before, Japan's complex distribution system has led to large markups in product prices, making many Japanese products, *especially medical devices*, among the most expensive in the world. Pacemakers and balloon catheters, for example, are respectively 1.7-6.9 times and 1.7-7.6 times more expensive in Japan than in the US and Europe.^{xxv}

As a result, the MHW and Japanese medical equipment manufacturers are now trying to lower medical equipment prices by changing the way suppliers, wholesalers and hospitals conduct business with each other. At present, for example, the Japanese medical equipment industry operates mainly through verbal contracts, which fail to reveal "hidden costs" like charges for additional services not requested by the customer. The MHW is therefore proposing a system of *written* contracts that reveal such hidden costs, thereby improving the transparency of transactions between manufacturers and dealers in the medical equipment market, valued at about ¥500 billion (\$3.6 billion) a year.^{xxvi}

Direct Marketing

Instead of marketing through a distributor, some foreign medical companies can avoid Japan's costly distribution system altogether by marketing their products directly. Direct marketing through mail-order catalogues and the Internet is becoming increasingly popular in Japan, with direct marketing sales for *all* products (including medical equipment) totaling \$20 billion in 1994.

However, companies engaging in direct marketing of medical products need to comply with certain government regulations. For example, medical products listed in mail-order catalogues must be approved and licensed by the MHW, and the catalogue must include approval numbers and license dates. Without such approval, medical equipment cannot legally be advertised, sold, transferred, or leased through direct marketing. Nevertheless, many unapproved medical products are still marketed directly in Japan. If competitors find out, publishers including these unapproved medical products *in principle* face repercussions from the government.

Companies that plan to market approved medical products should follow a few guidelines. Catalogues should be *professionally* translated into Japanese or have a Japanese-language insert that clearly explains each of the products. Also, since the Japanese mail-order list industry is not as sophisticated as its Western counterparts, in order to make sure that the correct list is purchased, a foreign medical company should work with an international or Japanese list expert who clearly understands the U.S. and European list systems. Also, to speed up mail delivery, labels should be printed in Japanese characters with *Japan* written in English.

To support direct marketing of medical products, foreign manufacturers might set up a call center with ordering and customer information *in Japanese*. A call center should also be able to

process payments in yen, handle COD transactions, accept credit cards, and process refunds and returns. Call centers, however, must be located *outside* of Japan so as not conflict with other Japanese regulations.

Finally, the Internet has become an increasingly popular vehicle for direct marketing. About 6-7 million personal computers have been sold annually in Japan since 1995. More and more Japanese consumers are also purchasing products from the Web, making the Internet an attractive venue, in some instances, for foreign medical companies to market their products.

IX. Conclusion

As a whole, foreign companies are still underrepresented in Japan's medical device market vis-à-vis their presence in other major marketplaces. As Japan continues to reform its regulatory, healthcare, and business environments for medical devices, foreign medical device companies can expect growing opportunities in Japan's medical device market for the next several decades. Foreign companies should also keep abreast of the changes occurring in Japan's medical device market in order to devise the best strategy for market penetration.

Problems in Japan's medical industry today have caused the MHW to look to U.S. and European managed care systems as models for Japan's evolving healthcare market. Product reimbursements for foreign drugs and devices have been cut, and the MHW is increasing incentives to cut the length of hospital stays. The Japanese government's efforts to increase co-payments for health insurance, and the formation of group purchasing decisions, are other examples of the growth of managed care. Thus, foreign medical companies specializing in unique and cost-effective equipment are and will continue to become very successful in Japan.

X. U.S. Medical Company Strategies in Japan

Boston Scientific Corporation (Massachusetts)

Major medical products:

Catheters, guidewires, neuro endovascular intervention products, vascular and endovascular grafts, stents, occlusion coils, surgical tools, biopsy systems, intravascular ultrasound systems, rotational atherectomy, balloon angioplasty

Major strategies in Japan:

New Product Strategy: In February 1998, Boston Scientific received reimbursement approval for its Rotablator™ system, a unique high speed rotational device for the treatment of atherosclerosis in coronary and peripheral arteries. Especially effective for use on complex and highly calcified lesions, the Rotablator is extremely useful for Japan where the incidence of calcified lesions is high relative to other patient populations. Reimbursement of the Rotablator system is also a significant step towards increasing the share of less invasive technologies in Japan's medical market and thus strengthening Boston Scientific's leadership position in interventional cardiology. Boston Scientific is also expecting sales of its endoscopic systems to increase as Japan places a greater emphasis on reducing healthcare costs.

Marketing Strategy: To successfully introduce the Rotablator into the Japanese market, Boston Scientific organized a multi-phase Rotablator training program at its Northwest Technology Center in Redmond, Washington. Japanese physicians receiving the training worked closely with international training colleagues in lecture and training workshops that used simulated heart models and live case presentations. Aside from making sure that Japanese medical professionals would maximize their use of the product, the program was also a way for Boston Scientific to illustrate their emphasis on customer service.

R&D Strategy: Boston Scientific has established R&D "centers of excellence" in Japan to better respond to inventors, collaborators, and customers in the country.

Manufacturing Strategy: Boston Scientific's Japanese branch, Boston Scientific Japan, is switching from the import and sales of cardiac catheters to the actual manufacturing of these catheters in Japan. Manufacturing of the catheters began in June 1998 at the company's Miyazaki prefecture factory, with an initial monthly production of 20,000 units. Compared to the three months it would take the catheters to be imported, Boston Scientific's Miyazaki factory can now *produce* the same number of catheters in about two weeks. Also, Boston Scientific Japan is developing a system to custom-make medical devices based on design requests from individual physicians. When implemented, this production system will be the first of its kind in the world.

Sales Strategy: SCIMED Life Systems Inc., a wholly owned subsidiary of Boston Scientific, engages in direct sales operations in Japan for the company's heart-related products.

Stryker Corporation (Michigan)***Major medical products:***

Orthopedic implants, powered surgical instruments, endoscopic systems, patient care and handling equipment

Major strategies in Japan:

Marketing/Distributor Strategy: Stryker sells its orthopedic, ophthalmic, and general surgery products in Japan via a distributor. The company's main distributor in Japan is Matsumoto Medical Instruments, Inc., with whom it has maintained a relationship since 1969. Stryker also has ownership in Matsumoto, and last year invested \$30 million in the company to increase its ownership position to 75%.

Thoratec Laboratories Corporation (California)***Major medical products:***

Ventricular Assist Device (VAD) Systems, Vascular Access Grafts (VAC) and Coronary Artery Bypass Grafts, Portable Drivers

Major strategies in Japan:

New Product Strategy: Thoratec's Vectra VAG has been very successful in Japan due to its innovative design and ability to permit dialysis of a patient without the placement of an expensive secondary central catheter. In addition, published data from a Japanese clinical study showed that Thoratec's Vectra had a 12-month patency rate (open to blood flow) of 91 percent, which is far superior to currently available graft technologies. The worldwide market for Thoratec's VAG is estimated to be \$120 million, 10-20% of which is accounted for by the Japanese market. Furthermore, the annual growth rate of this market is expected to be about 8-10%.

Distribution Strategy: Thoratec is marketing the VAG in Japan through its exclusive distributor, Goodman Company, Ltd.

CardioDynamics International Corporation (California)***Major medical products:***

Noninvasive digital cardiac output monitoring devices for hospital and clinical use

Major strategies in Japan:

New Product Strategy: CardioDynamics has manufactured a new product, the portable BioZ System, which is a noninvasive digital heart monitoring system that can monitor up to 12

hemodynamic parameters within one minute. The product was approved in Japan in July 1998, and the Japanese medical community has welcomed the product as a new way to lower healthcare costs without having to deal with expensive and potentially dangerous invasive PAC (Pulmonary Artery Catheterization) procedures.

Marketing and Distribution Strategy: CardioDynamics has chosen B.C.S., Inc., an established distributor in Japan, to represent the company. CardioDynamics' first priority after receiving approval is to get the BioZ Systems as quickly as possible to the customers and provide training to B.C.S.'s sales team.

American BioMed, Inc. (Texas)

Major medical products:

Site-specific drug delivery and fluid removal products, stents, cardiac-assist devices, atherectomy and thrombectomy catheters, silicone-based catheters, spinal dissectors

Major strategies in Japan:

Product Approval Strategy: In April 1998, American BioMed received initial orders from its two Japanese distribution partners — K's Projects and Medical Leaders, both based in Tokyo — for the company's OmniCath Atherectomy Catheter product. This purchase will be used in upcoming clinical trials needed for the product's registration in Japan. Medical Leaders and K's Projects have also signed a multi-year agreement to register and distribute American BioMed's 100% silicone balloon catheter product line. This includes procuring the necessary regulatory documentation needed for the sale of products in Japan.

Heartport, Inc. (California)

Major medical products:

Minimally invasive cardiac surgery systems

Major strategies in Japan:

Product Approval Strategy: Heartport has entered into an exclusive agreement with Getz Bros. & Co. Ltd. of San Francisco to register, distribute, and obtain reimbursement for its new Port-Access™ minimally invasive cardiac surgery systems in Japan.

Marketing and Sales Strategy: A committee comprised of Heartport and Getz representatives will oversee marketing and sales of Heartport's products. Heartport will be in charge of training Japanese surgical teams.

Medtronic, Inc. (Minnesota)***Major medical products:***

Implantable pacemaker systems, implantable tacharrhythmia management devices, ablation systems, heart valves, balloon and guiding catheters, coronary and peripheral stents, stented grafts, neuroradiology products, implantable neurostimulation and drug delivery systems, neurosurgical devices, diagnostic systems, perfusion systems

Major strategies in Japan:

Marketing Strategy: Medtronic has built its reputation in Japan not only through its long-standing network of doctors and government officials, but also with a strong emphasis on marketing. Last year, for example, Medtronic established an educational center in Tokyo for its medical products that drew more than 800 customers and 1,400 employees.

New Product Strategy: Medtronic's success in Japan is attributable, in part, to its heavy emphasis on quality and affordability. Medtronic's Wiktor coronary stent, for example, has achieved huge success in Japan. Sales of this product have contributed heavily to Medtronic's 8.4% total sales growth in its "Other Cardiovascular Business" area (balloon and guiding catheters, stents, heart valves, etc.)

United States Surgical Corporation (Connecticut)***Major medical products:***

Surgical Stapling, laparoscopy, sutures, minimally invasive breast biopsy systems, cardiovascular surgery/interventional cardiology systems, orthopedic and neurosurgery devices

Major strategies in Japan:

Marketing Strategy: USSC emphasizes training and customer education to market its products and enhance its competitiveness. It has three wholly-owned, state-of-the-art educational centers worldwide, one of which is located in Fujinomiya, Japan. USSC also links its worldwide surgical suites, some of which are also located in Japan, to corporate headquarters through the Internet and video teleconferencing.

St. Jude's Medical (Minnesota)***Major medical products:***

Heart valves, cardiac rhythm management devices, catheters

Major strategies in Japan:

Distribution and Sales Strategy: St. Jude's pacing distributors in Japan are Getz Bros. and Fukuda, with whom St. Jude has been able to maintain a large share in Japan's pacing market. Sales for St. Jude in this area have increased over 20% since 1995.

XI. European Medical Company Strategies in Japan

Smiths Industries Medical Systems (UK)

Major medical products:

Single-use devices used in surgery and intensive care (anesthesia and respiratory devices, apnoea monitors, syringe drivers and infusion pumps, transport ventilation equipment, single use pressure transducers and systems for haemodynamic monitoring), home care products (ostomy pouches, incontinence devices), dental equipment

Major strategies in Japan:

Distribution Strategy: Last year, SIMS took majority ownership of Japan Medico, its distributor in Japan for over 25 years. By taking a majority interest, SIMS has increased its profit margin in Japan and hopes to improve further on its strong position on the Japanese market for medical systems.

Siemens (Germany)

Major medical products:

MRI equipment, angio systems, CT equipment, nuclear medicine diagnostic equipment, ESWL equipment, ultrasound imaging units, network image management systems, dental X-ray and treatment devices

Major strategies in Japan:

Marketing Strategy: A participant in Japan's medical market for over 100 years, Siemens was the first company in the industry to engage in nationwide, full-page newspaper advertising. The company also advertises its products extensively on TV.

Strategic Alliances: In 1988, Siemens established a joint venture with Asahi Chemical Industry, Co., Ltd., a leader in the field of magnetic resonance tomography. This partnership, called Siemens-Asahi Medical Technologies Ltd., greatly increases Siemens' market share in Japan and currently generates more than \$330 million in annual sales. Also, the Nuclear Medicine Group of Siemens Medical Systems, Inc. has reached a non-exclusive agreement with Toshiba Corporation to supply its new photon emission camera, E.CAM™. The agreement will open up new sales channels, and make the nuclear medicine product lines of both companies more competitive.

Niche Strategy: Siemens established Siemens Hearing Instruments K.K. in 1985 to meet the growing demand for hearing aids in Japan.

Novo Nordisk (Denmark)

Major medical products:

Diabetes care products and devices (insulin and insulin injection systems), pharmaceuticals, hormone preparations for gynecological use and human growth hormone

Major strategies in Japan:

New Product Strategy: In 1997, Novo Nordisk introduced three new products into the Japanese diabetes care market: 1) a new 6-millimeter NovoFine™ needle, shorter than any other needle available on the market; 2) new colored versions of its already-popular NovoPen™ 3 insulin injection system; and 3) PenMate™, a new device that helps people with diabetes who have a fear of needles gain confidence in self-injection.

R&D Strategy: Novo Nordisk has spent more than 15 years doing local research in Japan. In 1997, the company spent 16.3% of its turnover on R&D, and about 20% of its 15,000 employees are involved in research. Novo Nordisk has recruited additional researchers in Japan by holding an annual Enzyme Research Symposium in Tokyo, which attracts about 500 Japanese professors, research students and customers. Novo Nordisk has also set up a research center in the Chiba Prefecture near Tokyo.

Corporate Strategy: Novo Nordisk maintains a good relationship with its distributors, which has helped the company gain trust and acceptance in the Japanese medical market. For example, Novo Nordisk provides Mitsui & Co. Ltd., its exclusive distributor since 1970, with constant technical support through its Application Technology Division. Mitsui also has a 10% ownership interest in Novo Nordisk Bioindustry Ltd. in Japan.

Sales Strategy: In April 1998, Novo Nordisk took over the sales and distribution of its own products from Yamanouchi Pharmaceutical Co in order to develop closer ties with its customers. The company has been working with Yamanouchi on marketing and distributional activities for over 20 years. Since 1993, the company has been hiring about 50-60 new sales people annually, and its current sales force in Japan totals 350.

Manufacturing Strategy: In April 1998, Novo Nordisk inaugurated a new, ultra-modern finished goods factory in Koriyama, about 200 miles from Tokyo. The new factory supplements operations at Novo Nordisk's other manufacturing facility in Atsugi. It also provides the latest automated technology in the packaging and labeling of medical products, since Japanese consumers pay a great deal of attention to product packaging.

Bayer Group (Germany)

Major medical products:

Pharmaceuticals, diagnostic systems for hospital laboratories, physicians' offices and patient self-testing.

Major strategies in Japan:

Manufacturing Strategy: Bayer has its own manufacturing facilities in Japan, and has established a successful polyurethanes service center in Nihama. In the future, Bayer is also looking to establish industrial parks for its healthcare products, where utilities and infrastructure can be shared efficiently.

R&D Strategy: Due to the large size of the Japanese healthcare market, Bayer is committed to establishing Japan as the third point of the company's global R&D triad, along with the U.S. and Europe. In 1997, R&D expenses in Japan reached about \$113 million, about 21% of its total global R&D expenses for that year.

Pall Gelman Sciences (UK)

Major medical products:

Filtration products for drug delivery, hemodialysis and classical and minimally invasive surgery; medical set components, healthcare venting products, membrane technology

Major strategies in Japan:

R&D Strategy: Pall Gelman maintains three principal laboratories worldwide, one of which is located in Tsukuba, Japan and the other two based in the U.S. and UK. From these sites, Pall Gelman's Scientific and Lab Services (SLS) groups conduct long-term diagnostic, analytical testing and modeling procedures by networking with its 30 SLS facilities worldwide. With this system of networking, Pall Gelman is able to maintain close relationships with its customers and respond quickly to their needs. Pall Gelman also has two offices in Tokyo.

Schering AG (Germany)

Major medical products:

Pharmaceuticals, X-ray diagnostic imaging media

Major strategies in Japan:

Corporate Strategy: Schering has established a joint venture in Japan, Nihon Schering K.K., which employs about 1200 people and develops contrast media for X-ray, ultrasound and magnetic resonance.

R&D Strategy: About 16% of Nihon Schering K.K.'s employees are involved in R&D. R&D activities in Japan are particularly focused on the fields of magnetic resonance imaging and oncology research.

Strategic Alliances: Schering formed a licensing agreement last year with the Japanese pharmaceutical company Teijin for DSPA, a thrombolytic used for acute myocardial infarction and stroke. Nihon Schering retains the option for co-development and co-marketing.

Solvay Group (Belgium)

Major medical products:

Pharmaceuticals, chemical products and bio-pharmaceutical intermediates; medical grade plastics, films and tubing for the manufacture of medical products

Major strategies in Japan:

Manufacturing Strategy: Solvay has not been discouraged by the Asian crisis. It will continue to invest in its \$6 million manufacturing facility on the Kawagoe site near Tokyo, which it established in 1994.

R&D Strategy: Solvay has 10 main research centers worldwide, one of which is established in Tokyo. About 2% (or \$6.9 million) of Solvay's research takes place in Japan, and is mainly focused on pharmaceuticals. The company's pharmaceutical research in Japan is divided into projects covering the central nervous system, gastroenterology, cardiology, and gynecology.

Roche Diagnostics (Switzerland)

Major medical products:

In-vitro diagnostics and medical equipment in molecular biochemicals and molecular systems, laboratory systems, and patient care (which includes urinalysis equipment, coagulation/patient self-testing systems, and cardiocare diagnostics)

Major strategies in Japan:

Strategic Alliances: Roche has developed alliances with Japanese companies and international firms to penetrate the Japanese market. For example, Roche recently agreed to collaborate with Japan's Toa Medical Electronics in the sales and marketing of each other's products. Under the agreement, both companies will also cooperate in joint R&D activities for future products.

Marketing Strategy: Roche has established Nippon Roche K.K. to market the company's chemical and pharmaceutical products, as well as its printing and packaging materials, in Japan. To pave the way for long-run growth, Nippon Roche K.K. is also strengthening its management foundation by establishing computer networks and emphasizing greater efficiency among its

managerial staff. This strategy is also aimed at building up the requisite structure to market several new, promising drugs which will most likely be launched in the year 2000.

Merck KGaA (Germany)

Major medical products:

Pharmaceuticals, laboratory products (chemicals, consumable materials, instruments/systems, small-scale implements and laboratory equipment); specialty chemicals (cosmetics, health, and nutrition; pigments, electronic chemicals and liquid crystals)

Major strategies in Japan:

Corporate Strategy: Merck has established Merck Japan Ltd. in Tokyo as a major supplier of the Japanese *and* global markets for liquid crystal displays (LCDs). In the medical industry, LCDs are used for the manufacture of display and visual monitoring systems.

Manufacturing Strategy: Merck Japan is establishing a production facility at its Onahama plant (Fukushima) to supply products in Japan and in global markets.

R&D Strategy: Merck Japan has research centers in Japan, Korea, and Taiwan; 25 percent of its employees work in the research and development of new products. Merck is currently increasing R&D expenditures at its Atsugi plant in order to reinforce its strength in developing liquid crystal mixtures. Finally, Merck's French subsidiary, Liplha, and the Japanese pharmaceutical company ONO have signed heads of agreement on the R&D of a new generation of drugs for the treatment of diabetes mellitus. The two companies will use ONO's screening technology and both of their libraries in the project.

Strategic Alliances: Merck and the Japanese pharmaceutical company Yamanouchi concluded an agreement this year to jointly develop two medicines. The first medicine will treat patients with acute myocardial infarction, and the second will treat patients suffering from stroke, acute coronary syndromes and thromboses (all of which are rapidly increasing in Japan). Merck and Yamanouchi have been cooperating in the field of cardiovascular research since 1995. The present alliance will help both companies share the risks associated with product development and speed up market introduction.

SmithKline Beecham (UK)

Major medical products:

Pharmaceuticals, vaccines, dermatological products, oral and nutritional care, molecular diagnostics

Major strategies in Japan:

Corporate Strategy: SB's operations in Japan consist of over 160 staff working in either SmithKline Beecham Seiyaku (SBS), K.K. or in SBS Laboratories in Takasaki. Both of these operations are capable of progressing development drugs from their early stages through registration in Japan.

Strategic Alliances: SB has formed an agreement with ALZA Corporation of Palo Alto, California, to market ALZA's Nicoderm™ patch in Japan. The market for this product is large in Japan since the country has one of the highest levels of cigarette consumption in the world.

New Product Strategy: SB has been marketing its new product Kytril™ in Japan, in a co-promotion alliance with Nippon Kayaku. Twelve months after being put on the market, sales for Kytril in Japan reached over ¥10.6 billion (\$76.8 million) and the product is currently the number-one antiemetic in Japan. SB has also formed a co-distribution agreement with Mochida for SB's product Famvir™, and with Meiji Seika for SB's product Levanex™. Up through the year 2000, SB is planning to introduce 5 new pharmaceuticals in Japan.

IX. Conclusion

As a whole, foreign companies are still underrepresented in Japan's medical device market vis-à-vis their presence in other major marketplaces. As Japan continues to reform its regulatory, healthcare, and business environments for medical devices, foreign medical device companies can expect growing opportunities in Japan's medical device market for the next several decades. Foreign companies should also keep abreast of the changes occurring in Japan's medical device market in order to devise the best strategy for market penetration.

Problems in Japan's medical industry today have caused the MHW to look to U.S. and European managed care systems as models for Japan's evolving healthcare market. Product reimbursements for foreign drugs and devices have been cut, and the MHW is increasing incentives to cut the length of hospital stays. The Japanese government's efforts to increase co-payments for health insurance, and the formation of group purchasing decisions, are other examples of the growth of managed care. Thus, foreign medical companies specializing in unique and cost-effective equipment are and will continue to become very successful in Japan.

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