No.69
March
2004

JETRO Japanese Market Report

Medical Equipment

Introduction

The Japanese market for medical equipment was 1,960 billion yen in 2001, the second largest in the world. There are many product areas that depend largely on imports, and the market is one that has potential for investment from overseas. However, as we will make clear in this report, in order to enter into the market, there is a need to first understand the special characteristics of the Japanese market, including its complex legal system and unique distribution channels.

Among the categories of "medical devices" set down in the Pharmaceutical Affairs Law, this report focuses mainly on those seven categories (bold border in the table below) that make up about 80% of the total market for medical equipment.

Table 1. Report Focus Area

Category	Equipment
Diagnostic imaging systems	X-ray diagnostic devices, CT, MRI, diagnostic ultrasound imaging devices, etc.
X-ray related apparatus for diagnostic imaging	X-ray imaging equipment, protective devices, etc.
Physiologic measuring/ monitoring systems	Thermometers, blood pressure gauges, stethoscopes, cardiac output monitors, tonometers, electrocardiographs, electroencephalograph, physiologic monitoring equipment, fundus camera, endoscopes, etc.
In vitro clinical test equipment	Clinical laboratory test equipment, blood testing apparatus, serum testing apparatus, etc.
Surgical equipment	Syringes, tubes and catheters, blood collection/ transfusion apparatus, infusion apparatus, suture machines and apparatus, etc.
Artificial internal organ apparatus and assistive devices	Dialyzers, cardiac pacemakers, artificial blood vessels, artificial joints, intraocular implants, artificial lungs, artificial respirators, anesthesia apparatus, etc.
Therapeutic and operating equipment	Radiation therapy equipment, laser therapy equipment, lithotripters, infrared ray therapy apparatus, low frequency electric therapy apparatus, ultrasound therapy apparatus, short wave therapy apparatus, etc.
Clinical equipment	Drug sprayers, medical suction units, inhalers, medical irrigators, equipment for diagnostic facilities, etc.
Dental equipment	Dental surgery equipment, dental units and related equipment, orthodontic materials and related equipment, dental technician equipment, etc.
Dental materials	Dental metals, tooth crown materials, denture baseplate materials, dental model materials, etc.
Steel products	Surgical amputaters, snares or excisers, sharp curettes and blunt curettes, retractors, aperture-opening devices, etc.
Ophthalmic goods and related products	Sight-correcting spectacles, cataract spectacles, contact lenses, optometric instruments, etc.
Sanitary materials and products	Sanitary products, sanitary materials, etc.
Therapeutic apparatus for household use	Household massage devices, devices and apparatus for medical baths, household electric and light-ray therapy apparatus, household inhalers, hearing aids, etc.

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Yen-US Dollar Exchange Rates

End of Year	Yen/US$
1998	129.2
1999	102.1
2000	114.9
2001	131.5
2002	119.4
2003	107.0

Note : Mean value between offer and bid in the inter-bank foreign exchange market in Tokyo.

Source: Bank of Japan, “Financial and Economic Statistics Monthly”

Summary

Outline of the Medical Equipment Market

The world market for medical equipment was roughly 169 billion dollars (about 18.6 trillion yen) in 2000. The Japanese market was second in size only to the U.S., and accounted for roughly 15% of the world market. The Japanese market was 1.96 trillion yen in 2001, and the past five years have seen a steady market size with no major gains or decreases.

In the breakdown of the market, the share of diagnostic imaging systems, artificial internal organ apparatus and assistive devices, and surgical equipment are prominent, and together account for 75% of the total.

Medical equipment is a market in which foreign product entry is relatively advanced, and imports account for roughly half of the Japanese market. In particular, there a tendency towards excessive dependence on imports in the therapeutic equipment category, and the import rate for this category is 61%.

From the perspective of foreign market entry, attention will be paid to equipment with high import rates, equipment with steadily increasing import rates, equipment covered under the Highly Advanced Medical Technology (HAMT) program, and products for which markets will form based on technical advances and changes in the market environment.

The Pharmaceutical Affairs Law and the Health Care Insurance System

Under the Pharmaceutical Affairs Law, medical equipment is required to receive in turn, approval, licensing and notification, and then application procedures for coverage under health insurance can be taken.

The Pharmaceutical Affairs Law was largely revised in 2002, and the contents of this revision are in the process of coming into enforcement step-by-step from 2003 to 2005, and it is important to fully understand the changes.

Business Practices and Business Models in the Medical Equipment Industry

In the Japanese medical equipment industry, only a very small percentage of equipment is sold directly from manufacturers and import retailers to hospitals, the final users, and there exists a retail pattern in which sales are made via medical equipment dealers (agents, retailers). There are also characteristic aspects to market prices, inventory control and distribution, and it is necessary to pay attention to these factors when entering the market.

There are three representative types of business models in the industry: sales via general dealers, sales via specialist dealers and direct sales.

Advice for Market Entrants

In order to enter the Japanese market, it is extremely important to understand not only the business practices of the medical equipment market, but also the characteristics of the Japanese. In reality, important facets of doing business in Japan are: development of products aimed at Japan, securing of distribution channels, dealer education, building-up after-service bases, facilitating Pharmaceutical Affairs Law approval, user education and choosing appropriate sales targets.

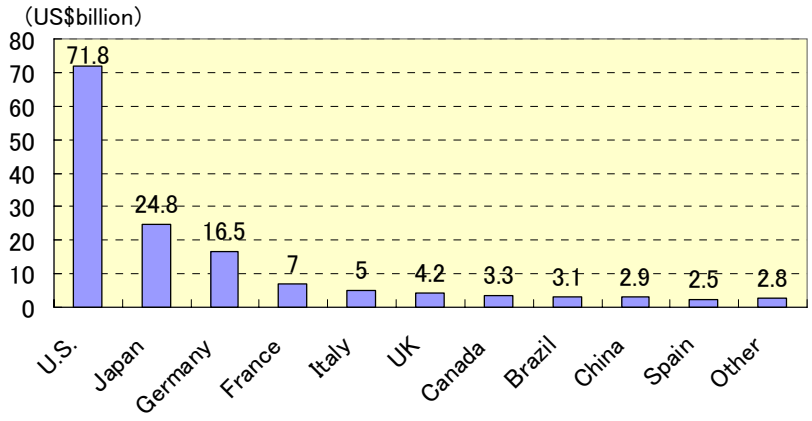
I. Outline of the Market

1. Market Size

1-1 Market Trends

The world market for medical equipment was roughly 169 billion dollars (about 18.6 trillion yen) in 2000. The Japanese market was second in size only to the U.S., and accounted for roughly 15% of the world market.

Figure 1. Medical Equipment Market Size in Major Countries (2000)



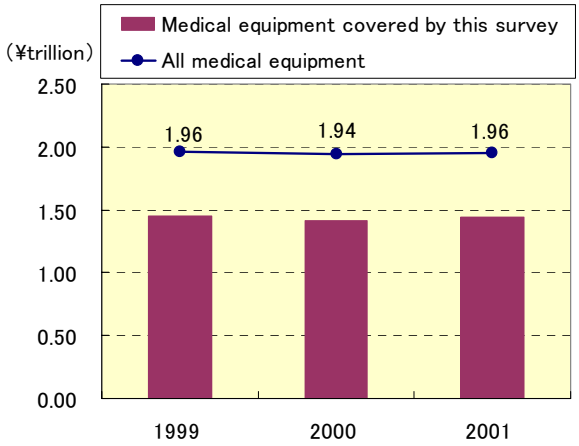
Note : The statistics used in this chart include data for medical equipment other than that shown in Table 1 such as welfare devices.

Source: Prepared based on data from the Advanced Medical Technology Association (AdvaMed), *Access and Outlook in Key Overseas Market 2000*

According to the Annual Report on the Survey of Pharmaceutical Industry Production compiled by the Health Policy Bureau of the Ministry of Health, Labour and Welfare, the total market for medical devices in Japan was 1,960 billion yen. (production: 1,520 billion yen, export: 400 billion yen, import: 840 billion yen). These statistics are for all business entities that are licensed manufacturers or import retailers of medical equipment under the Pharmaceutical Affairs Law, and are show the market size based on retail value of manufacturers and import retailers.

The seven categories of medical devices that this report focuses on make up about 80%of the total market. Development of the market for the three years from 1999 to 2001 is shown in Figure 2. The total market size has remained steady over this period.

Figure 2. Trends in the Medical Equipment Market Total



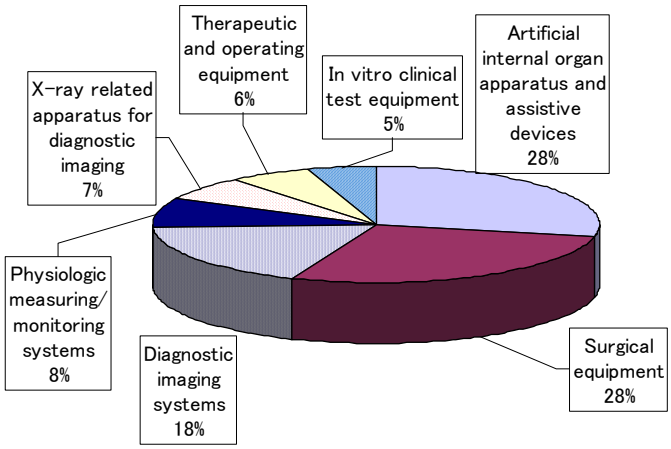
Note : Categories for medical devices were changed in 1999, and data is shown for following years only.
Source: Prepared based on data from the *Annual Report on the Survey of Pharmaceutical Industry Production*

In the Japanese medical equipment industry, there exist wholesalers and retailers that stand between manufacturers/ importers and consumers. If the size of the terminal market that these operators create is added in, it is believed that 100 ~200 billion yen can be added to the market size displayed in Figure 2.

1-2 Trends by Category

The breakdown of the 2001 market by category is displayed in Figure 3. The market for artificial internal organ apparatus and assistive devices, surgical equipments and diagnostic imaging systems and are most prominent, and together these three categories account for 75% of the total.

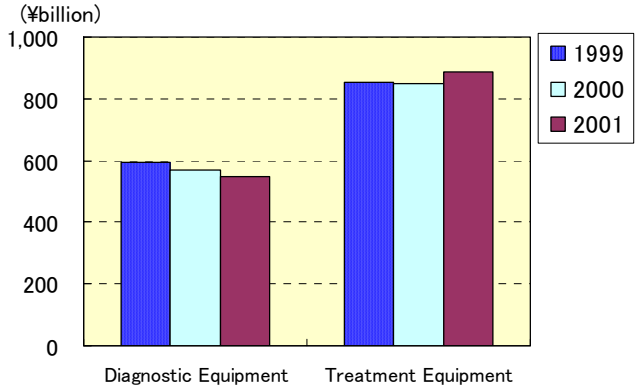
Figure 3. Category Breakdown in the Japanese Medical Equipment Market (2001)



Source : Prepared based on data from the *Annual Report on the Survey of Pharmaceutical Industry Production*

When the total market for medical equipment is divided into two categories: diagnostic equipment (diagnostic imaging systems, X-ray related apparatus for diagnostic imaging, physiologic measuring/ monitoring systems, in vitro clinical test equipment) and therapeutic equipment (artificial internal organ apparatus and assistive devices, therapeutic and operating equipment), it can be seen that the market for therapeutic devices is larger, and that the market for diagnostic equipment is slightly decreasing while the market for therapeutic equipment is slightly increasing.

Figure 4. Market Trends by Category

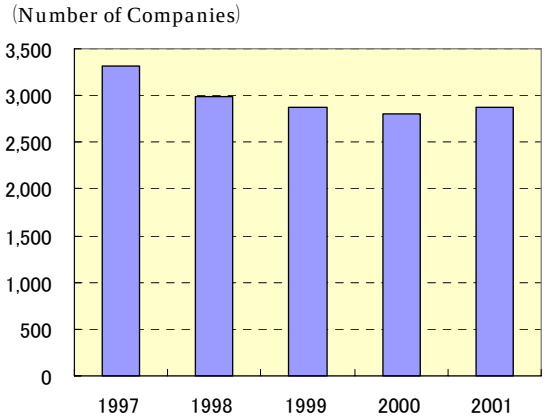


Source: Prepared based on data from the *Annual Report on the Survey of Pharmaceutical Industry Production*

1-3 Number of market entrants

The number of entrants (manufacturers and import retailers) in the Japanese medical equipment industry is displayed in Figure 5.

Figure 5. Medical Equipment Market Entrants



Source: Prepared based on data from the Ministry of Labour, Health and Welfare, *Survey on the Actual Status in the Medical Devices Industry, FY2001*

The figures shown in Figure 5 are the numbers of companies that have been licensed as manufacturers and import retailers, and it is estimated that slightly under half of these are in fact functioning in the market. Even then, when comparing this number to the 9,200 hospitals that exist in Japan, it can be seen that this industry is one where the number of market entrants versus clients is extremely high. Another characteristic is that more than 80% of entrants are small- or medium-sized businesses.

Of market entrants, roughly 60% are manufacturers, 20% and import retailers and the remainder are both manufacturers and import retailers.

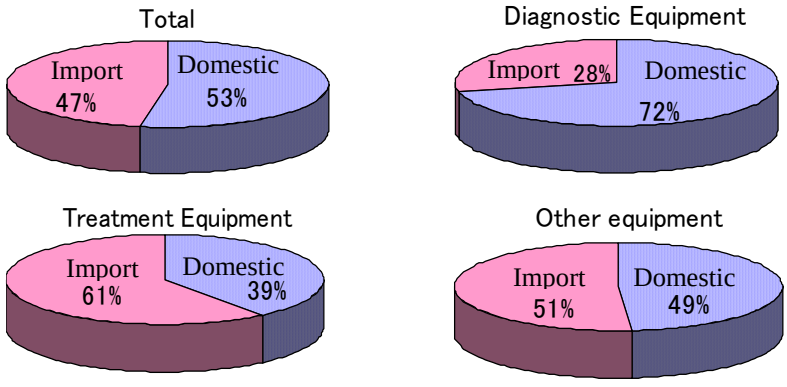
Approximately 6% of market entrants are foreign companies.

2. Market Entry by Foreign Companies

2-1 Overall Trends

The overall import rate, and import rate by category for medical equipment is displayed in Figure 6 (figures from 2001). Imports account for almost half of the Japanese market, and medical equipment is a market in which foreign product entry is relatively advanced. Looking by category, there is a trend towards high imports of therapeutic equipment, and the import rate is 61%.

Figure 6. Import Rate by Category



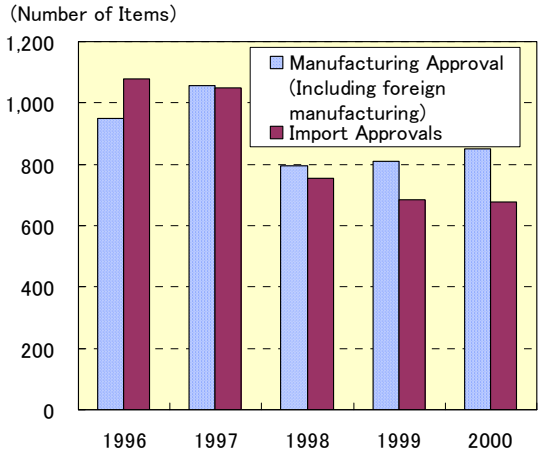
Source: Prepared based on data from the *Annual Report on the Survey of Pharmaceutical Industry Production*

Under the Pharmaceutical Affairs Law, it is necessary to apply for approval to manufacture or import and sell medical equipment (Refer to section II.1 for more details). Figure 7 displays trends in the total number of items that received approval from 1996 to 2000. Approval given to imported items accounts for almost half the total, and again the active

nature of foreign product entry can be seen.

Further, looking into the breakdown of medical equipment that has gained approval, the number of therapeutic equipment items that has gained approval has increased to more than four times the number of diagnostic equipment items, and roughly 70% of these approvals were for imported items.

Figure 7. Trends in Approval Item Totals for Medical Equipment



Note : All medical equipment (devices, equipment and apparatus) that received approval under the Pharmaceutical Affairs Law

Source: Prepared based on data from Yakumukoho-sha, Ltd., *Medical Equipment Permission Data Handbook*

3. Trends and Foreign Entry for Promising Products

3-1 Promising Medical Equipment with High Import Rates

Table 2. Promising Products (High Import Rate, Large Market Size)

	Item	Market Size	Characteristics	Top Market Shares
1	Cardiac pacemakers	47.3 billion yen	Imports: almost 100% Several manufacturers	Medtronic Japan: 33.3% Japan Lifeline: 17.4%
2	Artificial joints (artificial hips, artificial knees)	67.8 billion yen	Imports: 80% 3 major players	Zimmer: 25.7% Stryker Japan: 25.1%
3	Coronary stents	36.8 billion yen	Imports: over 95% 4 major players	Guidant: 34.6% Johnson & Johnson: 23.9%
4	PTCA Balloon Catheters	35.7 billion yen	Several manufacturers	Boston Scientific: 36.9% Goodman: 15.0%

Note : Data is as of 2002. Even when market share of Japanese companies is high, if those companies are selling imported products, the import rate is high.

Source: Prepared based on data from R&D Corp., *Medical Equipment/ Supplies Yearbook 2003*

For cardiac pacemakers, the import rate is almost 100% and, and there are a number of entrants in the market. Medtronic Japan continues to hold its place as the market leader.

Cardiac pacemakers are receiving attention as a product that has a large difference in price between Japan and overseas, and in the revision of the Medical Fee System in 2002, prices were dropped by 70,000 ~ 90,000 yen (Refer to section II.2-1 for more details on the Medical Fee System).

The import rate for artificial joints is about 80% and the market is dominated by three manufacturers (Zimmer, Stryker Japan and DePuy Japan[1]). The market is increasing in size with the aging of the Japanese population and the according increase in cases.

For coronary stent, the top four manufacturers (Guidant, Medtronic Japan, Johnson & Johnson and Boston Scientific) account for more than 95% of the total market, and the import rate is extremely high.

Boston Scientific has about 30% of the market for PTCA balloon catheters, and the remainder of the market is comprised of several companies.

Coronary stents are a device used after percutaneous transluminal coronary angioplasty (PTCA) to reduce acute coronary stoppage and re-stricture. The number of PTCA operations being performed is rising each year, and accordingly the market for coronary stents is expanding each year. On the other hand, due to a rise in the functionality of the stents that are being used in conjunction with PTCA balloon catheters, there has been a decrease in the number of catheters being used per procedure, and while the total number of procedures is increasing, the market itself is contracting.

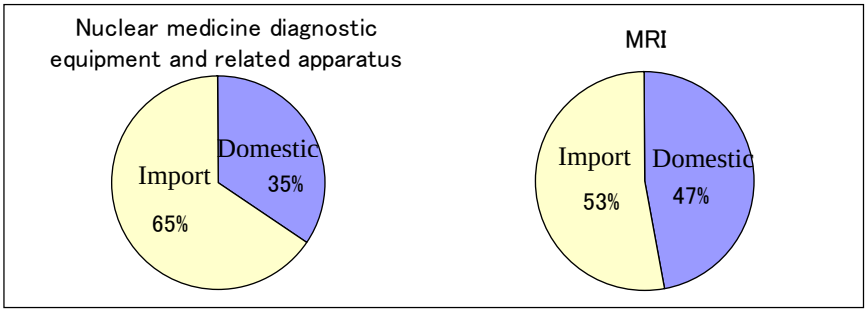
3-2 Promising Medical Equipment with Increasing Import Rates

While Japanese firms had most of the market share for diagnostic imaging equipment such as Magnetic Resonance Imaging (MRI) systems until a few years ago, three large manufacturers General Electric Company (GE), Phillips, and Siemens are increasing their market share.

As mentioned earlier, diagnostic equipment is an area in which the overall import rate is low, however, for high precision imaging equipment such as nuclear medicine related apparatus and MRI, a trend towards high import rates can be seen. (Figure 8) In the case of MRI, while the number of machines being produced domestically is high, almost half of domestic production is exported, and as a result there is a high import rate in the domestic market.

[1] Depuy Japan is an affiliated company of Johnson & Johnson Group.

Figure 8. Import Rate for High Precision Diagnostic Equipment



Source: Prepared based on data from the *Annual Report on the Survey of Pharmaceutical Industry Production* (Data for 2001)

3-3 Promising Medical Equipment as Highly Advanced Medical Technology

As a step in the process of gaining insurance coverage for new medical equipment, there are cases in which equipment first receives coverage under the Highly Advanced Medical Technology[2] program. Highly Advanced Medical Technology treatment is treatment that uses cutting-edge technology that is not covered by regular social insurance, and can be used in conjunction with treatment covered by regular insurance. Those treatments that begin as Highly Advanced Medical Technology and are then recognized as being popular and a standard part of medical treatment throughout the country are then included in the coverage area of regular health care insurance. As of August 2003, 68 types of Highly Advanced Medical Technology (79 including dentistry) have been approved.

Amongst the technologies that received approval, there were 13 items related to genetic testing that were approved, and medical equipment related to genetic testing is a field that is receiving attention at the moment as the market can be expected to expand as these genetic technologies begin to be covered by regular insurance.

[2] Application for approval as Highly Advanced Medical Technology is made to the Ministry of Health, Labour and Welfare, and the Council on Medical Insurance Welfare, an advisory council of the Ministry is responsible for approval. Applications are submitted to regional social insurance offices, and under present conditions, approval can take from 6 to 21 months.
Highly Advanced Medical Technology may only be used in treatment at medical organizations that have received individual approval from the Minister of Health, Labour and Welfare. These are medical organizations, known as Specific Approved Social Insurance Treatment Organizations, that have the specific infrastructure in place to perform treatment using Highly Advanced Medical Technology and includes university hospitals, etc.,

3-4 New Medical Equipment that Markets are expected to Arise for as a Result of Technological Improvements and Changes in the Market Environment

There is a great deal of expectation that new markets will be created in line with the arising of improvements in technology such as regenerative medicine, gene therapy, micro-machines and drug delivery systems (DDS). All these fields are being studied intensively at present, and it is expected that they will become fields with fierce competition.

Looking at the number of patent applications in the this fields, it can be seen that gene therapy, micro-machines and drug delivery systems (DDS) are fields where Japan is struggling to keep up with the U.S. and European countries, and there may be a large chance for foreign entry into these markets in the future (Japan Patent Office, *Survey on Trends in Patent Application Technologies*).

There are also a number of types of medical equipment that are presently being sold overseas but have not yet been brought into Japan, and there two major reasons for this.

First, there are items of equipment for which it has been judged that there is little need for, based on the current state of Japanese medical treatment. For example, in the case of organ transplants, while a market already exists in many overseas countries, the Japanese market has been judged as not yet having potential due to regulatory restrictions and ethical problems. In these cases, there is a chance the market may expand as regulatory reform is carried out.

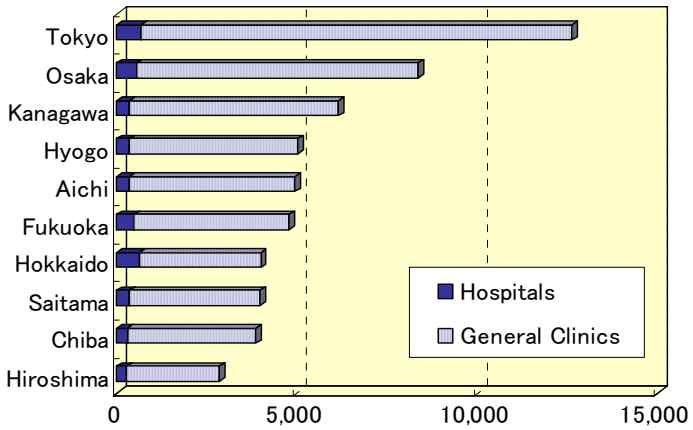
Second, there are items of equipment that are either slow coming into Japan, or are not coming into Japan as a result of problems gaining approval under the Pharmaceutical Affairs Law that result in the need for additional clinical trials. One example of this is the slow rate that new versions of equipment are released. In the case of pacemakers, it is said that devices that are three generations older than those in the U.S. are in the market in Japan. In interviews with foreign companies, the opinion was voiced that application for approval under the Pharmaceutical Affairs Law can not keep up with changes made to devices. It is hoped that these problems can be lessened with the advances being made in international harmonization of pharmaceutical approval that is being carried out at present.

4. The Japanese Market Environment for Medical Equipment

As of 2001, the total number of hospitals in Japan was 9,200, and the total number

of medical facilities including general clinics was about 100,000[3]. The total number of medical facilities has shown very little change from 1997 through to 2001. Figure 9 shows the total number of medical facilities by prefecture.

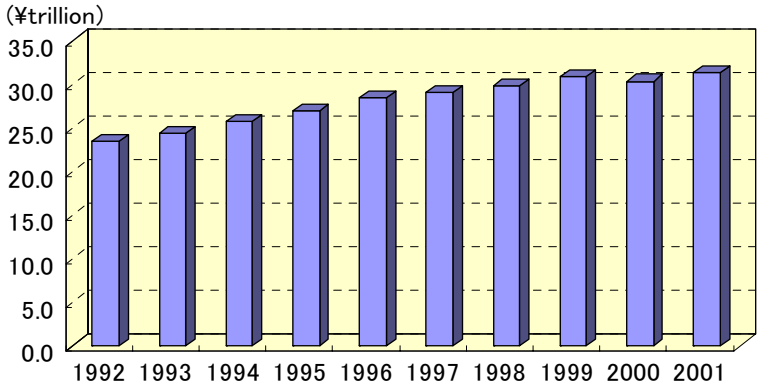
Figure 9. Total Medical Facilities by Prefecture - Top 10 (2001)



Source: Prepared based on data from the Ministry of Health, Labour and Welfare, *Survey on Medical Facilities*

The Japanese National Health Expenditure, as shown in Figure 10, continues to increase steadily, and reached 31 trillion yen in 2001. This shows that the Japanese healthcare market is steady and of considerable size.

Figure 10. Trends in the Japanese National Health Expenditure



Source: Prepared based on data from the Ministry of Health, Labour and Welfare, *Outline of National Health Expenditure 2001*

[3] A "hospital" is defined as a medical facility that has the capacity for 20 or more inpatients, while a "general clinic" is a facility that has an inpatient capacity of less than 20 patients, or no inpatient facilities at all. There are roughly ten times more general clinics in Japan than there are hospitals.

5. Future Markets

The Japanese market for medical equipment has reached a certain level of maturity and can be expected to maintain approximately the same market size in the future.

The import rate is comparatively low at present for diagnostic equipment. However, there have been examples of Japanese companies that have changed roles from manufacturers to retailers of imported items, and especially in the case of diagnostic imaging equipment, the market share of major multinational corporations is expected to increase.

In therapeutic equipment, judging from the high number of import permits being issued to foreign manufacturers and the number of permits being issued to foreign manufacturers in areas where technological advances are being made, it is expected that foreign manufacturers will continue to capture a large market share.

As the aging of the Japanese population continues to accelerate, it is expected that demand for artificial internal organ apparatus and assistive devices will increase. It is expected that the high import rate for these devices will continue in the future.

II. Legal Systems

Under the Pharmaceutical Affairs Law, medical equipment is required to receive in turn, approval, licensing and notification, and then application procedures for coverage under health insurance can be taken. A medical equipment item is then able to be used inside the framework of the National Health Insurance System[4].

1. Outline of the Pharmaceutical Affairs Law

The Pharmaceutical Affairs Law aims to improve the public health through creating necessary regulation to ensure the quality, efficacy and safety of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical equipment; and through implementing the necessary measures to ensure that research and development is carried out in medicines and medical equipment that particularly needed in medical care.

1-1 The Application and Approval System for Medical Equipment

115 types of medical equipment that are laid down under the Pharmaceutical Affairs Law Enforcement Ordinance (Distributed July 2002) are subject to regulation. The major regulations under the Pharmaceutical Affairs Law as of 2003 are laid out below.

1) Regulations on the quality, efficacy and safety of medical equipment

- Manufacturing approval per item

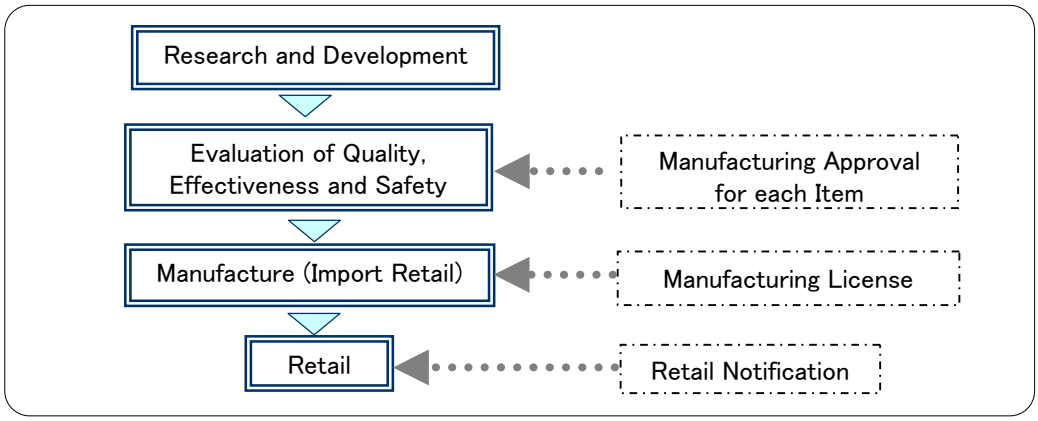
2) Regulations on the qualifications and requirements for operators handling medical equipment

- Licensing for manufacturers (import retailers)
- Notification for retailers

The relationship between the manufacturing and retail stages of medical equipment and approval/ licensing are shown in Figure 11.

[4] The National Health System in Japan is an all encompassing system, and the user must cover 30% of their medical costs by themselves (Refer to section II.2. for more details)

Figure 11. Relationship Between the Manufacturing and Retail Stages of Medical Equipment and Approval/ Licensing



(1) Approval for Each Item

Manufacturing approval for each item of medical equipment is given based on the efficacy and safety of that item of medical equipment.

Amongst medical equipment, while there are items in which a malfunction can have devastating consequences, there also items for which problems are of little consequence. Accordingly, approval screenings are classified according to the extent that the item being classified may impact the human body and procedures are based on this classification. For specific low-risk items, approval is not required.

(2) Manufacturer/ Retailer Licensing

Licensing for manufacturers (import retailers) is given to the factory (place of business) that will produce (import) the medical equipment for which approval has been received, and must be renewed every five years. There are however some changes to these rules that will be effected in April 2005. (Refer to section II.1-4 for details).

Licensing for the manufacturer (import retailer) is necessary for all items of medical equipment. There are some specific low-risk items for which notification by the retailer is not required.

Table 3 summarizes the approval, licensing and notification system for medical equipment.

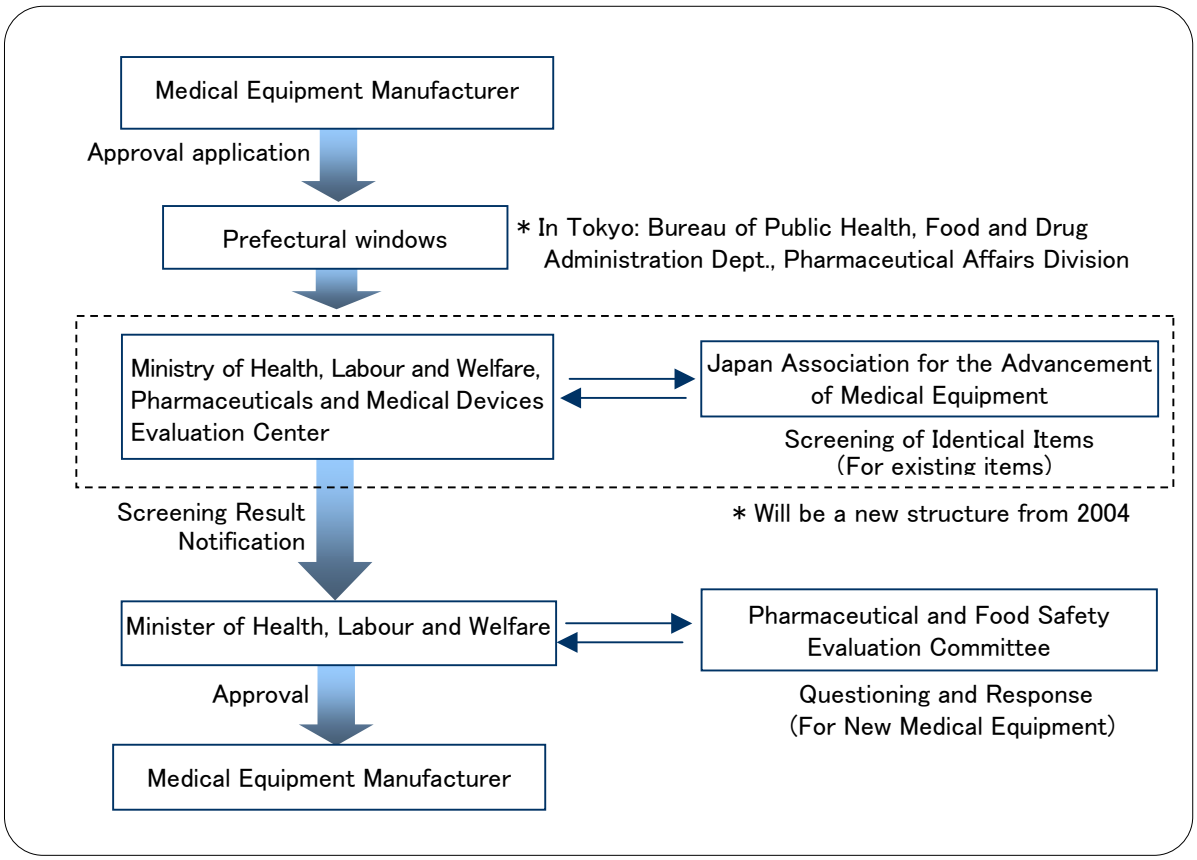
Table 3. Approval, Licensing and Notification System for Medical Equipment

Category	Medical Equipment in this Category	Items	Per Item Approval	Operator Licensing/ Notification	
			Manufacturer/ (Import Retailer) Approval	Manufacturer (Import Retailer)	Retailer
I	Equipment that is extremely unlikely to cause bodily harm in the event of a malfunction	External diagnostic equipment, copper tools, X-ray film	Approval not required	License required for each item	Notification not required
II	Equipment that is comparatively unlikely to cause bodily harm in the event of a malfunction	MRI, electronic blood pressure gauges, electronic endoscopes, gastral catheters, ultrasound diagnostic equipment	Ministerial approval required		Notification required (Submitted to the prefectural governor)
III	Equipment that is comparatively likely to cause bodily harm in the event of a malfunction	Dialysis machines, artificial bones, balloon catheters			
IV	Invasive equipment that could directly result in bodily harm in the event of a malfunction	Pacemakers, artificial cardiac valves, stents			

Source: Prepared based on data from the Ministry of Health, Labour and Welfare, *Reference Material for the Law to Revise Part of the Pharmaceutical Affairs Law and Bleeding and Blood Donor Supply Service Control Law*, July 2002

The flow for manufacturing (import retail) application and approval of each individual medical equipment item is shown in figure 12.

Figure 12. Flow of Approval Screening (Individual Item)



Note : Refer to section VI.5. for details on the application window for each prefecture
Source: Prepared based on the Pharmaceuticals and Medical Devices Evaluation Center Homepage

The following standard application processing times are laid down for medical equipment that requires approval.

Table 4. Standard Application processing Times for Approval Applications

Subject Medical Equipment		Standard Application processing Times
New medical equipment	Medical equipment that is obviously different from existing, approved equipment in terms of structure, method of use, efficacy, effect, performance, etc.	1 year
Modified medical equipment	Medical equipment that is not so different as to require a new screening process, but in terms of structure, method of use, efficacy, effect, performance, etc can not be said to be identical to existing, approved equipment.	1 year
Generic medical equipment	Medical equipment that is identical to existing approved equipment.	4 months

Source: Prepared based on the homepage of the Bureau of Public Health, Tokyo Metropolitan Government

(3) Measures to Ensure Safety of Biologically Derived Products

There are heavy expectations being placed on biologically derived products for their high efficacy, and it is viewed that the development of new products will be furthered by progress made in technology. On the other hand, one of the characteristics of biologically derived products is that contamination of primary materials could result in a risk of infection, etc., and there is a need to pay particular attention in this regard. Based on these points, in the 2002 revision of the Pharmaceutical Affairs Law, efforts were made to introduce a framework to ensure safety of these products.

Biologically derived products are defined as "those pharmaceuticals and medical equipment items that are manufactured using primary materials that derive from humans or animals (cells, organs, blood, etc.), and require special attention health-wise", and examples of medical equipment items that fit this definition are cadaveric dura mater, catgut sutures, cardiac valves, and pericardium patches.

1) Ensuring quality and safety in the primary material extraction and manufacturing stages (Ensuring safety of primary materials, security for requirements for facilities handling biologically derived products, record storage, contamination prevention devices)

2) Measures for appropriate usage of products (Appropriate labeling, provision of information, appropriate usage)

3) Completeness of security measures after market sales (Tracking donors/ users, regular infection reports)

1-2 International Comparison of Approval Application Systems

Table 5 presents an outline of the approval application systems in Japan, the U.S. and the E.U.

Table 5. Approval Application Systems in Japan, the U.S. and the E.U.

<table>
<tr><th>Category</th><th>Risk</th><th>Japan / Ministry of Health, Labour and Welfare</th><th>U.S./ FDA</th><th colspan="2">E.U.</th></tr>
<tr><td>Class I</td><td>Extremely Low</td><td rowspan="2">Manufacturing approval not required
Retail notification not required</td><td>Approval not required</td><td colspan="2">Approval not required</td></tr>
<tr><td rowspan="2">Class II</td><td rowspan="2">Low</td><td rowspan="3">Approval required</td><td rowspan="3">Third party approval system*</td><td>Practical screening only</td></tr>
<tr><td rowspan="2">Ministerial approval required for manufacture
Retail notification</td></tr>
<tr><td>Class III</td><td>Medium</td><td rowspan="2">Documentation screening performed</td></tr>
<tr><td>Class IV</td><td>High</td><td colspan="2"></td></tr>
<tr><td colspan="2">Approval system type</td><td>Manufacturing approval</td><td>Retail approval</td><td colspan="2">Retail approval</td></tr>
</table>

* Under the Standards Approval system etc., while the system is based on self-confirmation, there is a procedure in place that requires additional confirmation by a third party for products that are recognized as having a certain probability of causing harm.

Source: Prepared based on data from the Ministry of Health, Labour and Welfare, *Reference Material for the Law to Revise Part of the Pharmaceutical Affairs Law and Bleeding and Blood Donor Supply Service Control Law*, July 2002

Under the current system in Japan, it has been pointed out that there are no safety measures in place based on the possibility of bodily harm, there are insufficient safety measures in place after sales have been made, and that although in the U.S. and E.U., “retail approval” is standard, in Japan this is “manufacturer approval”. This was recognized in the revision of the Pharmaceutical Affairs Law in 2002 and was included into the reformed text (Refer to section II.1-4 for details on changes).

In this manner, there are facets of the approval application system in Japan that differ from those of other countries, but progress has been made with harmonization[5] of international approval applications, and data from clinical trials that were performed overseas can be used in applications in Japan.

However, in the current state of affairs, as described in a later section, even in the case of products that have received approval from the U.S. FDA, when applying for approval in Japan, a need to perform further trials can arise as the content of the approval granted by the FDA and the Japanese Ministry of Health, Labour and Welfare differ. It is pointed out that this reduces the time saving effect of implementing harmonization in the first place. It is believed that this situation will improve in turn with the further development of international harmonization.

1-3 Actual State of Approval Applications

Through interviews with manufacturers, we were able to ascertain that foreign companies were having more difficulties with approval applications in comparison with domestic companies.

For example, there are cases where the approval procedures are not completed inside the standard processing period, and took up to twice the usual time.

As for international harmonization, while system-wise the use of clinical trial data from overseas is possible, in actual fact there are few cases where such data can be used. Reasons for this include the fact that risk categories (Table 3) for medical equipment differ from country-to-country and so required trials are different, and the fact that the types of data required is different from in each country.

Due to the delays that occur in receiving approval, there are types of equipment for which the items on the market are several generations behind those on the market in the U.S., and opinions were expressed that this can become a large drawback for patients.

In addition, it is said that there has been a recent tendency for more data to be

[5] The process of creating an environment that allows approval application data from other countries to be used mutually and speeds up the approval application procedure.

required for applications that ever before. From the point of view of ensuring the safety of medical equipment, which is one of the aims of the reform of the Pharmaceutical Affairs Law, this tendency is likely to increase in the future. When firms enter the market by creating a Japanese subsidiary, they are able to gain data from their parent company, but in the case of import retailers, there is no assurance that they may receive clinical trial data from overseas manufacturers on grounds of confidentiality, and the approval application process can be a large obstacle for firms.

1-4 Content of the Revision Planned to be Enforced in 2005

The Revised Pharmaceutical Affairs Law that was issued July 31, 2002, is coming into enforcement step-by-step from 2002 to 2005. We cover the content of this revision that is planned to be enforced by 2005.

Under this revision, a radical review of the safety measures in place for medical equipment, enhancement of after-sales safety measures and a review of the approval/ licensing system were carried out. The current system of approving the manufacturing of equipment itself was changed, and the system was changed to approval of the act of manufacturers placing goods on the market (Manufacturing/ retail approval).

As a whole there is tendency to reduce regulations on those products with a low risk factor, and strengthen regulations on high-risk items.

(1) Business Licensing and Notification

A full review of the safety measures on place for medical equipment was carried out in order to “Strengthen safety measures in the retail and lending of medical equipment”.

In light of the need to further pursue safety measures in the retail and lending of medical equipment, the current law was changed. For the retail and lending of medical equipment that required notification to prefectural governors, the law was changed to require that a license be obtained fro the prefectural governor for high-risk equipment and for medical equipment requiring expert knowledge for maintenance (Refer to section II.1 for details about the system before the revision).

Further, the following provisions were included into the law for the enhancement of after-sales safety measures and a review of the approval/ licensing system.

1) Shift from licensing of the manufacturer to licensing of the manufacturing retailer
   (Separation of the “act of manufacturing”, and the “act of placing on the market”)
2) Combination of retail importers with manufacturers (“Import Retailers” abolished)
3) Approval of manufacturing related facilities

Accordingly, the regulations on licensing and notification for operators will be the following three types.

- Manufacturing license (Specific to manufacturing)
- Manufacturing retail license (Focusing on market responsibility and after-sales safety measures)
- Retail notification/ license

The licensing for manufacturing retailers will be divided into three categories.

1) General medical equipment
2) Monitored medical equipment (Requiring monitoring)
3) Highly monitored medical equipment (Requiring strict monitoring)

Licensing for manufacturers will change from the current structure of licensing for each individual item, to licensing for each of the following four product categories.

1) General
2) Sterile medical equipment
3) Cellular tissue medical equipment, etc.
4) Packaging, labeling, storage

(2) Approval for Individual Items

The following provisions were included into the revised law as a radical review of safety measures.

1) Introduction of a classification category based on the risk level of medical equipment
2) Introduction of a third party certification system for low risk medical equipment

With the revisions described above, the approval, licensing and notification system for medical equipment shown in Table 3 becomes that shown in Table 6 below.

Table 6. Approval, Licensing and Notification System after Revision of the Pharmaceutical Affairs Law

Category	Risk*[1]	Items	Per Item Approval	Operator Licensing/ Notification		
			Manufacturing retail regulations*[2]	Manufacturer	Manufacturing Retailer	Retailer
General medical equipment	Extremely low Class I	External diagnostic equipment, copper tools, X-ray film	Approval not required	Licensing for each of the following four categories 1) General 2) Sterile medical equipment 3) Cellular tissue medical equipment, etc. 4) Packaging, labeling, storage Note 1,2,4) licensed by prefectural governors, 3) by the Minister of Health, Labour and Welfare	License required from the Minister of Health, Labour and Welfare in each category*[3]	Notification not required
Monitored medical equipment	Low Class II	MRI, electronic blood pressure gauges, electronic endoscopes, gastral catheters, ultrasound diagnostic equipment	Third party certification system		As above	Notification required to be submitted to the prefectural governor*[4]
Highly monitored medical equipment	Medium Class III	Dialysis machines, artificial bones, balloon catheters	Approval required from the Minister of Health, Labour and Welfare		As above	Notification required to be submitted to the prefectural governor
	High Class IV	Pacemakers, artificial cardiac valves, stents				

Notes *1: Risk to humans in the case of a malfunction (Corresponds to categories I to IV)

*2: Manufacturing retail: The act of shipping and placing a product on the market (Primary distributor). Existing import retailers are included in manufacturer retailers.

*3: The licensor is expected to be set down as the individual prefecture in all or some cases in a government ordinance at a later date.

*4: Amongst monitored medical equipment, medical equipment requiring special maintenance will come under a licensing system in the same manner as for highly monitored medical equipment. The application windows for each prefecture are given in Section VI.5.

Source : Prepared based on data from the Ministry of Health, Labour and Welfare, *Reference Material for the Law to Revise Part of the Pharmaceutical Affairs Law and Bleeding and Blood Donor Supply Service Control Law*, July 2002

About Approval for Products Manufactured Overseas

In accord with the content of the revisions detailed above, the "in-country caretaker" system that required a domestic company, etc. to act as proxy for a foreign manufacturer making an approval application will be abolished.

In future, this management will be carried out by a manufacturing retailer with domestic approval appointed by the manufacturing retailer (an operator that has the correct

license the correct license for manufacturing retail required for the type of product aiming to receive approval.) It will no longer the registration of an in-country caretaker separately.

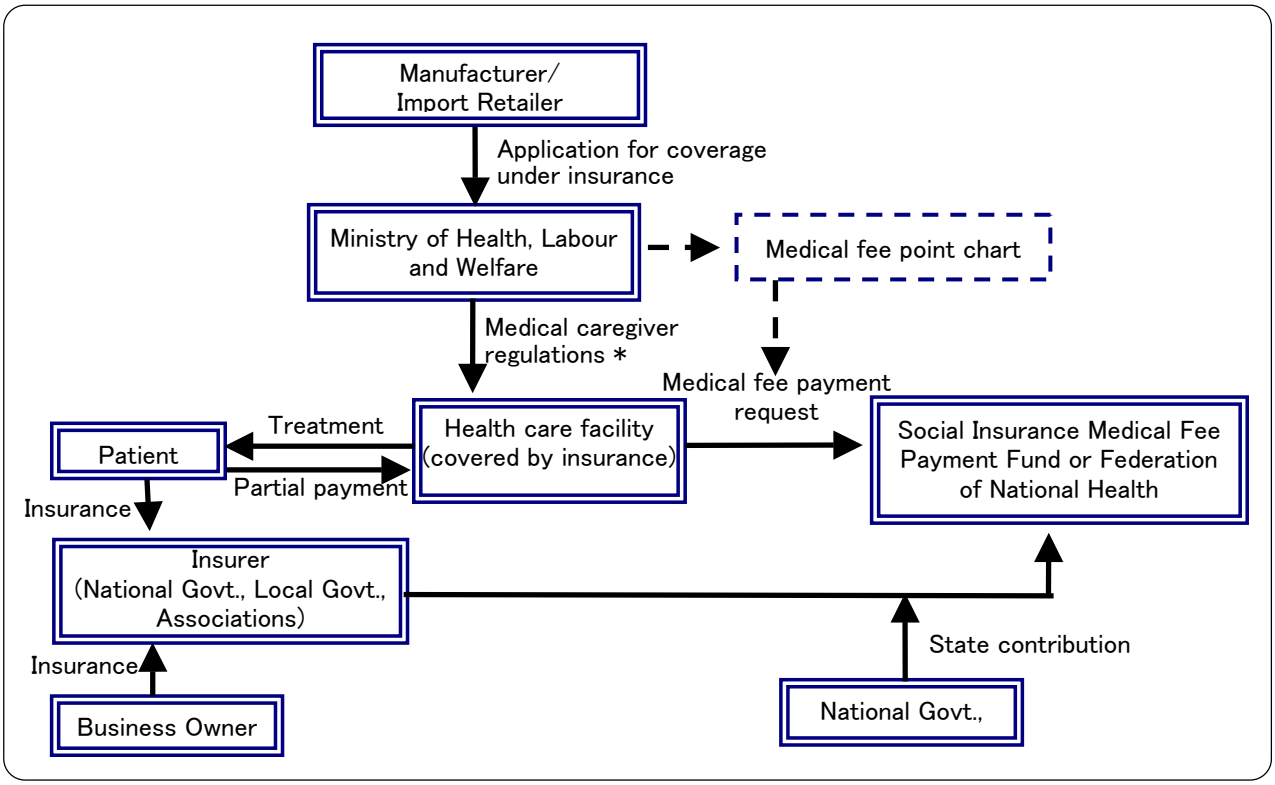
2. Medical Care Insurance System

2-1 Medical Fee System

In Japan, the public pays insurance premiums into a public health insurance system, and can receive health care at any medical facility in the country providing insurance-covered care (universal medical care insurance system). Under this medical care insurance system, the reimbursement for medical care provided is the medical fees that are paid by the insurer (national government, local government, unions) to the medical treatment facilities and pharmacies. The details of which items are covered under the medical fee system are reviewed approximately once every two years by the Council on Medical Insurance Welfare.

The structure of the medical fee system is displayed in Figure 13.

Figure 13. Structure of the Medical Fee System



Note : Those medical facilities that perform treatment covered by health insurance are required to provide medical care according to the method proscribed in the Health Insurance Law

Source: Prepared based on data The Japan Federation of Medical Devices Associations, *Medical Devices and Healthcare Insurance*, August 2000

Medical Fees for medical equipment are paid as a technical fee for treatment, and a set price for the medical equipment itself (certain items only).

In the reform of the medical treatment material system for treatment covered by insurance that was carried out from 2000 to 2002, the establishment of an appropriate method for calculating prices of medical treatment materials was a major issue, and the handling of medical equipment under the healthcare insurance was reformed as follows.

- With exceptions for only a few items, the insurance reimbursement for medical treatment material was changed to a system based on prices set according to functionality category, and the previous system of purchase price payouts from prefectures (in effect, the purchase prices were being refunded to medical institutions as insurance reimbursement) was abolished.
- For materials where there was a large price gap with overseas prices, adjustment was performed
- Regulations were implemented to deal with "Medical equipment requiring special method of calculating medical fees"

The results of these reforms and the handling of medical fees for medical equipment are categorized in the following table.

Table 7. Assessment of Medical Equipment in the Medical Fee System

Category			Medical Equipment Examples
Assessed included in the technical fee	Assessed at an average rate and included in the technical fee	Relatively inexpensive materials that are used frequently	Tubes, sutures, disposable syringes, gauze, elasticized bandages, certain catheters, etc.
		General fixtures and fittings used in medical institutions	Medical equipment not in the list above (that is not medical equipment requiring special method of calculating medical fees)
	Assessed as Medical equipment requiring special method of calculating medical fees	Assessed included in the technical fee	Electro-cardiographs, ultrasound therapy equipment, MRI equipments, artificial respirators, intraocular implants, lithotriptors, anesthesia apparatus
		Assessed added on to the technical fee	Oxygen supply devices, microwave surgical instruments
Assessed separately from the technical fee	**Equipment for which an insurance reimbursement price is set down in the material price standards**		Dialyzers, film, pacemakers, artificial joints, catheters, etc. (291 areas, 797 categories as of April 2002)
	Equipment for which a material price standards is not set down as is detailed as "the purchase price paid by the medical institution performing insurance covered work"		Artificial joint materials, custom made artificial joints and custom made artificial bones, etc. (4 areas, 8 categories as of April 2002)
Not covered by insurance	Medical equipment that has not yet been assessed under the health care insurance system, and is not commonly used is not listed in the medical fee scale		Equipment used in Highly Advanced Medical Technology treatment

Source: Prepared based on data The Japan Federation of Medical Devices Associations, *Medical Devices and Healthcare Insurance*, August 2000

Examples of the insurance reimbursement prices for common medical equipment items under the material price standards are given below (as of October 2003).

Dialyzer (Except special stacked models)	Approximately 3,000 yen
PTCA balloon catheter	200,000 ~ 220,000 yen
Pacemaker	1.3 ~ 1.6 million yen

As mentioned previously, medical fees are revised roughly every two years, and in 2002, a review of medical fees for expensive medical equipment was carried out. Due to the fact that the market price for MRI machines had dropped in line with market growth, and that the price per screening differential with CT scans had decreased, the simple screening fee for MRI equipment was reduced by 30%.

2-2 Procedure to Receive Insurance Coverage

In order for medical equipment used in treatment to be eligible to receive medical fee payment, that equipment must be covered by insurance. In order to receive coverage, after approval has been applied for and received for an item of medical equipment, an application for insurance coverage must be made, and the insurance coverage screening process of the Ministry of Health, Labour and Welfare must be passed through.

(Previously, there was a column to select the insurance coverage category on the form used to apply for approval under the Pharmaceutical Affairs Law, but as of March 18, 2003, a separate application using the “Insurance Coverage Request Form” must be made.)

2-3 International Comparison of Health Insurance Systems

A universal medical care insurance system was introduced into Japan in 1961, and citizens are required to enter some form of public health insurance system. In general, users pay 30% of treatment costs and can receive treatment at any medical institution. There are insurance systems in foreign countries that are not available for all citizens, or restrict which medical organizations are available for treatment, etc.

In the U.S., there is no public health insurance system that covers the general population. The elderly, disabled persons and low-income earners are able to join the public health insurance schemes Medicare, Medicaid, but other people are required to join private health schemes on their own behalf.

In the U.K., there is the National Health Service (NHS) which covers the general

population, and as a rule treatment is free. However, users must receive their initial treatment from a specified general practitioner, and are not allowed to freely choose which medical institute they use as in Japan. The system allows users to gain an introduction to specialist hospital when required after first visiting their general practitioner.

III. Business Practices and Business Models in the Medical Equipment Industry

1. Business Practices

1-1 Distribution Patterns

The Japanese medical equipment industry has a unique distribution pattern as shown in Figure 14.

Only a very small percentage of equipment is sold directly from manufacturers and import retailers to hospitals, the final users. Most common is the retail pattern in which sales are made via medical equipment dealers (agents, retailers). There is a tendency for large, high-priced equipment to be sold directly more, and smaller equipment and supplies to be sold more often via dealers.

Further, in regional areas, manufacturers can not provide supplies as easily as in urban areas, and accordingly dealers are involved more in outlying areas.

It also appears that it is common for direct sales to be made to national government and local public bodies.

Figure 14. Distribution Patterns for Medical Equipment

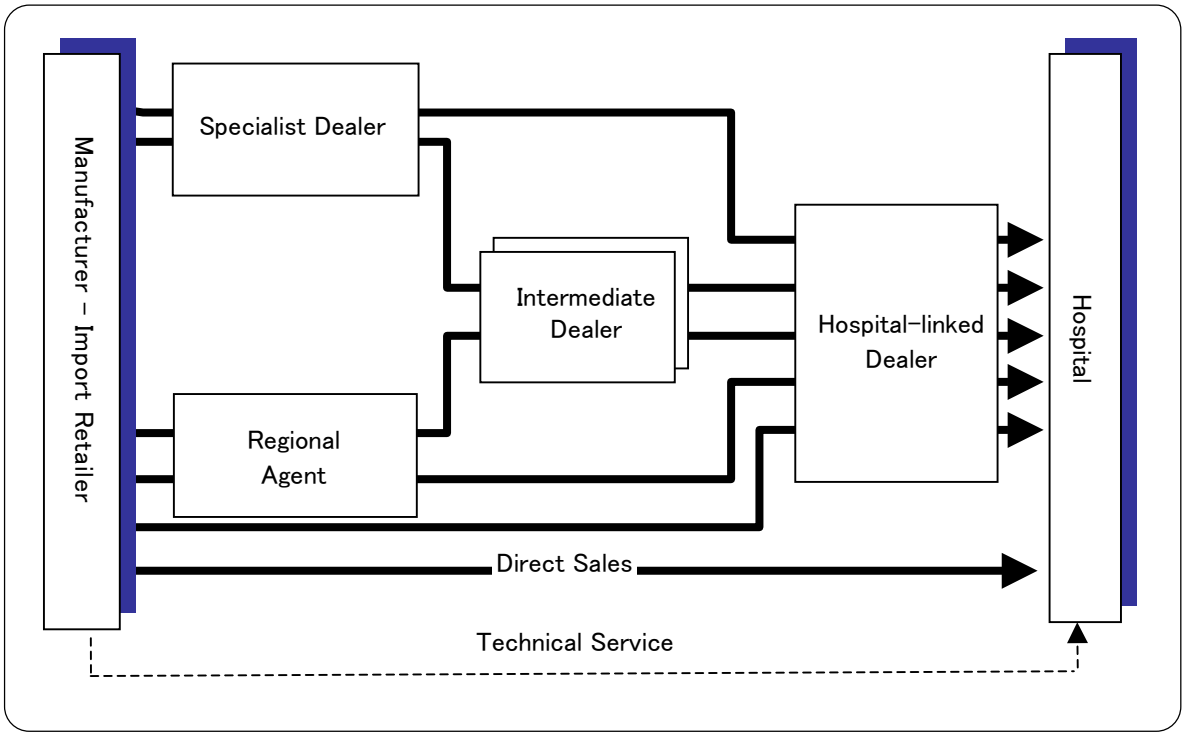
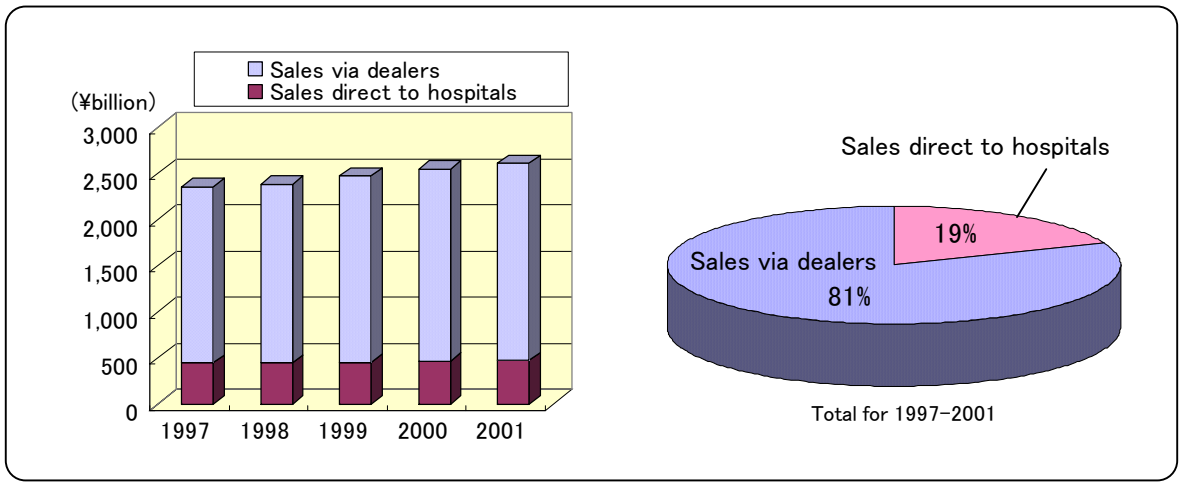


Figure 15 gives market size for each retail route. It can be seen that the market is a unique one where about 80% of sales are made via dealers.

Figure 15. Market Size by Retail Route



Source: Prepared based on data from R&D Corp., *Medical Equipment/ Supplies Yearbook 2003*

1-2 Medical Equipment Dealers

As mentioned previously, it is common for dealers to play an intermediary role in the distribution of medical equipment. There are no accurate estimates of the number of medical equipment dealers. There are more than 300,000 companies that have submitted notification to act as a medical equipment retailer, but it is estimated that only several thousand companies are active in the market.

In general, hospitals try to buy all their medical equipment through one specific dealer, and so sales of medical equipment are usually required to go through a “hospital-linked dealer”. As there is a huge number of medical equipment that is needed in each hospital, if a hospital was to deal with each manufacturer individually, the necessary paperwork would be a large burden. In order to avoid this burden, many hospitals specify a specific dealer as their contact point. As a result, manufacturers market their products directly to hospitals, but sell them via dealers.

This is one of the unique business practices of the Japanese market, but it does have the benefit for manufacturers that they are able to use the market information and retail network of the dealers to their own benefit. Hospital-linked dealers visit their hospitals almost daily, and know the market very well. Further, it is very difficult for manufacturers to grasp the conditions in medical facilities throughout the country by themselves, and dealers, especially in regional areas play a large role in this area. For manufacturers, educating dealers is an

important part of their business activities. Programs that manufacturers have implemented to increase sales by dealers include setting margins based on sales targets, and study sessions on product characteristics.

As dealers mainly stick to one region, most manufacturers have dealers that they trade with in each region. In each prefecture, there are many cases where 2 or 3 prominent dealers exist, and when newly entering the market, it is very important to team up with an influential dealer.

In addition to general dealers that handle all varieties of products, there are also specialist dealers that handle cardiac related items (artificial heart lung-machines, catheters, pacemakers) and dialysis related items.

1-3 Market Price Characteristics

In general, the market price of medical equipment is high when compared to prices overseas. While this price gap between overseas and domestic prices has been pointed out for several items including pacemakers, and corrective measures have been made, the Japanese market remains one with higher profit margins than overseas markets. Reasons for these high market prices include the characteristic distribution practices in which an intermediary margin is taken by dealers, and the breadth of technical services that are required of manufacturers. Further, a price war resulting in decreasing prices is likely to happen with goods being sold directly by manufacturers, but prices are likely to remain high when sales occur via dealers.

On the other hand, the market price for diagnostic imaging equipment is lower in Japan than overseas. Reasons for low prices are the fact that most of these items are sold directly to hospitals, and insurance reimbursement prices are low for these items. Further, for large imaging equipment, while the list price for items is often several hundred million yen, the market price is often one ten of this, and it can be said that this is an industry where the market price can be very difficult to grasp accurately.

The average market price in Japan calculated on data from 2001 is 35 million yen for a superconductor MRI, 1.2 million yen for general ultrasound diagnostic imaging machine, and about 1 million yen for an implanted cardiac pacemaker.

1-4 Inventory Control and Distribution

(1) Commissioned Inventory System

The commissioned inventory system involves placing a large inventory of products

with a hospital or hospital-linked dealer and only charging them as they use the products.

This system is only used for products that may be required urgently, or have finely stratified specifications (artificial joints, pacemakers, high-performance catheters, etc.) As the inventoried stock is the property of the manufacturer, manufacturers would prefer not to use this inventory system, however they do allow limited use of it when requested to by hospitals.

(2) Supply Processing and Distribution System (SPD)

A SPD system attempts to manage medical supplies by centralizing and outsourcing the supply, processing and distribution of products.

Attempts to introduce SPD have been seen in the medical market since around 1990, but at present it is only used by 7% of suppliers, and is not very popular.

(3) Supply Joint Purchasing System

Joint purchasing is a system where a number of hospitals join together to but a large amount of products at one time from a single deal and buy the products at a cheaper rate.

1-5 Technical Services

(1) Support Using Equipment (Including during Operations)

In many cases, the purchasers of equipment request that manufacturers are present when the equipment is first used.

Especially for pacemakers, manufacturers are asked to be present for the implant surgery, and for post-operation follow-ups (battery checks, operation checks, etc.). As the attendee may operate the device on the instruction of a doctor, a medical engineer is a requirement. The attendee is either a sales or technical representative of the manufacturer or dealer (that has the required training). It is usual for a representative to be present for the actual operation in the U.S. as well.

(2) Training Services

In accompaniment to sales of equipment, training to teach how to use the equipment is also provided. Many manufacturers hold study meetings in their own training centers for doctors (users), sales representatives and dealers.

In the U.S., training is viewed as a legitimate medical cost, and there is no resistance to hospitals paying for training. However, in Japan such a system does not exist, and there is awareness that training expenses (training for doctors and technicians) should be borne by the manufacturers.

(3) Maintenance Services

For large equipment, there are cases where yearly contracts are concluded for maintenance, but most contracts for medical equipment are spot contracts where maintenance is carried out when required. However, in light of the relationship with their customers, it is difficult for manufacturers and dealers to charge for this maintenance, and much of it is performed free of charge by manufacturers and dealers. For this reason also, manufacturers like to perform user training as much as possible to allow users to carry out maintenance themselves.

1-6 Other Free Services

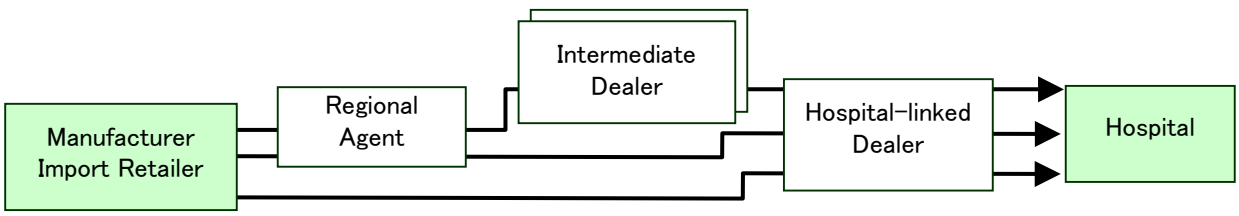
It has been pointed out that there has long been a trend in the medical industry for excessive services to be performed by manufacturers. However, in the medical equipment industry, fair trading regulations were created in 1998, and free services that accompanied sales became subject to scrutiny. This outlawed many free services, and the number of services provided by manufacturers and dealers decreased severely.

For example, restrictions were placed on donations to academic societies, creation of slides for presentations, paying for travel expenses and arranging for hotels and other enticement activities.

2. Business Models

There are three general business models for medical equipment, sales through general dealers, sales through specialist dealers, and direct sales.

2-1 Sales Through General Dealers



Dealers can be categorized into specialist dealers that handle cardiac related items (artificial heart lung-machines, catheters, pacemakers) and dialysis related items and general dealers that handle all varieties of products. Except for large, high-priced equipment such as MRI that is usually sold direct, and equipment that is sold via specialist dealers, most products are sold via general dealers.

Sales routes pass not only through the hospital-linked dealer, but in some cases also through regional agencies and intermediate dealers. Sales routes are not based on the product being sold, but more on the circumstances of the hospital or dealers.

(1) Hospital-linked Dealers

As hospitals tend to purchase their medical equipment through one specific dealer, sales to hospitals are usually made through this dealer. Even in cases where manufacturers carry out sales activities and negotiations with the hospitals, the sales routes pass through the hospital-linked dealer.

There are cases where a hospital deals with not one hospital-linked dealer, but different dealers for different types of medical equipment or different wards. Accordingly, there are cases where the same manufacturer or import retailer that sells several products to a hospital will need to go through several different sales routes.

(2) Regional Agents

In the cases of sales in regional areas, often manufacturers/ import retailers can not perform sales as easily as in urban areas, and they use regional agents as their sales points.

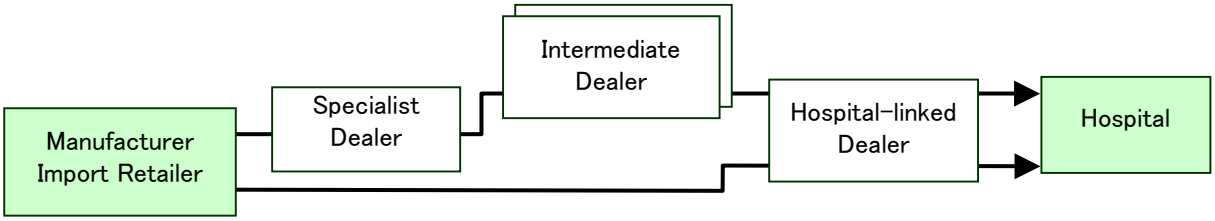
As regional agents usually closely linked to their region, and there are no agents working on a nation-wide basis, it is necessary for manufacturers/ import retailers to deal with an agent in each region. There are many cases where manufacturers deal with a different agent for each prefecture.

(3) Intermediate Dealers

It is usual for two companies to exist in the sales route between manufacturers/ import retailers and hospitals, but there are cases where another one or two companies intervene in the sales route. The reason for the existence of these intermediate dealers is often not clear, and there are manufacturers that do not completely understand what dealers exist.

This existence of intermediate dealers is unique to Japan, and according to sales representatives of foreign companies, it is difficult for them to explain this distribution pattern to representatives in their home country.

2-2 Sales Through Specialist Dealers



Cardiac related items (artificial heart lung-machines, catheters, pacemakers) and dialysis related items are sold through their respective specialist dealers.

The same conditions exist with regards to hospital-linked dealers and intermediate dealers as does for general dealers.

2-3 Direct Sales

Direct sales are performed mostly for large, high-priced equipment (MRI, nuclear medicine related apparatus, etc.). As the number of sales is low, there is little merit for dealers to enter this market. For other medical equipment, there are cases where direct sales are performed as part of a sales strategy, but as the number of sales increases, often sales are directed through dealers with better local roots in order to decrease selling and delivery costs.

IV. Examples of Market Entry by Foreign Companies

1. Entry Style

1-1 Entry by Establishing a Japanese Subsidiary

Many foreign companies that have gained a large share in the medical equipment market have established a Japanese subsidiary. It appears that a common pattern is to first conduct sales via an import/ retailer in Japan, and then establish a Japanese subsidiary after market demand has been confirmed and distribution routes established to a point.

As described later, it is believed that establishing a Japanese subsidiary is the most effective way to meet the detailed product requests from the Japanese market and to establish level of trust in technical and maintenance services similar to domestic manufacturers.

Examples of foreign firms that have set up Japanese subsidiaries are given in Table 8.

Table 8. Japanese Subsidiaries established by Foreign Medical Equipment Manufacturers

Company Name	Year Established	Major Products
Baxter Limited	1969	Dialysis related products, artificial cardiac valves, cardiac catheters, etc.
Medtronic Japan Co., Ltd.	1975	Cardiac pacemakers and related item, etc.
Zimmer K.K.	1975	Artificial joints
Johnson & Johnson Inc. (Medical Company)	1978	Stents, catheters, etc.
Japan Lifeline Co., Ltd.	1981	Cardiac pacemakers, implanted defibrillators, catheters, etc.
Phillips Medical Systems Japan Corp.	1987	MR Equipment, X-ray diagnostic devices, ultrasound imaging devices, monitoring systems, etc.
Boston Scientific Japan K.K.	1987	Catheters, endoscopes, etc.
Guidant Japan K.K.	1994	Stents, catheters, implanted defibrillators
Nihon Mathys K.K.	1994	Artificial joints
Stryker Japan K.K.	1998	Artificial knees, artificial hips, artificial shoulders and other implant products

Note : Year of foundation for companies that have changed name.
Source: Prepared based on data from individual company homepages.

Most Japanese subsidiaries gain market share by selling products produced by their parent companies, but there have been examples such as Boston Scientific Japan and Baxter

that have increased their product range through merger and acquisitions.

For example, Boston Scientific Japan has acquired and absorbed many companies with promising products beginning with SciMed Life Systems in 1995, and has grown to be a company with yearly sales of over 60 billion yen.

1-2 Other Ways of Market Entry

While establishing a Japanese subsidiary is the most common method of entering the Japanese market, there also methods such as:

- Joint Venture
- Merger and Acquisition

A typical example of market entry thought a joint venture is GE Yokogawa Medical Systems.

Originally, GE had signed an agency agreement with Yokokawa Electric for the sale of CT equipment. Later, in 1982, a joint venture company (GE Yokogawa Medical Systems, Ltd.) was established, and GE entered the market in full-scale.

An example of market entry through acquisition is the purchase by St. Jude Medical Inc. in April 2003 of the major import/ retailer Getz Bros, making it a 100% subsidiary. It can be said that by absorbing the import/ retailer, St. Jude Medical has acquired distribution routes in Japan.

2. Analysis of Market Entry Examples

2-1 Background to Market Entry

Major reasons that foreign companies entered the Japanese market are given below.

(1) The Japanese market is large; it is a market with high margins.

The Japanese market for medical equipment accounts for roughly 15% of the worldwide total, and is of such a market size that it can not be ignored by global companies.

Further, prices are high in Japan compared with overseas, and the market is attractive as one with high profit margins. High prices in the Japanese market are acknowledged as a problem, and price adjustments are underway. However, there are still large price differences with overseas.

(2) Stable medical economy

Health care in Japan is supported by a stable health care insurance system, and it is a market where payment for equipment supplied can definitely be recovered. Overseas, there are cases where payment can not be recovered, but Japan is a stable market, and there is almost no worry of this occurring.

(3) Lack of rivals for new products

While depending largely on the device in question, there is little development of leading-edge technology being carried out in Japan, and when introducing revolutionary devices into the Japanese market there is a good chance that there will be few rival firms.

2-2 Keys to Success Seen in Market Entry Example

(1) Accurate forecasting of growing needs in the health care market

In the case of therapeutic equipment manufacturers, Company “A” and Company “C”, forecasting growing needs in the Japanese health care market was a key to success. They were able to introduce equipment that matched needs arising from the trend for less invasive treatment and the increase in cases involving an aging population and lifestyle-related diseases.

(2) Introducing products new to the Japanese market

Company “A” actively introduces leading-edge technology into the market, and has strategically dealt with products new to the Japanese market. In this case, there is a great deal of interest in new medical equipment in use overseas from Japanese doctors, and sales will often be gained through approaches from hospitals. Accordingly, there is sometimes no need to be troubled with building up a sales network. Also, for new products, a 100% share of the market can be had.

Companies that handle leading edge products also place an emphasis on providing users with technical information and information from overseas.

(3) High-level technical expertise and a powerful brand

Company “B” and Company “D” that have a high share in a certain field both have a very high level of technical expertise. Their key to success was that they were able to bring the specialist technology of their parent companies into Japan. By providing stable products based on a high-level of technical expertise, these companies were able to gain trust from the market, and are now a fixture in the market.

Further, Company “B” tied-up with a Japanese company with a high-level of technical expertise in order to enter the market, and this was one of its keys to success. They development team of the tie-up company has developed at least one of the core products of the company.

(4) Management that understands the Japanese market

Many companies believe that having management that understands the characteristics of the Japanese market is key to entering the Japanese market successfully. Many Japanese subsidiaries of foreign companies even now have time getting their parent companies to understand the actual conditions in the Japanese market. There are many characteristics of the Japanese market that arise from Japanese culture and its national character, and it is said that having management that understand these issues can be a short-cut to success.

(5) Manufacture in Japan

Company “B” not only sells imported items, but also manufactures items in Japan. This is one of the points that differs vastly with its competitors, and can be though of as one of its keys to success. As it has a domestic manufacturing base, it naturally employs Japanese engineers and can swiftly answer technical questions from users. Conversely, for enterprises based on imports, it is believed that there would be issues that could not be resolved without first contacting the manufacturer.

(6) Business based on disposable items

Company “A” has strategically focused on disposable items. Machines require maintenance after sales, and for this there is a need to set up maintenance bases or sign maintenance contracts with dealers. Company “A” viewed this maintenance procedure as being an area with little room for profit, and has found success by focusing on disposable items.

(7) Creating a favorable relationship with dealers

Foreign companies that have entered the Japanese market recognize that building-up a favorable relationship with dealers is very important, and it is not going too far to say that this is an essential task for companies wishing to enter the market.

For example, if deals are made that ignore profit margins for the dealer and that dealer decides to cut ties, then there is a chance that sales can no longer be made to those hospitals serviced by that dealer. Also, even in the case of dealers not currently under contract, if a company encroaches on that dealer’s territory and performs sales, difficulties may be faced

if the need to deal with that dealer arises at a later date.

In other words, it is believed that dealing with dealers in a manner that emphasizes daily trust and building-up a good relationship are vital.

2-3 Issues for Market Entry by Foreign Firms

(1) Very detailed product requirements demanded

Doctors and other medical professionals in Japan give very detailed product requirements compared to overseas, and often changes in shape and feel are requested. Further, the build and physical attributes of Japanese differ to Westerners, and some equipment requires changes to be made for use in Japan. This tendency is particularly high for therapeutic devices that are implanted inside a patient's body.

However, there appear to be many Japanese subsidiaries that have trouble explaining this situation to their parent company.

(2) Government regulation (Pharmaceutical Affairs Law approval)

A number of foreign companies feel that receiving approval under the Pharmaceutical Affairs Law is a large obstacle to market entry. It is felt that acquiring approval takes a long time in Japan, and there has been an example recently of where a leading edge item of medical equipment took almost two years to gain approval. Further, while clinical trial data from the U.S. can be used in applications in Japan, the content of the approval granted by the FDA and the Japanese Ministry of Health, Labour and Welfare differ, and a need to perform further trials can arise, leading to an eventual lengthening of the time required for approval.

These regulations are obstacle to entry, and there are many leading-edge products around the world that have not yet been introduced into Japan. Opinions have been expressed that this is a large negative from the point of view of patients as well.

(3) Trade practices unique to Japan

It is believed that for new entrants into the Japanese market, building-up new relationships with dealers can be a difficult process. When the products being introduced into the market are new medical equipment items and users are requesting such products, often there will be dealers coming asking to do business, but in the cases of generic products entering the market later, companies must find dealers for each region and this can be large burden on companies.

V. Advice for Market Entrants

1. Development of Products Aimed at Japan

In order to enter the Japanese market, it is extremely important to understand not only the business practices of the medical equipment market, but also the characteristics of the Japanese.

As mentioned previously, due to the detailed specifications demanded by Japanese doctors and differences in build and physical characteristics of the Japanese, there are some medical equipment items that require revisions to be made. In particular, this trend can be seen in therapeutic equipment that is implanted into the body.

Payment for medical treatment performed using medical equipment is a fixed amount made set down for the technical part and the equipment part of treatment (Refer to Section II.B.1). In other words, whether revisions are made to machines or not, the same amount is paid for machines that are of the same sort, and accordingly detailed specifications are requested in Japan.

However, it is not an easy task to produce products specifically for the Japanese market, which account for between ten and fifteen percent of the global market. Also, it is difficult to get parent companies to understand these characteristics of the Japanese market, and some Japanese subsidiaries of foreign companies modify standard products in Japan. Even when changes made to products are not significant clinically, it is important to be able to deal flexibly with the needs of Japanese users. The more competing products there are in a market, the more effective meeting user's needs can be in achieving differentiation in the market, and capturing a larger market share.

In the case of angiographic catheters for example, there are many types exist with different shapes, widths and materials, and order-made products are also common. In this case, a wide product range and the ability to meet the user's needs in detail can lead to a competitive edge for the manufacturer.

2. Securing Distribution Channels

Securing distribution channels is a major issue for new foreign market entrants. In contrast to well-known Japanese companies, hospitals may not be willing to accept direct sales approaches from new foreign market entrants.

The first step in securing distribution channels is to introduce one's products to a

major dealer in the region targeted for market entry, and conclude a sales partnership. The next step is to develop and educate dealers that meet your company's requirements.

For detailed information on dealers refer to the sources listed in Section VI. 6.

3. Dealer Education

In the sales of medical equipment, a manufacturer's relationship with its dealers is of prime importance. As manufacturer's sales representatives are in responsible for dozens of hospitals, they are only able to visit such hospitals an average of once a week. In contrast to this, hospital-linked dealers visit their hospitals almost daily.

In general, the sales and technical representatives of manufacturers carry out sales negotiations and technical services, while dealers are in charge of sales and delivery. Educating dealers (providing incentives, inputting technical information, etc.)– who are in a much closer position to the customers – is a most import and effective way to increase sales. Especially in the case of products with competing products, educating dealers is extremely important.

4. Building-Up After-Service Bases

It is important to create a base for after-service in Japan that can respond promptly to a range of requests and enquiries. As to be expected of medical equipment, the reliability of a manufacturer and its products is extremely important.

In Japan, in the case of a breakdown or other trouble, it is customary for an engineer or dealer to visit immediately and perform repairs or part replacement. For this reason, it is necessary to have bases in each region, and creation of a dealer network is important.

Also, as mentioned previously, Japanese doctors demand more detailed specifications of products than overseas, and it is said that complaints are more likely to happen. There are cases where items with the same specifications do not receive any complaints overseas, but will receive complaints in Japan. It is necessary to create a support system that can deal with this kind of complaints.

Also, to ensure that responding to doubts from customers of such a nature as "might the company quit Japan", or "are imported products to be trusted" is carried out promptly and replies are not made from overseas, it is necessary to establish a substantial base in Japan.

5. Facilitating Pharmaceutical Affairs Law Approval

Many Japanese companies have favorable dealings with the Ministry of Health, Labour and Welfare through their routine dealings, but in the case of new foreign market entrants, the situation is totally different. It is to be expected that many companies will have trouble obtaining the knowledge necessary to deal smoothly with the Ministry and its application procedures. It is believed that in the early stages of market entry, measures must be taken such as employing a Japanese employee familiar with the Pharmaceutical Affairs Law application procedures, or requesting assistance in application procedures from an operator.

6. User Education

The performance of medical equipment has matured, and finding differences in product performance with competitor products is not simple. Accordingly, the added value of a product can be the deciding factor. An example of this is the increase in manufacturers that are holding training camps targeted at medical equipment users such as doctors, technicians and nurses. This has the hoped for merits of not only being able to increase user satisfaction, but also reducing maintenance and technical servicing costs.

7. Choosing Appropriate Sales Targets

For foreign entrants into the Japanese market, it is believed that it is effective to enter the market with revolutionary, high-performance products that do not yet exist in the Japanese market. Especially in the case of medical equipment items that are already in use overseas, often a strong desire on the part of doctors to purchase such machines can be seen, and without making an effort to develop dealer relationships from the manufacturer-side, dealer relationships can be built up based on the requests from hospitals. After this, it is effective to work hard at creating a favorable relationship with dealers, and increasing sales routes.

One method of increasing sales in the early stages is to introduce your products at exhibitions attached to conferences, demonstrations, seminars and symposiums, etc. Alternatively, the strategy of performing market research and identifying influential doctors and researchers in the target market and getting them to use equipment first in order to increase sales can also be effective. However, when introducing new medical equipment, the

time required to receive Pharmaceutical Affairs Law approval and insurance certification is as explained in previous sections.

In the case of manufacturers that already have products popular in Japan being sold by import retailers entering the market, it would be advantageous to effectively use those sales routes built up by the import retailer, and increase sales points from there.

VI. Appendices

1. Expositions and Trade Fairs (Regularly held events)

Name	Inquiries / URL	Tel
International Modern Hospital Show	Nippon Omni-Management Association, Hospital Show Office http://www.noma.or.jp/hs/index.html	03-3403-8615
Medical Show Japan & Business Expo	Japanese Society of Medical Instrumentation (Held in conjunction with the Conference of the Japanese Society of Medical Instrumentation) http://homepage3.nifty.com/jsmi/index1.html (in Japanese)	03-3813-1062
The International Technical Exhibition of Medical Imaging	Japan Industries Association of Radiological Systems http://www.jira-net.or.jp/item/item_2004.html (in Japanese)	03-3816-3450

2. Societies and Associations

Name	URL	Tel
Japanese Society of Medical Electronics and Biological Engineering	http://geron.nils.go.jp/me/mestatus.html	03-5814-5801
Japanese Society of Medical Imaging Technology	http://www.jamit.jp/	03-5684-1636
Japanese Society of Medical Instrumentation	http://wwwsoc.nii.ac.jp/jsmi/ (in Japanese)	03-3813-1062
Japanese Society for Artificial Organs	http://jsao.bcasj.or.jp/ (in Japanese)	03-5814-5801
The Japanese Association of Medical Sciences	http://www.med.or.jp/jams/	03-3946-2121 (ext. 3241-2)
The Japanese Society of Internal Medicine	http://www.naika.or.jp/ (in Japanese) http://www.naika.or.jp/imindex.html	03-3813-5991
Japan Surgical Society	http://www.jssoc.or.jp/docs/english/index.html	03-5733-4094
The Japanese Circulation Society	http://www.j-circ.or.jp/english/	075-751-8643
The Japanese Respiratory Society	http://www.jrs.or.jp/english/index.html	03-3254-3103
The Japanese Society of Gastroenterological Surgery	http://www.jsgs.or.jp/	03-3234-2501
The Japanese Society of Nephrology	http://www.jsn.or.jp/jsn_new/eng/index_e.html	03-3269-8251
The Japan Cancer Association	http://www.jca.gr.jp/ (in Japanese) http://cancer-sci.bcasj.or.jp/	03-3918-0111 (ext. 4231)
The Japanese Orthopaedic Association	http://www.joa.or.jp/english/english_frame.html	03-3816-3671
Japan Neurosurgical Society	http://jns.umin.ac.jp/ (in Japanese)	03-3812-6226
Japanese Society for Magnetic Resonance in Medicine	http://www.jsmrm.jp/index.html	03-3443-8622
The Japan Society of Ultrasonics in Medicine	http://wwwsoc.nii.ac.jp/jsum/	03-3813-5540

3. Ministries and Industry Organizations

Name	Address / Tel / Fax / URL
Ministry of Health, Labour and Welfare - Pharmaceutical and Food Safety Bureau; Evaluation and Licensing Division - Health Insurance Bureau; Medical Economics Division	1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916 TEL: 03-5253-1111 http://www.mhlw.go.jp/ (in Japanese) http://www.mhlw.go.jp/english/index.html
Ministry of Economy, Trade and Industry; Commerce and Information Policy Bureau; Service Industry Division, Medical/ Welfare Equipment Industry Room	1-3-1, Kasumigaseki, Chiyoda-ku, Tokyo 100-890 TEL: 03-3501-1790 http://www.meti.go.jp/ (in Japanese) http://www.meti.go.jp/english/index.html
Regional Social Insurance Office (Tokyo)	Shinjuku NS Bldg. 8F, 2-4-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0808 TEL: 03-5322-1603 http://www.sia.go.jp/intro/soshiki/so05.htm (in Japanese)
The Japan Fair Trade Council of the Medical Devices Industry	Hongo-Ishiwata Bldg. 2F, 3-38-1 Hongo, Bunkyo-ku, Tokyo 113-0033 TEL: 03-3818-1731 FAX: 03-3818-1732 http://www.jftc-mdi.jp/ (in Japanese)
Japan Association for the Advancement of Medical Equipment	NKD Building 6-7th Floor 3-42-6 Hongo, Bunkyo-ku, Tokyo 113-0033 TEL: 03-3813-8571 FAX: 03-3813-8733 http://www.jaame.or.jp/ (in Japanese) http://www.jaame.or.jp/english/index.html
The Japan Federation of Medical Devices Associations	Iidabashi Square Bldg. 8FB, Shimomiyabi-cho 3-2, Shinjuku-ku, Tokyo 162-0822 TEL: 03-5255-6234 FAX: 03-3260-9092 http://www.jfmda.gr.jp/ (in Japanese) http://www.jfmda.gr.jp/JFMDA2.htm
Japan Industries Association of Radiological Systems	Yushima KC Bldg. 4F, 2-18-12 Yushima, Bunkyo-ku, Tokyo 113-0034 TEL: 03-3816-3450 FAX: 03-3818-8920 http://www.jira-net.or.jp/ (in Japanese) http://www.jira-net.or.jp/e/index.htm
Japan Association of Medical Equipment Industries	Ika-Kikai Kaikan 5F, 3-39-15 Hongo, Bunkyo-ku, Tokyo 113-0033 TEL: 03-3816-5575 FAX: 03-3816-5576 http://www.jamei.org/ (in Japanese)
The Organization for Pharmaceutical Safety and Research	Shin-Kasumigaseki Bldg. 9F, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 TEL: 03-3506-9541 FAX: 03-3506-9417 http://www.kiko.go.jp/ (in Japanese and English)
Pharmaceuticals and Medical Devices Evaluation Center	Toranomon 33rd Mori Bldg. 10F, 3-8-21 Toranomon, Minato-ku, Tokyo 105-8409 TEL: 03-5403-1411 FAX: 03-5403-1417 http://www.nihs.go.jp/pmdec/index.htm (in Japanese) http://www.nihs.go.jp/pmdec/outline.htm

4. Companies

Name	Address / Tel / Fax / URL
Aloka Co., Ltd.	6-22-1 Mure, Mitaka, Tokyo 181-8622 TEL: 0422-45-5111 http://www.aloka.com/japanese/index.html (in Japanese) http://www.aloka.com/english/e_index.html
Asahi Medical Co., Ltd.	MD Kanda Bldg., 9-1 Kanda Mitoshiro-cho, Chiyoda-ku, Tokyo 101-8482 http://www.asahi-kasei.co.jp/medical/ (in Japanese)
Baxter Limited	Eizen Bldg. 4 Rokuban-cho, Chiyoda-ku, Tokyo 102-8468 TEL:03-5213-5100 FAX: 03-5213-5101 http://www.baxter.co.jp/ (in Japanese) http://www.baxter.com/
Boston Scientific Japan K.K.	1-14-11 Nishi-Shinjuku, Shinjuku-ku, Tokyo 160-0023 TEL: 03-5322-3711 FAX: 03-5322-3700 http://www.bostonscientific.jp/ (in Japanese) http://www.bostonscientific.com/
Getz Bros. Co., Ltd.	Avex Bldg. 4F, 3-1-30 Minami-Aoyama, Minato-ku, Tokyo 107-0062 TEL: 03-3423-6450 FAX: 03-3402-5586 http://www.getz.co.jp/ (in Japanese) http://www.getz.co.jp/english/index.html
GE Yokogawa Medical Systems, Ltd.	4-7-127 Asahigaoka, Hino, Tokyo 191-8503 TEL: 042-585-5111 http://www.gemedical.co.jp/ (in Japanese) http://www.gemedicalsystems.com/
Goodman Co., Ltd.	108 Fujigaoka, Meito-ku, Nagoya, Aichi 465-0032 TEL: 052-774-4350 http://goodmankk.com/ (in Japanese and English)
Guidant Japan K.K.	Shinagawa East One Tower 10F, 2-16-1 Konan, Minato-ku, Tokyo 108-0075 TEL: 03-6717-0100 FAX: 03-6717-0151 http://www.guidant.jp/ (in Japanese) http://www.guidant.com/
Hitachi Medical Corporation	Hitachi Kamakura-bashi Annex, 1-1-14 Uchi-kanda, Chiyoda-ku, Tokyo 101-0047 TEL: 03-3292-8111 FAX: 03-3291-6392 http://www.hitachi-medical.hbi.ne.jp/ (in Japanese) http://www.hitachi-medical.hbi.ne.jp/english/index.htm
Japan Lifeline Co., Ltd.	2-38-1 Ikebukuro, Toshima-ku, Tokyo 171-0014 TEL: 03-3590-1620 http://www.jll.co.jp/ (in Japanese) http://www.japanlifeline.com/
Johnson & Johnson K.K.	East 21 Tower, 6-3-2 Toyo, Koto-ku, Tokyo 135-0016 http://www.jnj.co.jp/ (in Japanese) http://www.jnj.com/

Medtronic Japan Co., Ltd.	Solid Square West Bldg. 6F, Horikawa-cho 580, Saiwai-ku, Kawasaki, Kanagawa 212-0013 TEL: 044-540-6111 http://www.medtronic.co.jp/ (in Japanese) http://www.medtronic.com/
Nihon Mathys K.K.	Koji-machi Crystal City East Bldg. 4F, 4-8-1 Koji-machi, Chiyoda-ku, Tokyo 102-0083 TEL: 03-3239-8891 FAX: 03-3239-8892 http://www.mathys.co.jp/ (in Japanese) http://www.mathysmedical.com/
Olympus Corporation	Shinjuku Monolith Bldg., 2-3-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0914 TEL: 03-3340-2111 http://www.olympus.co.jp/ (in Japanese) http://www.olympus-global.com/en/global/
Phillips Medical Systems Japan Corp.	Phillips Bldg, 2-13-37 Konan, Minato-ku, Tokyo 108-8507 TEL: 03-3740-3213 http://www.medical.philips.com/jp (in Japanese) http://www.medical.philips.com/
Siemens-Asahi Medical Technologies Ltd.	Takanawa Park Tower, 3-20-14 Higashi-Gotanda, Shinagawa-ku, Tokyo 141-8644 TEL: 03-5423-8489 FAX: 03-5423-8491 http://www.med.siemens.co.jp/ (in Japanese) http://www.med.siemens.com/
Shimadzu Corporation	Kuwabara-cho 1, Nishi-no-kyo, Nakagyo-ku, Kyoto 604-8511 TEL: 075-823-1111 FAX: 075-823-3188 http://www.shimadzu.co.jp/ (in Japanese) http://www.shimadzu.com/
Stryker Japan K.K.	3-25-3 Yoyogi, Shibuya-ku, Tokyo 151-0053 TEL: 03-5352-9080 FAX: 03-5352-1789 http://www.stryker.co.jp/ (in Japanese) http://www.strykercorp.com/
Terumo Corporation	2-44-1 Hatagaya, Shibuya-ku, Tokyo 151-0072 TEL: 03-3374-8111 http://www.terumo.co.jp/ (in Japanese) http://www.terumo.co.jp/English/index.html
Toray Medical Co., Ltd.	Alca Central Bldg. 21F, 1-2-1 Kinshi, Sumida-ku Tokyo 130-0013 TEL: 03-5610-6511 http://www.toray.co.jp/tmc (in Japanese)
Toshiba Medical Systems Corporation (Tokyo Office)	3-26-5 Hongo, Bunkyo-ku, Tokyo 113-5486 TEL: 03-3818-2061 FAX:03-3814-6170 http://www.toshiba-medical.co.jp/ (in Japanese) http://www.toshiba-medical.co.jp/tmd/english/
Zimmer K.K.	Shiroyama MT Bldg. 7F, 4-1-17 Toranomon, Minato-ku, Tokyo 105-0001 TEL:03-6402-6600 FAX:03-6402-6620 http://www.zimmer.co.jp/ (in Japanese) http://www.zimmer.com/

5. Prefectural Application Windows for Pharmaceutical Affairs Law Approval

Prefecture	Department*	Address / Tel
Hokkaido	Public Health and Welfare Dept., Medical and Pharmaceutical Affairs Division	6 Kita 3-jo Nishi, Chuo-ku, Sapporo 060-8588 TEL: 011-231-4111
Aomori	Public Health and Welfare Dept., Pharmaceutical Affairs and Public Health Division	1-1-1 Nagashima, Aomori 030-8570 TEL: 017-734-9289
Iwate	Public Health and Welfare Dept., Public Health, Welfare and Medical Division	10-1 Uchimaru, Morioka 020-8570 TEL: 019-629-5472
Miyagi	Public Health and Welfare Dept., Pharmaceutical Affairs Division	3-8-1 Honcho, Aoba-ku, Sendai 980-8570 TEL: 022-211-2652
Akita	Public Health and Welfare Dept., Medical and Pharmaceutical Affairs Division	4-1-1 Sanno, Akita 010-8570 TEL: 018-860-1401
Yamagata	Public Health and Welfare Dept., Public Health and Pharmaceutical Affairs Division	2-8-1 Matsunami, Yamagata, 990-8570 TEL: 0236-30-2332
Fukushima	Public Health and Welfare Dept., Pharmaceutical Affairs Group	2-16 Sugitsuma-cho, Fukushima 960-8670 TEL: 024-521-7232
Ibaraki	Public Health and Welfare Dept., Pharmaceutical Affairs Division	978-6 Kasahara-cho, Mito 310-8555 TEL: 029-301-3393
Tochigi	Public Health and Welfare Dept., Pharmaceutical Affairs Division	1-1-20 Hanawada, Utsunomiya 320-8501 TEL: 028-623-3119
Gunma	Public Health and Welfare Dept., Pharmaceutical Affairs Division	1-1-1 Otemachi, Maebashi 371-8570 TEL: 027-226-2662
Saitama	Public Health and Welfare Dept., Pharmaceutical Affairs Division	3-15-1 Takasago, Urawa-ku, Saitama 336-8501 TEL: 048-830-3620
Chiba	Public Health and Welfare Dept., Pharmaceutical Affairs Division	1-1 Ichiba-cho, Chuo-ku, Chiba 260-0855 TEL: 043-223-2621
Tokyo	Bureau of Public Health, Food and Drug Administration Dept., Pharmaceutical Affairs Division	2-8-1 Nishi-Shinjuku, Shinjuku-ku 163-8001 TEL: 03-5320-4517
Kanagawa	Public Health Dept., Pharmaceutical Affairs Division	1 Nihon-Odori, Naka-ku, Yokohama 231-8588 TEL: 045-210-5214
Niigata	Welfare and Public Health Dept., Pharmaceutical and Public Health Division	4-1 Shinko-cho, Niigata 950-8570 TEL: 025-280-5183
Toyama	Health and Welfare Dept., Pharmaceutical Policy Division	1-7 Shinso-kawa, Toyama 930-8501 TEL: 076-444-3234
Ishikawa	Public Health and Welfare Dept., Pharmaceutical Affairs and Public Health Division	1-1 Kuratsuki, Kanazawa 920-8580 TEL: 076-225-1441
Fukui	Welfare and Environment Dept., Medical and Pharmaceutical Affairs Division	3-17-1 Ote, Fukui 910-8580 TEL: 0776-20-0345
Yamanashi	Welfare and Public Health Dept., Public Health and Pharmaceutical Affairs Division	1-6-1 Marunouchi, Kofu 400-8501 TEL: 055-233-1491
Nagano	Public Health Dept., Pharmaceutical Affairs Division	692-2 Habashita, Minami Nagano, Nagano 380-8570 TEL: 026-235-7157

Gifu	Public Health, Welfare and Environment Dept., Pharmaceutical Affairs Division	2-1-1 Yabuta-Minami, Gifu 500-8570 TEL: 058-272-1111 (ext. 2570-2574,2576)
Shizuoka	Public Health and Welfare Dept., Lifestyle and Public Health Office, Pharmaceutical Affairs Room	9-6 Outemachi, Shizuoka 420-8601 TEL: 054-221-2411
Aichi	Public Health and Welfare Dept., Medicine Safety Division	3-1-2 Sannomaru, Naka-ku, Nagoya 460-8501 TEL: 052-954-6303
Mie	Public Health and Welfare Dept., Pharmaceutical Affairs and Food Team	13 Komei-cho, Tsu 514-8570 TEL: 059-224-2330
Shiga	Public Health and Welfare Dept., Medical and Pharmaceutical Affairs Division	4-1-1 Kyomachi, Otsu 520-8577 TEL: 077-528-3634,3635
Kyoto	Public Health and Welfare Dept., Pharmaceutical Affairs Division	Shinmachi Nishiiru, Shimotachiuri-Dori, Kamigyo-ku, Kyoto 602-8570 TEL: 075-414-4786
Osaka	Public Health and Welfare Dept., Pharmaceutical Affairs Division	2-1-22 Otemae, Chuo-ku, Osaka 540-8570 TEL: 06-6941-0351 (ext. 2556,2557)
Hyogo	Department of Citizens' Affairs, Public Health Bureau, Pharmaceutical Affairs Division	5-10-1 Shimoyamate-Dori, Chuo-ku Kobe 650-8567 TEL: 078-362-3268
Nara	Welfare Dept., Pharmaceutical Affairs Division	30 Noborioji-cho, Nara, 630-8501 TEL: 0742-27-8670
Wakayama	Welfare and Public Health Dept., Pharmaceutical Affairs Division	1-1 Komatsubara-Dori, Wakayama 640-8585 TEL: 073-441-2660
Tottori	Public Health and Welfare Dept., Medical and Pharmaceutical Affairs Division	1-220 Higashimachi, Tottori 680-8570 TEL: 0857-26-7188
Shimane	Public Health and Welfare Dept., Pharmaceutical Affairs and Public Health Division	1 Tonomachi, Matsue 690-8501 TEL: 0852-22-5260
Okayama	Public Health and Welfare Dept., Medicine Safety Division	2-4-6 Uchisange, Okayama 700-8570 TEL: 086-226-7340
Hiroshima	Welfare and Public Health Dept., Pharmaceutical Affairs Room	10-52 Motomachi, Naka-ku, Hiroshima 730-8501 TEL: 082-513-3222
Yamaguchi	Public Health and Welfare Dept., Pharmaceutical Affairs Division	1-1 Takimachi, Yamaguchi 753-8501 TEL: 083-933-3023
Tokushima	Public Health and Welfare Dept., Pharmaceutical Affairs Division	1-1 Bandai-cho, Tokushima 770-8570 TEL: 088-621-2231
Kagawa	Public Health and Welfare Dept., Pharmaceutical Affairs and Infectious Disease Prevention Division	4-1-10 Ban-cho, Takamatsu 760-8570 TEL: 087-832-3299,3300
Ehime	Public Health and Welfare Dept., Pharmaceutical Affairs and Public Health Division	4-4-2 Ichiban-cho, Matsuyama 790-8570 TEL: 089-912-2390
Kochi	Public Health and Welfare Dept., Pharmaceutical Affairs and Public Health Division	1-2-20 Marunouchi, Kochi 780-8570 TEL: 088-823-9681
Fukuoka	Public Health and Welfare Dept., Pharmaceutical Affairs Division	7-7 Higashikoen, Hakata-ku, Fukuoka 812-8577 TEL: 092-643-3284
Saga	Health and Welfare Dept., Pharmaceutical Affairs Division	1-1-59 Jonai, Saga 840-8570 TEL: 0952-25-7082

Nagasaki	Public Health and Welfare Dept., Pharmaceutical Affairs Room	2-13 Edomachi, Nagasaki 850-8570 TEL: 095-826-5833
Kumamoto	Public Health and Welfare Dept., Pharmaceutical Affairs Division	6-18-1 Suizenji Kumamoto 862-8570 TEL: 096-381-8412
Oita	Public Health and Welfare Dept., Medical and Pharmaceutical Affairs Division	3-1-1 Otemachi, Oita 870-8501 TEL: 097-536-1111 (ext. 2649,2650,2651)
Miyazaki	Public Health and Welfare Dept., Public Health and Pharmaceutical Affairs Division	2-10-1 Tachibana-Dori Higashi, Miyazaki 880-8501 TEL: 0985-26-7078
Kagoshima	Public Health and Welfare Dept., Pharmaceutical Affairs Division	10-1 Kamoike Shinmachi, Kagoshima 890-8577 TEL: 099-286-2811 (ext. 2806,2807)
Okinawa	Public Health and Welfare Dept., Pharmaceutical Affairs and Public Health Division	1-2-2 Izumizaki, Naha 900-8570 TEL: 098-866-2215

* Provisional translation

6. Medical Equipment Dealers

The followings sources have detailed information on dealers (Only Japanese editions available).

Title*	Publisher
Medical Equipment/ Supplies Yearbook 2003, Wholesale and Retail Volume	R&D Corp.
2003 Edition National Medical Devices Dealer Yearbook	Yano Research Institute Ltd.

* Provisional translation

Procedures for Investment in Japan

1. Summary and Procedures for Setting Up a Base in Japan

Table 1. shows the tasks, and the order in which they need to be implemented, required of a foreign company, from the Japan investment planning stage to the establishment of a base. There is particular focus on the stage of establishing a company.

For details of each procedure (such as documents to be submitted and where to submit them), please consult with experts, make inquiries to authorities concerned (including JETRO IBSC) listed in Section 2, or check JETRO publications and the JETRO web site "Invest Japan!" (http://www.jetro.go.jp/investjapan/index.html).

1-1 Setting Up a Base

(1) Start-up Types

Table 1. shows each start-up type and its requirements. When a foreign business desires to set up a base in Japan, there are generally three different choices of organization: 1) a joint-stock company (*kabushiki kaisha*), 2) a limited liability company (*yugen kaisha*), or 3) a branch (*shiten*) of the parent company overseas.

Among these three choices, establishing a joint-stock company is the most popular due to the limited liability of its investors, high social credibility, and advantages in financing. However, since a joint-stock company requires ten million yen or more as minimum capital, small- to-medium-sized enterprises sometimes choose to establish a limited liability company (*yugen kaisha*) for which the minimum capital requirement is three million yen, or even a branch, which does not have minimum capital requirements[1].

A joint-stock company can be established two ways; 1) promotive incorporation where promoters take all issued shares, and 2) subscriptive incorporation where a public offering is made to attract outside investors. Each method requires different procedures and documents to be submitted. Figure 1. only shows promotive incorporation details as it is more common when foreign businesses make direct investment in Japan.

[1] For details of an exceptional measure for minimum capital requirements, please refer to section 1-1, (2).

Table 1. Start-up Types and Requirements

Start-up type	Business activity	Registration	(Minimum capital requirements)	Directors required	Internal Auditor(s)	Remittance
Representative office	Not allowed	None	None	None	No	—
Branch (Shiten)	Allowed	Required	None	None	No	No tax is imposed
Joint-stock company (Kabushiki Kaisha: K.K.)	Allowed	Required	10 mil. Yen	At least three	Yes	Profits, dividends and royalties are taxable
Limited liability company (Yugen Kaisha)	Allowed	Required	3 mil. Yen	At least one	No	Profits, dividends and royalties are taxable

(2) An Exceptional Measure for Minimum Capital Requirements

As an exceptional measure for minimum capital requirements, the government forced "the Law for Supporting for the Challenge of SMEs *(Chusho Kigyou Chosen Sien Hou)*", revised the part of the Law for Facilitating the Creation of New Business, since Feb. 1, 2003 and practically abolished the regulations of minimum capital requirements under some conditions (http://www.meti.go.jp/english/information/data/cMinimumCapitale.html).

Both a joint-stock company and a limited liability company can be established with a capital of over 1 yen under the following conditions: 1) The company need to prepare and get the notification of articles of incorporation and after that need to get the confirmation of Bureau of Economy, Trade and Industry that sited in the local area the company will be established in advance. 2) The established organization will be changed or liquidated in the case that it cannot fulfill the minimum capital requirements already mentioned within five years from incorporation. 3) The distribution for stockholders cannot be acknowledged during the time the company does not fulfill the minimum capital requirements. 4) The company is liable to open its financial condition to the public broadly. It is necessary for the company to pay attention to fulfill the minimum capital requirements in Table.1 within five years from incorporation.

Since this law is the time-limited law until Mar. 31, 2008, the company must get the confirmation of Bureau of Economy, Trade and Industry until this limit. This law is under the jurisdiction of Office for New Business, Economic and Industrial Policy Bureau, Ministry of Economy, Trade and Industry.

(3) Important Points Concerning Incorporation

As procedures of registration of incorporation and application for the certificate of eligibility for status of residence are very complicated and require professional knowledge, foreign companies investing in Japan normally commission such tasks to Japanese qualified experts (such as lawyers and public accountants) who can do business in English[2]. In such a case, it should be noted, since in Japan there are very few joint offices of lawyers and public accountants which can provide one-stop service, and since lawyers and public accountants may re-commission some tasks to other qualified experts such as judicial scriveners and administrative scriveners, which are not present in Europe and North America.

When a registration of incorporation is filed at a registry office, it is necessary to attach a "certificate of a seal impression" of a representative director. If a promoter or a representative director of a joint-stock company is a non-Japanese person who has not obtained an alien registration certificate, since the person is not able to obtain the certificate of seal impression, the person may endorse by signature in place of affixing a seal. However, in this case, each time a signature is presented it is necessary to attach a "certificate of signature" issued by a notary public in the home country of the non-Japanese promoter or the representative director.

1-2 Investment-Related Laws and Regulations

Major investment-related laws and regulations include the Foreign Exchange and Foreign Trade Control Law, the Commercial Code (Corporate Law), and the Antimonopoly Act. In addition, regulations under the Labour Law and the Intellectual Property Rights Law should also be considered at the start of, and during operation of, a business in Japan. Depending on the type of business, it may be necessary to have a license or approval from a competent authority in accordance with applicable laws and regulations.

(1) Foreign Exchange and Foreign Trade Control Law (The Foreign Exchange Law)

The Foreign Exchange and Foreign Trade Control Law stipulates rules for proper management of foreign trade based on the principle of freedom of foreign trade. When a foreign company makes direct investment in Japan, it must follow a series of procedures based on the principle of "ex post facto notification in principle, prior permission or notification in part" under the law.

[2] Please refer to *"Directory for Setting Up Enterprises in Japan 2000"* (by JETRO, 4,000 yen) for information on contacts of major qualified experts and supportive companies.

(2) Commercial Code (Corporate Law)

The Commercial Code (Corporate Law) in Japan defines three types of companies, excluding a limited liability company (*yugen kaisha*)[3]. In recent years, many revisions and modifications of the law have been made to promote more flexible restructuring of companies. Specifically, these have included simplification and rationalization of M&A related laws and regulations, introduction of legislation on stock-swap and stock-transfer systems, establishment of legislation on company split-offs, revision of Corporate Reorganization Law, and the adoption of a system complying with internationally accepted accounting standards.

(3) Antimonopoly Act (The Act Concerning Prohibition of Private Monopolization and Maintenance of Fair Trade)

The Antimonopoly Act restricts private monopoly and unfair trade for the purpose of promoting free and fair competition. In recent years, however, deregulation is underway, which includes lifting the ban on establishing holding companies in principle, and simplifying the notification system of M&A activities.

1-3 Preferential Treatment Associated with Investment in Japan

(1) Law on Extraordinary Measures Related to the Promotion of Imports and the Facilitation of Inward Investment Activities (Import and Inward Investment Promotion Law, FAZ Law)

Foreign companies that invest in the areas designated as FAZ (Foreign Access Zones) and can also meet the requirements for specific investors in Japan can receive the following preferential treatment. The application period of this law has been extended to May 2006.

1) Although the carry forward period of operating losses is usually five years from the start of business, this law allows investors to carry forward losses up to 7 years.
2) Industrial Structure Improvement Fund (ISIF) guarantees of debt incurred to loans to buy equipment and to obtain working capital for businesses.
3) When a small- and medium-sized foreign private company obtains loans, the Japan Small and Medium Enterprise Corporation (JASMEC) guarantees the loans.
4) Development Bank of Japan (DBJ) and Japan Finance Corporation for Small Business offers low-interest, long-term loans.

As of December 2003, 22 areas are designated as FAZs. For further information on each FAZ, please refer to the JETRO web site (http://www.jetro.go.jp/ov/e/faz/index.html).

[3] Rules and regulations related to limited liability companies (yugen kaisha) are stipulated in the Limited Liability Company Law *(Yugen Kaisha Hou)*.

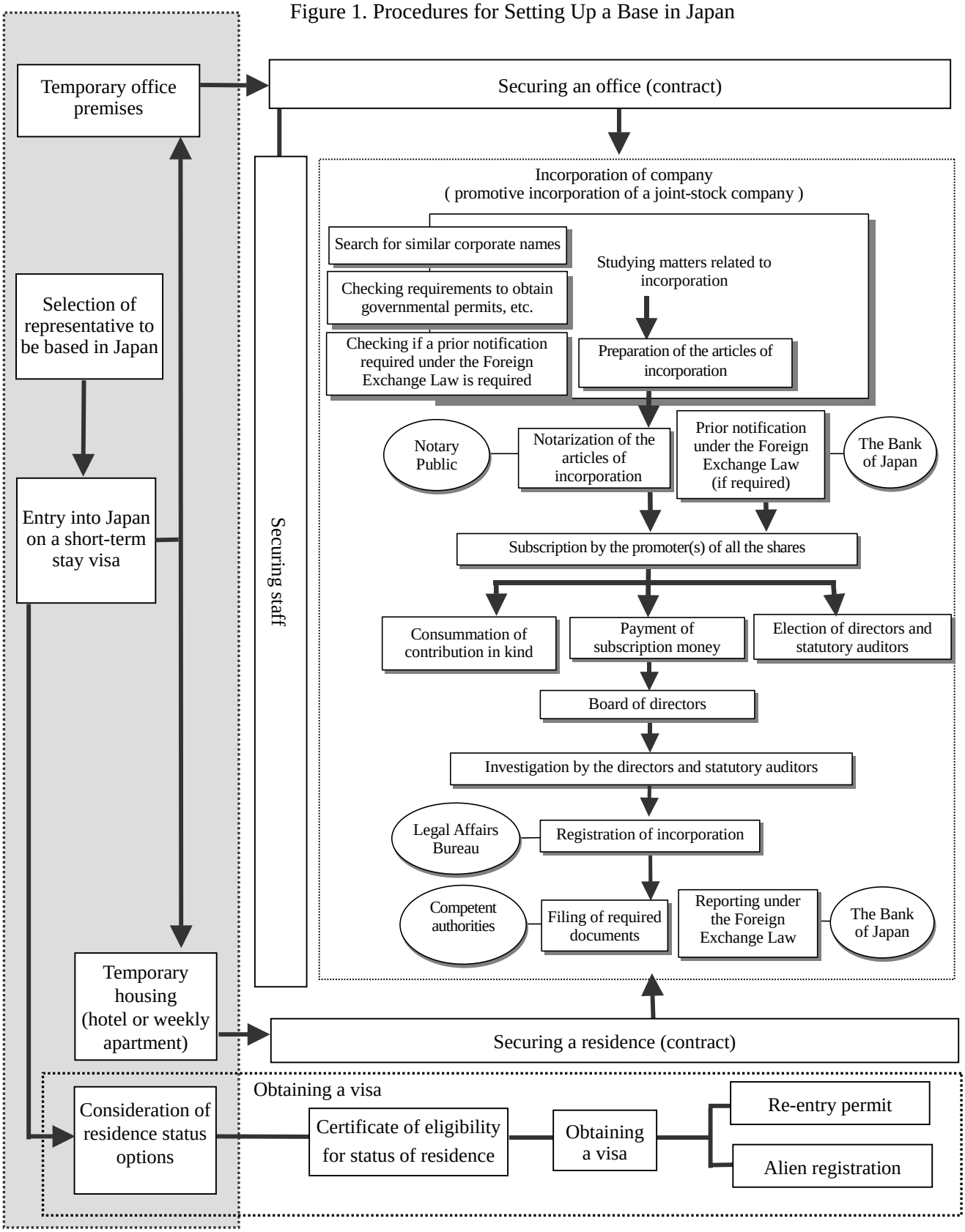
(2) Low-Interest Loans by Development Bank of Japan (DBJ)

DBJ offers low-interest, long-term loans to foreign companies that make full-scale investment in Japan for the first time or whose investment is expected to contribute to the upgrading of the Japanese industry structure, the creation of a new industry, or an increase in employment.

(3) Subsidies, Tax Exemptions, Low-Interest Loans by Prefectural Governments

Prefectural governments also offer various forms of support to foreign businesses investing in Japan. As supportive measures are different in each prefecture, please contact each prefectural government or JETRO Trade Information Center for further information on support offered in each area. Contact points for each center are given at <http://www.jetro.go.jp/ov/e/domestic_offices.html>.

Figure 1. Procedures for Setting Up a Base in Japan



Note 1: Application for certificate of eligibility for status of residence and opening of a bank account should be made after establishing an office and a residence (i.e. after signing lease contracts of an office or residence).

Note 2: For inquiries about incorporation procedures and visa applications, please refer to Section 2 of this reference.

Source: *"Setting Up Enterprises in Japan"* by JETRO (1995) and *"The Japan Start-up Handbook: Procedures and Costs for Foreign Companies Establishing a Japanese Base"* by JETRO (1999)

2. Sources of Information on Investment in Japan

2-1 Governmental Offices: "Office of INVEST JAPAN"

	Organization	Division	Contact	Web site (Invest Japan)
1	Cabinet Office	Office of Foreign Direct Investment Promotion	03-3581-8950 (direct) 03-5253-2111 ext.45207 invest-japan.be@mfs.cao.go.jp	http://www5.cao.go.jp/access/english/jic_main_e.html
2	Financial Service Agency	Planning and Coordination Bureau, International Affairs Division	03-3506-6049 (direct) 03-3506-6000 ext.3199 invest-japan@fsa.go.jp	http://www.fsa.go.jp/invest/20030603e.html
3	Ministry of Public Management, Home Affairs, Posts and Telecommunications	Minister's Secretariat, Policy Planning Division	03-5253-5156 (direct) invest-japan@soumu.go.jp	http://www.soumu.go.jp/kyoutsuu/tainiti.html (in Japanese)
4	Ministry of Justice	Minister's Secretariat, Secretarial Division	03-3592-7420 (direct) 03-3580-4111 ext.2087 invest-japan@moj.go.jp	http://www.moj.go.jp/KANBOU/TAINICHI/tainichi01.html (in Japanese)
5	Ministry of Foreign Affairs	Economic Affairs Bureau, Second International Economic Affairs Division	03-3580-3311 ext.5055 invest-japan@mofa.go.jp	http://www.mofa.go.jp/mofaj/gaiko/tn_toshi/madoguchi/ (in Japanese)
6	Ministry of Finance	International Bureau, Research Division, Legal Office	03-3581-8015 (direct) invest-japan@mof.go.jp	http://www.mof.go.jp/invest_japan/index_e.htm
7	Ministry of Education, Culture, Sports, Science and Technology	Minister's Secretariat, Policy Division	03-5253-4111 ext.3472 invest-japan@mext.go.jp	http://www.mext.go.jp/a_menu/tainichi/main.htm (in Japanese)
8	Ministry of Health, Labour and Welfare	Counsellor's Office (Labour Policy) to Director-General for Policy Planning and Evaluation	03-5253-1111 ext.7718 invest-japan@mhlw.go.jp	http://www.mhlw.go.jp/general/seido/toukatsu/tousi/ (in Japanese)
9	Ministry of Agriculture, Forestry and Fishery	General Food Policy Bureau, Food Industry Policy Division	03-3502-8111 ext.3222, 3194 invest_japan@nm.maff.go.jp	http://www.maff.go.jp/sogo_shokuryo/toushi.htm (in Japanese)
10	Ministry of Economy, Trade and Industry	Policy Bureau, International Planning Division, International Transport Policy Office	03-3501-1774 (direct) invest-japan@meti.go.jp	http://www.meti.go.jp/english/policy/index_FDI_into_Japan.html
11	Ministry of Land, Infrastructure and Transport	Policy Bureau, International Planning Division, International Transport Policy Office	03-5253-8313 (direct) invest-japan@mlit.go.jp	http://www.mlit.go.jp/sogoseisaku/invest/index_.html (in Japanese)
12	Ministry of the Environment	Environmental Policy Bureau, Environment and Economy Division	03-5521-8324 (direct) invest-japan@env.go.jp	http://www.env.go.jp/policy/invest_j/ (in Japanese)

13	Japan External Trade Organization (JETRO)	Invest Japan Business Support Center (IBSC)[*1]	03-3584-6042 (direct) invest-japan@jetro.go.jp	http://www.jetro.go.jp/ip/e/bsc/ibsc.html
14	Development Bank of Japan	International Department, Center for the Promotion of Direct Investment in Japan	03-3244-1770 (direct) dbjmail@dbj.go.jp	http://www.dbj.go.jp/english/index.html

Note 1: JETRO IBSC opens windows to the administrative procedures for foreign companies looking to invest in a business in Japan. Please refer to section 3-1.
Note 2: For further information, please refer to JMR No.70 *"Japan's Investment Environment: Facility Services,"* Chapter VIII.

2-2 Sources of Information in Investment in Japan

	Information	Organization	Division	Contact	Web site
Applicable Laws and Regulations					
1	Foreign Exchange and Foreign Trade Law	Bank of Japan	Balance of Payment Division, International Department	03-3277-2107 post.ind6@boj.or.jp (direct)	http://www.boj.or.jp/about/tame/tameindex.htm (in Japanese)
2	Commercial Code	Ministry of Justice	Commercial and Corporation Registration and Deposit Division, Civil Affairs Bureau	03-3580-4111 webmaster@moj.go.jp (main)	http://www.moj.go.jp/MINJI/index.html (in Japanese) http://www.moj.go.jp/ENGLISH/CIAB/ciab-01.html (in English, summary of Civil Affairs Bureau only)
3	Antimonopoly Act	Japan Fair Trade Commission		03-3581-1998 intnldiv@jftc.go.jp (International Affairs Division)	http://www2.jftc.go.jp/e-page/legislation/antimonopoly.html
Preferential Treatment for Investors in Japan					
4	Law for Facilitating the Creation of New Business, Law for Supporting for the Challenge of SMEs *(Chusho kigyou Chosen Sien Hou)*	Ministry of Economy, Trade and Industry	Office for New Business, Economic and Industrial Policy Bureau	03-3501-1569 (direct)	http://www.meti.go.jp/policy/mincap/index.html (in Japanese) http://www.meti.go.jp/english/information/data/cMinimumCapitale.html (in English)
	Same as above	Same as above	Regional Bureaus of Economy, Trade and Industry	webmail@meti.go.jp (main)	http://www.meti.go.jp/english/network/index_b_bureaus.html (information on each Regional Bureau)

5	Law on Extraordinary Measures for the Promotion of Import and the Facilitation of Foreign Direct Investment in Japan	Industrial Structure Improvement Fund		03-3241-6283 webmaster@isif.go.jp (main)	http://www.isif.go.jp/english/frames_e/f_yunyue.html
	Same as above	Japan Small and Medium Enterprise Corporation	Credit Guarantee Corporations (CGCs) in the relevant area	03-3270-2371 (direct)	http://www.cig.jasmec.go.jp/top.html (information on CGCs, in Japanese)
	Same as above	Ministry of Economy, Trade and Industry	Regional Bureaus of Economy, Trade and Industry	webmail@meti.go.jp (main)	http://www.meti.go.jp/english/network/index_b_bureaus.html (information on each Regional Bureau)
6	Special loan program for the promotion of direct investment in Japan	Development Bank of Japan	International Department	03-3244-1990 (General Affairs Department)	http://www.dbj.go.jp/english/index.html
Procedures for Incorporation					
7	Procedures for Incorporation - Registration of joint-stock company - Acquisition of a certified copy of company registration - Certificate of a seal certificate of a representative director	Regional Legal Affairs Bureau and Registry Office in the relevant area			http://www.moj.go.jp/MINJI/minji10.html (a list of Legal Affairs Bureaus in each area is available, in Japanese)
	- Notification of articles of incorporation	Notary Office in the relevant area			http://www.koshonin.gr.jp/address.htm (a list of notary offices in each area is available, in Japanese)
Procedures after Incorporation					
8	Procedures after incorporation - Notification of establishment of corporation - Notification of consumption tax payer etc.	Taxation Office in the relevant area*[1]			http://www.nta.go.jp/category/syoukai/syozaiti.htm (a list of taxation offices in each area is available, in Japanese)
9	Filing of notifications related to the corporation (inside of Tokyo 23 ward)	Local Taxation Office in Tokyo			http://www.tax.metro.tokyo.jp/jimusho/tozei.htm (a list of counsel offices in each area is available, in Japanese)
	Filing of notifications related to the corporation (outside of Tokyo 23 ward)	Local Taxation Office and Commune Office in the relevant area			http://www.soumu.go.jp/czaisei/czaisei_seido/ichiran07.html (a list of local taxation offices in each area is available, in Japanese) - Information on each commune office is provided by web page of each prefecture.
10	Distribution of a guidebook of metropolitan tax in English, Chinese, and Korean, free of charge (postage should be paid)	Bureau of Taxation, Tokyo Metropolitan Government	General Affairs Division, General Affairs Department	03-5388-2927 tax@section.metro.tokyo.jp (direct)	http://www.tax.metro.tokyo.jp/oshirase/2003/200309a.htm (guidebook distribution information in 2003, in Japanese)

Procedures of Social Insurance					
11	Procedures related to industrial insurance - Business report - Employment policy - Labor insurance- related notifications	Labor Standards Bureau in the relevant area			http://www.mhlw.go.jp/general/sosiki/chihou/ (a list of Labor Standards Bureaus in each area is available, in Japanese)
12	Notification of establishment of relationship between an insurer and the insured under the industrial and employment insurance system - Notification of establishment of relationship between an insurer and the insured under the employment insurance	Public Employment Security Office in the relevant area			Same as above
13	Procedures related to health insurance and social security pension	Social Insurance Office in the relevant area			http://www.sia.go.jp/outline/index.htm (information web page on health insurance and social security pension provided by Social Insurance Agency, in Japanese)
Other Useful Sources of Information					
14	Search for telephone numbers and addresses	Town Page - Japan telephone directory -			http://english.itp.ne.jp/
15	Information on investment in Japan	Japan External Trade Organization		03-3582-5511 webmaster@jetro.go.jp (main)	http://www.jetro.go.jp/

Note 1: Only the Tokyo Taxation Bureau has set up a dedicated counter for non-Japanese people. The telephone number is: 03-3821-9070

3. JETRO Services

3-1 JETRO Invest Japan Business Support Center (IBSC)

JETRO IBSC provides foreign companies with information necessary for investment in Japan. IBSC has a wide range of services and facilities to help foreigners who would like to start or invest in a business in Japan. IBSC provides office space free of charge to foreign companies. Advisors and JETRO staff supplies you with useful information and consultation (http://www.jetro.go.jp/ip/e/bsc/ibsc.html).

For further information or application, please contact the nearest JETRO offices (http://www.jetro.go.jp/it/e/profile_network/worldmap.html).

(1) Providing Well-Equipped Facilities for Temporary Offices

IBSC has office space free of charge for foreigners hoping to enter the Japanese market or develop business operations in Japan. The Center's office space is equipped with all the tools necessary to immediately launch business activities in Japan.

(2) Consultation Services by Investment Advisors

IBSC has highly specialized resident advisors (market advisors and corporate management advisors) who can help you with offering market information and conducting individual consulting. Also, at some JETRO overseas offices, investment advisors provide information and consultation regarding direct investment in Japan to potential investors.

(3) Providing the Administrative Information

Backed by the Japanese government, the IBSC opens windows to the administrative procedures necessary for foreign companies looking to do business in Japan.

(4) Introducing Supportive Companies and Arranging a Visit to Potential Properties

IBSC introduces agents who can perform various procedures for setting up a base in Japan, recruiting companies, property companies, and other companies that can help foreign companies investing in Japan. Through a network with local governments, IBSC also gathers information on real estate property in specific regions, arranges visits to candidate properties, and sets up meetings with staff members of local governments.

3-2 Providing Information on Investment in Japan

(1) "Invest Japan!"

The JETRO web site "Invest Japan!" (http://www.jetro.go.jp/investjapan/index.html) provides comprehensive information and data on the investment environment in Japan to foreign businesses that are interested in investing in Japan. This includes Japanese macro economic data, related laws and regulations, and examples of foreign companies that have been successful in establishing their business in Japan.

(2) Publications

JETRO publishes many books that summarize laws and procedures concerning investment in Japan.

For example:

- Setting Up Enterprises in Japan
- Human Resource Management Guidebook: Q&As for Managers of Foreign Affiliates
- Directory for Setting Up Enterprises in Japan

etc.

For further information, please visit the following JETRO web site. (http://www.jetro.go.jp/it/e/pub/index.html).

(3) Seminars for Investment in Japan

JETRO organizes seminars and individual consultations in various countries in order to provide information on a variety of themes, such as trends in the Japanese market, investment climate, and laws and procedures concerning investment in Japan.

(4) Library

You can browse various materials on trade and investment in many countries and JETRO publications on the JETRO Library site (http://www.jetro.go.jp/li/e/index.html).