VI 1. Medical Equipment

1. Definition of Category

This category includes instruments and apparatuses in the medical devices set down in Article 2 of the Pharmaceutical Affairs Law.(Note 1) It does not include medical goods, dental materials, and sanitary goods.

HS Numbers(Note 2)	Commodity
9001.30, ~50	Lenses, prisms and other optical elements of polarizing material (ex. contact lenses, spectacle lenses of glass and other materials)
9004.90	Other spectacles, gobbles and the like, corrective, protective or others
9018	Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments (ex. sphygmomanometer, electro-cardiograph, MRI, ultrasonic diagnostic equipment, stethoscope, needles, catheters, medical scissors, dental drill, etc.)
9019	Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; azone therapy oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus (ex. *Shiatsu* substitutes, respiratory aids, clinical/household-use inhalers, household-use electrical therapeutic instruments, etc.)
9020	Other breathing appliances and gas masks, excluding protective masks having neither mechanical parts nor replaceable filters (ex. anesthesia masks, etc.)
9021.11, 19, 30 ~ 90	Orthopedic appliances, hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability (ex. hearing aids, pacemakers for stimulating heart muscles and orthopedic-use traction devices, etc.)
9022	Apparatus based on the use of X-rays or of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses and desks, screens, examination or treatment tables, chairs and the like (ex. Computed tomography apparatus, X-ray apparatus for medical use, X-ray tubes and screens)
9025	Hydrometers and similar floating instruments, thermometers, etc. (ex. clinical thermometer)
9402	Medical surgical, dental or veterinary furniture and barbers' chair, etc. (ex. operating tables, examination tables, hospital beds with mechanical fittings and dentists' chairs, etc.)

Note 1: Means "instruments and apparatuses, intended to be used for the diagnosis, treatment, or prevention of human or animal diseases or to have a structural or functional effect on the human or animal body, designated by Cabinet Order." The Cabinet Order designates a total of 103 types.

Note 2: The HS Codes include items other than instruments and apparatuses of medical devices set down in the Pharmaceutical Affairs Law. Further, depending on the material, items may be classified under other HS codes. For details, contact the customs authorities.

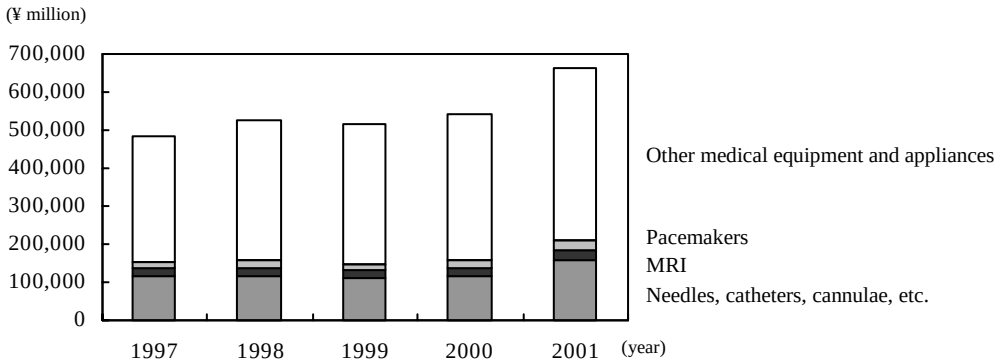
2. Import Trends

(1) Recent Trends in Medical Equipment Import

The value of imports of medical equipment cannot be accurately determined, so instead this report discusses the trends in imports based on figures given in Japan Exports & Imports. Imports of medical equipment rose by 21.8% from the year before to ¥661.9 billion, topping a ¥600-billion mark for the first time ever in 2001, and setting a new all-time record.

The leading type of medical equipment was tubing, needles catheters, cannulae and the like (¥156.9 billion, up 34.1% from the year before), followed by cardiac pacemakers (¥26.6 billion, up 23.9%) and MRI (magnetic resonance imaging scanners, ¥26.0 billion, up 34.0%). However, the "other" subcategory, which includes diverse types of medical equipment, registered imports of ¥452.4 billion (up 17.3%), or 68.3% of all Japan's imports.

Fig. 1 Japan's medical equipment imports



	1997		1998		1999		2000		2001	
	Volume	Value	Volume	Value	Volume	Value	Volume	Value	Volume	Value
Tubing, needles, catheters, cannulae, etc. (tons)	10,493	117,468	11,293	117,535	12,570	110,196	12,070	116,985	14,686	156,854
MRI (units)	10,346	18,716	9,055	19,122	8,438	19,423	7,234	19,410	27,374	26,005
Pacemakers for simulating heart muscles (units)	30,464	18,010	31,266	20,058	36,215	19,868	39,201	21,506	42,970	26,644
Other medical equipment and appliances	-	331,088	-	371,549	-	365,942	-	385,551	-	452,416
TOTAL	-	485,283	-	528,264	-	515,430	-	543,452	-	661,919

Unit: ¥ million *Source: Japan Exports and Imports*

Notes: Total volumes of "tubing, needles, catheters, cannulae, etc." and "other medical equipment" cannot be obtained since units of products differ. Here, volumes of only MRI and pacemakers for stimulating heart muscles, for which units of volume are standard, are given. The products classified under HS 9402 also include many not covered in this section such as barber and beauty shop chairs, so these figures are not included in graphs.

(2) Imports by Place of Origin

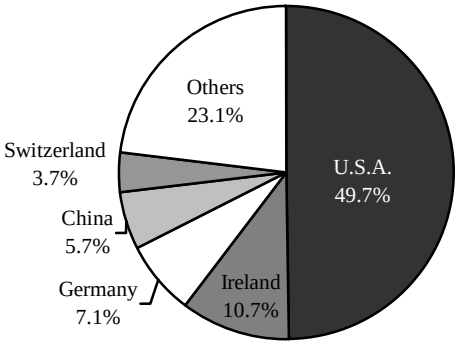
A breakdown by place of origin shows that imports from the U.S. accounted for 49.7% of the value of imports in 2001, followed by Ireland (10.7%), Germany (7.1%), China (5.7%), and Switzerland (3.7%). These five countries together accounted for 76.9% of total imports on a value basis. All the leading exporter nations posted higher export totals in 2001 than the year before. There was no change in the rankings, but China registered the highest rate of growth. The U.S. was one of the largest supplier of almost all individual items, including MRI (value share 56.9%) and tubing, needles, catheter, cannulae, etc. (51.5%),. while the largest suppliers of MRI was Germany, Switzerland leaded imports of pacemakers for stimulating heart muscles, and Ireland has the largest share in other medical equipment.

Thailand and China were one of the top suppliers of tubes, needles, catheters, and other relatively low added value items. Other Asian countries also appear among the suppliers of some items. Behind this is believed to be the fact that Japanese medical equipment manufacturers have begun establishing production operations in other Asian countries with lower personnel costs for exports to neighboring countries and reverse imports to Japan. (see Fig. 2-5)

(3) Imports' Market Share in Japan

The total size of the medical equipment market (including imports) in Japan reached ¥1.9 trillion in 2000 on a primary wholesale price basis. Imports have a widely varying market share in different product categories, but the overall trend is for imports to gain market share in each category. In 2000 imports had a 43.0% share of the total market. Fig. 6 lists imports' market shares in major product categories.

Fig. 2 Principal exporters of medical equipment (total) to Japan

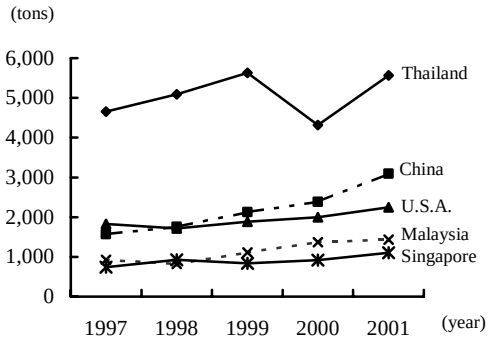


	1997	1998	1999	2000	2001	
	Volume	Volume	Volume	Volume	Volume	
U.S.A.	260,552	289,721	271,226	274,847	328,676	49.7%
Ireland	31,030	37,430	48,041	54,782	71,015	10.7%
Germany	40,081	40,881	40,702	41,338	47,008	7.1%
China	13,695	15,915	16,496	26,445	37,613	5.7%
Switzerland	12,090	15,050	15,437	19,555	24,725	3.7%
Other	127,835	129,266	123,530	126,485	152,881	23.1%
TOTAL	485,283	528,264	515,430	543,452	661,919	100.0%
(E U)	142,923	148,117	151,919	157,437	189,405	28.6%

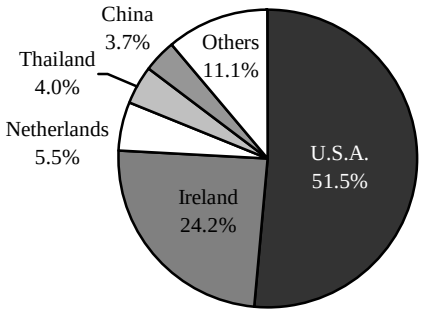
Unit: ¥ million *Source: Japan Exports and Imports*

Fig. 3 Principal exporters of tubing, needles, catheters, cannulae, etc. to Japan

Trends in import volume by leading exporters



Shares of imports in 2001 (value basis)

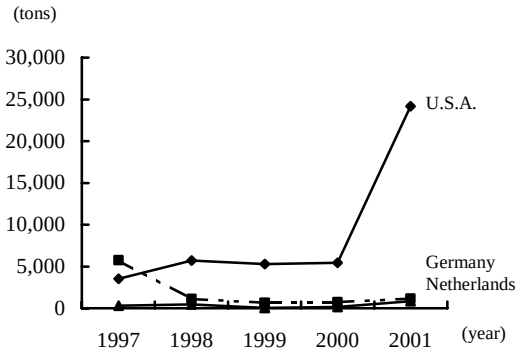


	1997	1998	1999	2000		2001			
	Volume	Volume	Volume	Volume	Value	Volume		Value	
Thailand	4,658	5,086	5,627	4,316	4,901	5,565	37.9%	6,276	4.0%
China	1,573	1,753	2,124	2,386	3,348	3,091	21.0%	5,759	3.7%
U.S.A.	1,825	1,715	1,885	1,997	55,053	2,250	15.3%	80,815	51.5%
Malaysia	927	822	1,111	1,368	3,448	1,433	9.8%	3,614	2.3%
Singapore	741	924	836	920	1,891	1,100	7.5%	2,255	1.4%
Other	769	993	987	1,083	48,343	1,247	8.5%	58,134	37.1%
TOTAL	10,493	11,293	12,570	12,070	116,985	14,686	100.0%	156,854	100.0%
(E U)	469	503	568	661	44,838	803	5.5%	55,247	35.2%

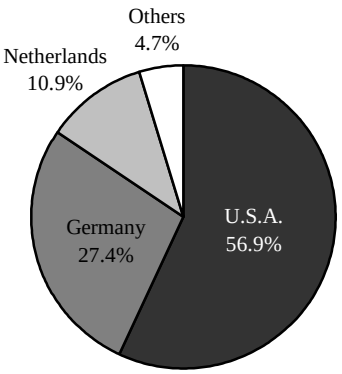
Units: tons, ¥ million *Source: Japan Exports and Imports*

Fig. 4 Principal exporters of MRI to Japan

Trends in import volume by leading exporters



Shares of MRI imports in 2001 (value basis)

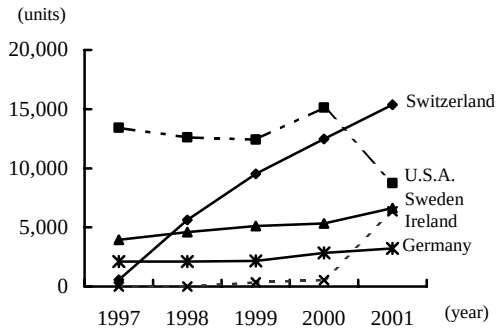


	1997	1998	1999	2000		2001			
	Volume	Volume	Volume	Volume	Value	Volume		Value	
U.S.A.	3,543	5,701	5,285	5,442	10,856	24,168	88.3%	14,809	56.9%
Germany	5,757	1,098	636	735	5,509	1,168	4.3%	7,138	27.4%
China	309	441	36	141	7	855	3.1%	323	1.2%
Netherlands	387	277	251	380	2,003	578	2.1%	2,825	10.9%
Thailand	-	-	-	-	-	358	1.3%	59	0.2%
Other	350	1,538	2,230	536	1,035	247	0.9%	852	3.3%
TOTAL	10,346	9,055	8,438	7,234	19,410	27,374	100.0%	26,005	100.0%
(E U)	6,266	1,468	970	1,195	8,430	1,850	6.8%	10,657	41.0%

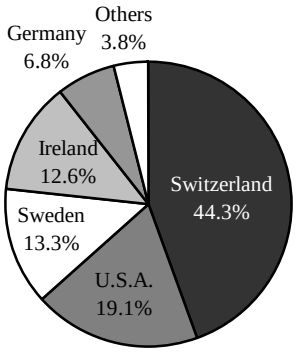
Units: tons, ¥ million *Source: Japan Exports and Imports*

Fig. 5 Principal exporters of pacemakers to Japan

Trends in import volume by leading exporters



Shares of pacemaker imports in 2001 (value basis)



	1997	1998	1999	2000		2001			
	Volume	Volume	Volume	Volume	Value	Volume		Value	
Switzerland	581	5,622	9,533	12,464	8,505	15,370	35.8%	11,808	44.3%
U.S.A.	13,414	12,607	12,433	15,134	7,826	8,750	20.4%	5,094	19.1%
Sweden	3,953	4,602	5,122	5,332	2,313	6,621	15.4%	3,552	13.3%
Ireland	0	0	363	533	223	6,354	14.8%	3,356	12.6%
Germany	2,119	2,101	2,170	2,832	1,446	3,209	7.5%	1,813	6.8%
Other	10,397	6,334	6,594	2,906	1,194	2,666	6.2%	1,021	3.8%
TOTAL	30,464	31,266	36,215	39,201	21,506	42,970	100.0%	26,644	100.0%
(E U)	13,371	12,160	13,372	11,424	5,077	18,795	43.7%	9,720	36.5%

Units: tons, ¥ million *Source: Japan Exports and Imports*

Fig. 6 Imports' share of major product categories in the Japanese market (2000)

	Total market size	Imports	Imports' share
Tubing and catheters	158,701	112,628	71.0%
Syringes	37,739	11,530	30.6%
Diagnostic imaging systems	252,470	78,870	31.2%
Organic testing equipment	24,921	9,062	36.4%
Organic implants (cardiac pacemakers)	390,856	261,455	66.9%
Artificial kidneys and renal dialysis machines, etc.	130,619	25,383	19.4%
Therapeutic and surgical equipment	91,244	43,515	47.7%
Dental materials	108,546	18,084	16.7%
Medical equipment total	1,911,426	821,114	43.0%

Unit: ¥ million *Source: Annual Report for Pharmaceutical Preparations in Japan*

Note: These figures are calculated by adding consumption tax to wholesale prices of primary wholesalers. So they differ from the totals given in Japan's Exports and Imports. The table lists figures separately for leading product subcategories, and the tabulated total differs from the sum of the individual subcategories.

3. Key Considerations related to Importing

(1) Regulations and Procedural Requirements at the Time of Importation

Imports of medical equipment are subject to provisions of the Pharmaceutical Affairs Law.

1) Pharmaceutical Affairs Law

Under the Pharmaceutical Affairs Law, anyone desiring to import medical equipment in business must obtain an importer's license from the Minister of Health, Labour and Welfare for every place of business. The Law also requires to obtain an approval to import for each product item from the Minister of Health, Labour and Welfare (or the appropriate prefectural governor for those items for which approval authority rests with the prefecture). Approval, however, is not necessary for items designated by Article 18 of the Enforcement Regulations of the Pharmaceutical Affairs Law.(Note)

Note: Under the Enforcement Regulations, approval is waived for 94 items such as medical use lighting, stethoscopes, and mercury thermometers, and designated medical equipment complying with the Japan Industrial Standard (126 products including, for example, electrocardiographs, encephalographs, low frequency therapy apparatuses, electronic thermometers for underarm and oral use, and hearing aids). For details, see the Enforcement Regulations of the Pharmaceutical Affairs Law.

When a foreign manufacturer obtains approval for manufacture, importers are not required to obtain approval of the items again. The manufacturer must, however, station a domestic administrator in Japan meeting the standards set down by ordinance of the Ministry of Health, Labour and Welfare. The application document in principle has to be submitted to the Ministry of Health, Labour and Welfare through the governor of the prefecture, in which the applicant (domestic administrator in the case of a foreign manufacturer) is located.

Japan, EU, and the U.S. are currently engaged in negotiations on establishment of a system for mutual certification of safety standards and specifications for medical equipment. Further, Japan established a bilateral agreement with Australia in 1993.

Fig. 7 on the following page presents process of licensing and approval. When the procedures or whether the medical equipment is new or not are unclear, contact the Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare or the consultation desk of the Japan Association for the Advancement of Medical Equipment (JAAME).

Contacts:

• Japan Association for the Advancement of Medical Equipment
TEL: 03-3813-8571 http://www.jaame.or.jp

(2) Regulations and Procedural Requirements at the Time of Sale

The sale of medical equipment is subject to the Pharmaceutical Affairs Law. Other regulations apply to medical equipment separately. In addition, containers and packaging may be subject to provisions of the Containers and Packaging Recycling Law and the Law for Promotion of Effective Utilization of Resources. For more detailed information about the subject, scope, labeling method, etc., please consult the competent government agencies listed below.

Fig. 7 Process of licensing and approval for importation of medical devices

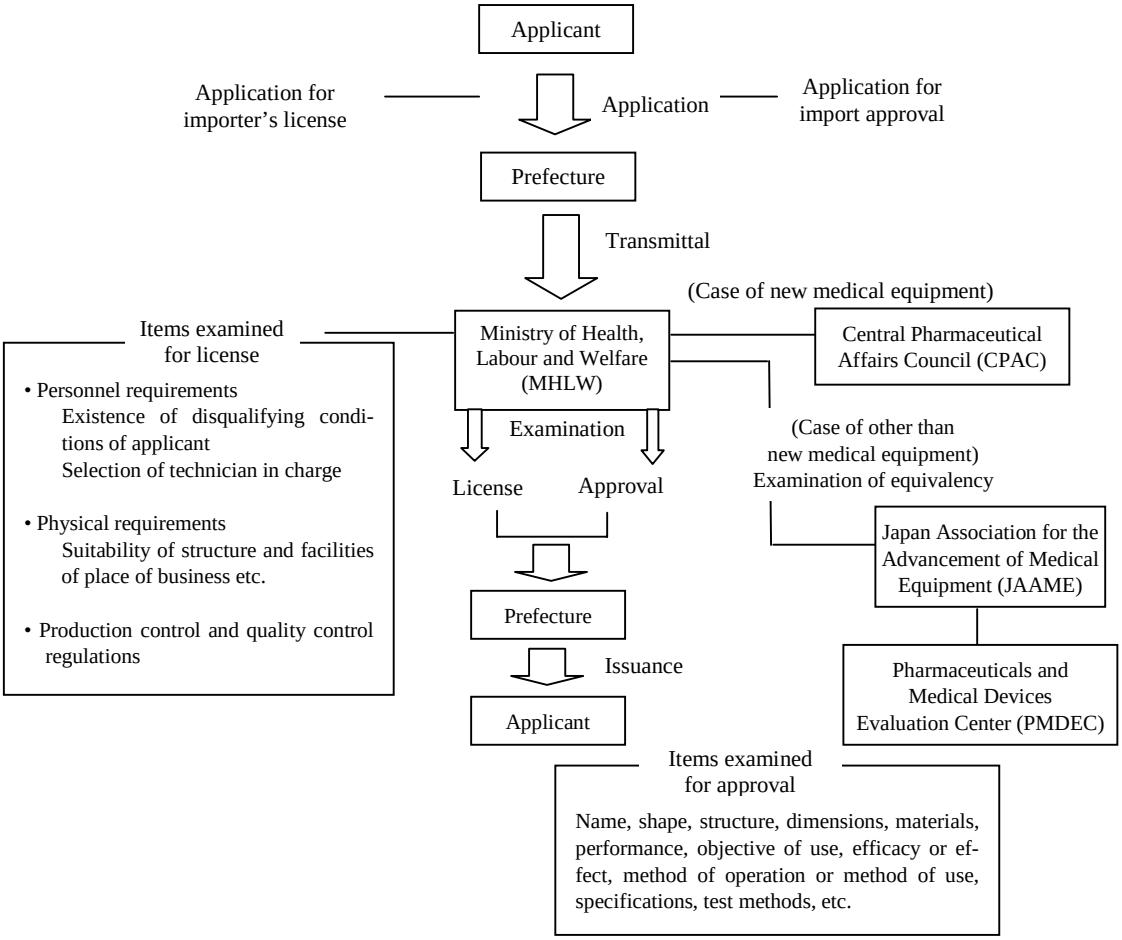
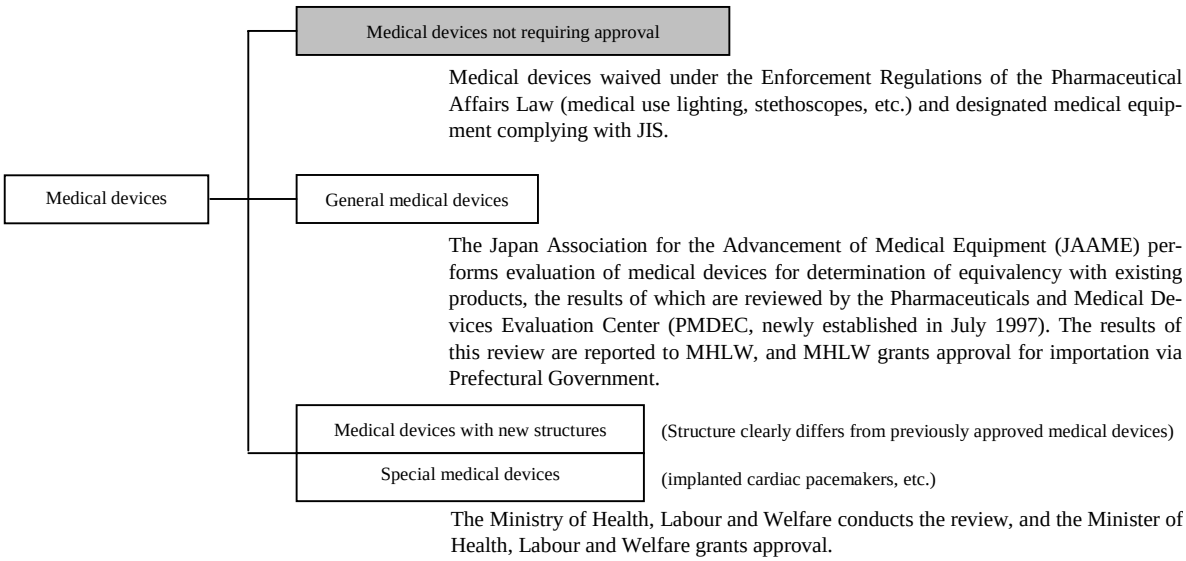


Fig. 8 Import approval examination and procedural requirements for medical devices



1) Pharmaceutical Affairs Law

An importer desiring to sell directly to consumers or medical institutions must first notify commencement of business with the prefectural governor for each place of business. Similar procedures as with sale are required for leasing medical equipment. When importers sell to other manufacturers, importers, wholesalers, etc., however, they may sell the imported medical equipment under the importer's license.

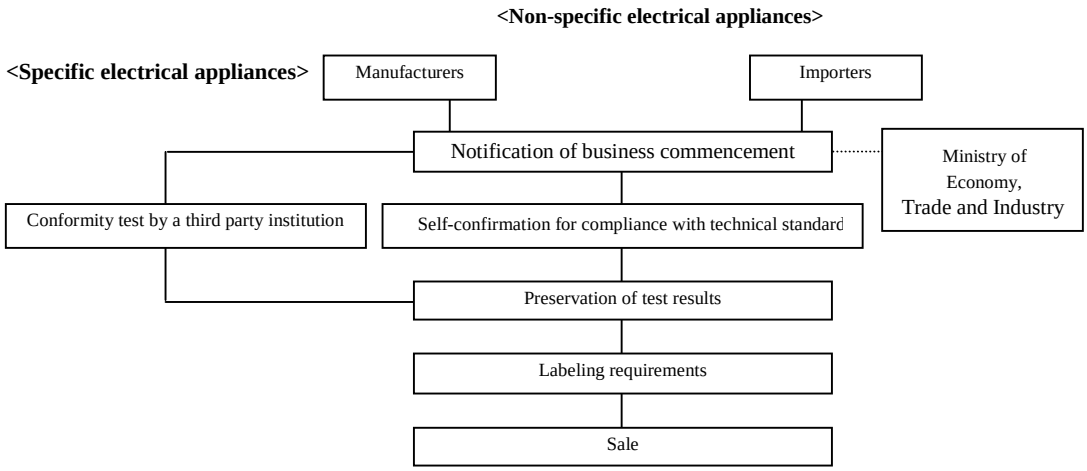
<Regulations subject to specific products>

Medical equipment is subject to various regulations according to the products. Examples of some regulations are given below.

1) Electrical Appliance and Material Safety Law

Electrical appliances such as household use low frequency therapy apparatuses and household use light therapy apparatuses are subject to provisions of the Electrical Appliance and Material Safety Law. Under the revised Law, the manufacturer or importer shall undertake in-house testing, and be obligated to conform to technical standards through self-confirmation. Any products that are not compliant with the technical standards are subject to improvement orders or are prevented from displaying particular labels. When deemed necessary, products with a high level of danger or trouble shall be imposed to the violation of the order. Importer must notify the commencement of business by each type classification to the Director-General of the competent Bureau of Economy, Trade and Industry (or to the Minister of Economy, Trade and Industry, for importers with business sites in multiple areas) within 30 days of commencing import operations.

Fig. 9 Procedures required under the Electrical Appliance and Material Safety Law



1) Specific electrical appliances ------- Household use light therapy apparatuses, etc.

Specific electrical appliances are required to take a conformity test conducted by a third party institution certified or authorized by the Minister of Economy, Trade and Industry. Manufacturers overseas may have their products tested by an approved testing organization in their own countries. Also, when a specific electrical appliance with the same type classification is imported from the same manufacturer, it is only necessary to present a copy of the certificate of qualification. In other words, a new original certificate need not be obtained for each import shipment of the same item.

2) Electrical appliances other than "specific electrical appliances"

---- Household use low frequency therapy apparatuses, etc.

When importing and selling a electrical appliance other than designated as "specific electrical appliance," manufacturers or importers must confirm on their own that their products are compliant with technical standards (self certification), and must display required label items and PSE mark on the product.

2) High Pressure Gas Safety Law

Certain equipment containing high-pressure gas has to meet safety standards set down in the Law.

3) Law for the Prevention of Radiation Sickness Caused by Radioactive Isotopes

Equipment using radioactive isotopes (diagnostic X-ray machines, etc.) has to meet safety standards set down in the Law.

4) Medical Service Law

The Law establishes standards for installation of equipment using radioactivity.

(3) Competent Agencies

- Pharmaceutical Affairs Law
  General Affairs Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare (Pharmaceutical Affairs Law in general)
  Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare (Import approval procedure)
  TEL: 03-5253-1111 http://www.mhlw.go.jp
- Electrical Appliance and Material Safety Law
  Product Safety Division, Consumer Affairs Department, Commerce and Information Policy Bureau, Ministry of Economy, Trade and Industry
  TEL: 03-3501-1511 http://www.meti.go.jp
- High Pressure Gas Safety Law
  Safety Division, Agency for Nuclear and Industrial Safety, Agency of Natural Resources and Energy, Ministry of Economy, Trade and Industry
  TEL: 03-3501-1511 http://www.enecho.go.jp
- Law for the Prevention of Radiation Sickness Caused by Radioactive Isotopes
  Nuclear Safety Division, Science and Technology Policy Bureau, Ministry of Education, Culture, Sports, Science and Technology
  TEL: 03-3581-4211 http://www.mext.go.jp
- Medical Service Law
  General Affairs Division, Health Service Bureau, Ministry of Health, Labour and Welfare
  TEL: 03-5253-1111 http://www.mhlw.go.jp
- Containers and Packaging Recycling Law / Law for Promotion of Effective Utilization of Resources
  Recycling Promotion Division, Industrial Science and Technology Policy and Environment Bureau, Ministry of Economy, Trade and Industry
  TEL: 03-3501-1511 http://www.meti.go.jp
  Recycling Promotion Division, Waste Management and Recycling Department, Ministry of the Environment
  TEL: 03-3581-3351 http://www.env.go.jp

4. Labeling

(1) Legally Required Labeling

1) Pharmaceutical Affairs Law

When selling medical equipment, the Pharmaceutical Affairs Law requires the direct container, the direct wrapping, or medical equipment itself is labeled with the following so as to ensure suitable usage and handling, ensure quality, and clarify liability:

- Name and address of manufacturer or importer (all devices)
- Manufacturing number or manufacturing code (products designated by Minister of Health, Labour and Welfare: medical devices, etc.)
- Weight, volume, number, and other details (products designated by Minister of Health, Labour and Welfare: medical devices, etc.)
- Limits on use (products designated by Minister of Health and Welfare: medical devices, etc.)
- Items designated in Subparagraph 2, Paragraph 42 of Pharmaceutical Affairs Law (disposable syringe needle standards, cardiac pacemaker standards, artificial heart valve standards, etc. covered)
- Name and country of location of approved foreign manufacturers and name and address of domestic administrator
  (products receiving approval under provisions of Article 29-2 of the Law)
- Approval number (license number when approval not required)
- Matters prohibited from being indicated on label (all devices covered)
  False or misleading matter
  Non-approved efficacy and effects
  Method of use, dosage, or times dangerous to health

The Pharmaceutical Affairs Law also mandates that manufacturers provide information on sophisticated, complicated medical equipment (X-ray CT, MRI, artificial kidney machines, etc.) and that required matters relating to maintenance and inspection be included in the attached documents.

2) Electrical Appliance and Material Safety Law

Medical equipment covered by the Electrical Appliance and Material Safety Law must be labeled with rated voltage, power consumption, frequency, name of the manufacturer, and PSE mark. In the case of specific electrical appliances, abbreviated name of testing organization that issued compliance certificate must be indicated.

PSE Mark (specific electrical appliances)

PSE Mark (non-specific electrical appliances)

3) Law for Promotion of Effective Utilization of Resources

When paper or plastic is used as a packaging material for wrapping of individual product items, or for labels, tags, external packaging or elsewhere, a material identifier mark must be displayed with information where the material is used.

< Example >

External packaging

Tag

(2) Voluntary Labeling based on Provisions of Law

JIS Mark

Medical equipment for which there are JIS standards may be labeled with the JIS mark if complying with the standards. Factories examined and approved by the ministry in charge (Ministry of Health, Labour and Welfare for most medical equipment) may be labeled as approved by the JIS.

Contacts:

- Japanese Standards Association TEL: 03-3583-8005 http://www.jsa.or.jp

(3) Voluntary Industry Labeling

There is no voluntary industry labeling for medical equipment.

(4) Other Labeling

Along with growing demand from consumers, more exaggerated expressions have been used in advertising pharmaceuticals, etc. Cases violating the Pharmaceutical Affairs Law have been increasing as well. When advertising pharmaceuticals, etc., note that the Pharmaceutical and Medical Affairs Bureau has established standards for suitable advertising of pharmaceuticals, etc., which include mandatory standards for observance. It is therefore necessary to take sufficient care over the expressions used.

5. Taxes

(1) Customs Duties

Almost all of medical equipment (other than corrective spectacles show below) is duty free.

Fig. 10 Customs duties on medical equipment

HS No.	Description	Rate of Duty (%)			
		General	WTO	Preferential	Temporary
9001	Optical fibers and optical fiber bundles; optical fiber cables, sheets and plates of polarizing material, lenses, prisms, mirrors and other optical elements				
9001.30	1. Contact lenses	Free	(Free)		
9001.40	2. Spectacle lenses of glass	Free	(Free)		
9001.50	3. Spectacle lenses of other materials	Free	(Free)		
9004	Spectacles, goggles and the like, corrective, protective or other				
9004.90	1. Other than sunglasses	6.4%	5.3%	Free	

Note: Refer to "Customs Tariff Schedules of Japan" (published by Japan Tariff Association) etc. for interpretation of tariff table.

(2) Consumption Tax

(CIF + Customs duties) x 5%

6. Product Characteristics

Medical equipment as a whole features the inclusion of numerous products having a direct effect on life or the body. From the viewpoints of safety and ensuring efficacy, it has to be regulated by the law. Further, it is marketed widely internationally. (Currently, imports account for about 40% of the products on the Japanese market. About 25% of Japanese production is similarly exported.)

The products are diverse in type and nature, but may be grouped into disposable products designed to be used once at the medical institution etc. (for example, pacemakers, catheters, syringes, needles, etc.) and products designed to be installed and used repeatedly at the medical institution, etc. (for example, CT, MRI, and other apparatuses and surgical tables and other equipment). Here, a look will be taken at the features of pacemakers and PTCA (percutaneous transluminal coronary angioplasty) catheters, two products in the group of disposable products with extremely high import shares, and MRI, a repeatedly used product of an extremely high import value. Note that there is not believed to be much of a difference in quality of disposable syringes and other so-called general use medical devices between imports and domestic products or by country of production.

<Pacemakers>

Pacemakers are devices for treating arrhythmia and preventing the heart from stopping beating. Implant type pacemakers, the majority of which are imported, are placed inside the body by surgery to assist heart functions. When implanting pacemakers, the heartbeat has to be programmed in accordance with the symptoms of the patient. Periodic inspection is required after installation as well. At the present time, almost all pacemakers in Japan are made in the U.S. Recently, there has been a trend toward domestic production. American pacemakers, which have pretty much become the global standard, are highly competitive however.

<PTCA catheters>

Catheters are thin tubes for medical use. They may be divided into general catheters used for discharge of body fluids etc. and high performance catheters used for diagnosis and treatment of diseases. Catheters classified in the latter category have balloons at their front ends and are used for PTCA. PTCA is a technique for treating is chemic heart diseases where the arteries become constricted such as angina and cardiac infarction. The catheter is inserted from the base of the leg up to the constricted portion of the artery where the balloon is then expanded to widen the vein. This eliminates surgery and therefore has the advantage of lightening the physical strain on the patient. While some are produced in Japan, imports hold an extremely high over 90% share of the market. American catheters are particularly strong.

<MRI>

Known also by the full name of magnetic resonance imaging scanners, these are apparatuses that create an image of the body tissue of the patient for use by diagnosis by a physician. CT (computer tomography) uses X-rays, but MRI amplifies the weak magnetic force of the hydrogen nucleii in the body by powerful magnetism and radio waves from the outside in order to analyze the structure of the tissue. Since magnetism and radio waves are not obstructed by bone, it is possible to obtain a three-dimensional image vertically, horizontally, at an inclination, or from any angle of even tumors and hemorrhaging of the tissue surrounded by hard bone such as the brain or spine cord. MRI includes superconductivity types, ordinary conductivity types, and permanent magnet types. A relatively large number of Japanese products are of the permanent magnet type. Most imports from the U.S., Germany, etc. appear to be of the superconductivity type. The superconductivity type is higher in price than other types and is higher in maintenance costs, but has advantages such as an ability to diagnose images clearly to the millimeter level.

7. Domestic Distribution System and Business Practices

(1) Domestic Market Conditions

The Japanese market for medical equipment as a whole was worth about ¥1.9 trillion in wholesale price basis in 2000. Soaring medical costs are now becoming a social problem in Japan. One of the reasons given is the use of expensive medical equipment. The price of Japanese made medical equipment is reportedly over three times that in the U.S. This difference in Japanese and overseas prices has often been pointed out. Several factors are considered to be behind this, but conventional business practices in medical equipment are said to also be involved.

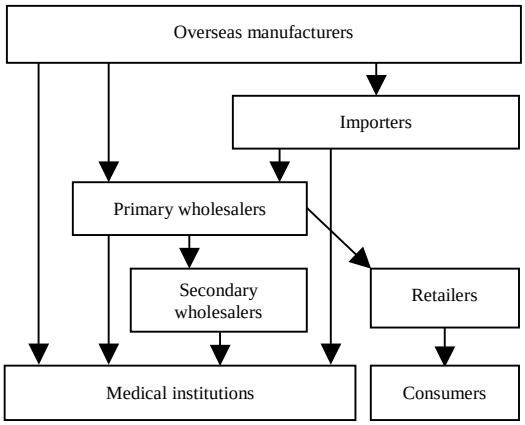
Manufacturers of medical equipment usually sell to medical institutions through wholesalers. The distribution channels are reportedly longer and more complicated than those in the western countries. Depending on the items handled, these wholesalers offer not only various services relating to physical distribution, surgical support, support in regular post-surgical diagnosis, free lending of measuring equipment (programmers, etc.), and other technical related services and thereby maintain close relations with medical institutions. Manufacturers in the western countries (U.S., Germany, France, and the U.K.) generally provide physical distribution related services and technical related services such as support at the time of surgery similar to those of Japan. The terms of services provided along with medical equipment, however, are generally all reflected in the price negotiations at the time of purchase of the equipment. As opposed to this, in Japan, the terms of ancillary services are seldom clearly set down contractually. There are reports that almost all costs are in fact passed along to the price of the products.

There is a trend in medical institutions toward use of comparative estimates and tenders for purchases of medical equipment, but in fact price competition reportedly operates only in the case of syringe tubes and other relatively low priced general medical devices where there is little difference in function between the products of one manufacturer and another. In the case of pacemakers, PTCA catheters, and other items, rather than price or other economic factors, familiarity to physicians and the ancillary services are considered important elements in the selection of the types of the products. The result is that the same type of product tends to be continuously used. This leads to extremely close relations. The Fair Trade Council's "report on a survey of distribution and business practices of medical devices" concluded that in order to eliminate the difference between Japanese and overseas prices, it was important that medical institutions be aware of the hidden costs of ancillary services and that they increase the number of vendors they do business with as much as possible through, for example, studying the functions and prices of a number of types of products in accordance with the disease to be dealt with.

(2) Distribution Channels

The distribution channel for MRI's and other high priced medical equipment is generally direct transactions between the hospital and manufacturer. In the case of almost all other equipment, however, manufacturers sell to medical institutions through wholesalers. Direct transactions are less common than general western countries. Transactions through first-tier, second-tier, and other intermediary wholesalers are more prevalent in Japan.

Fig. 11 Distribution channel for medical equipment



(3) Key Considerations for entering the Japanese Market

Note that as explained earlier, in many cases there are already very close relations between manufacturers or wholesalers and medical institutions and that entry by newcomers into the business is difficult. Since there are growing demands from medical institutions to lower prices, however, if it is possible to provide less expensive equipment through streamlining the distribution system, then it would not be impossible to open up new business routes. At that time too, however, it would be necessary to establish a relation of trust with the medical institution, etc. in view of the nature of the product. Note that the enforcement of the Product Liability Law means that the importer can be held liable for defects in imports which cause harm to people, so full care must be taken with quality control.

8. After-Sales Service

Due to the nature of medical equipment as involving human life, the importance of after-sales service is extremely high. In particular, as explained earlier, high priced medical equipment requires supervision during surgery, etc., follow-up after surgery, and other service.

Note that the Pharmaceutical Affairs Law instituted measures for ensuring safety after sale and mandated that manufacturers, etc. prepare and store records including contact addresses of users of medical devices so as to enable emergency medical steps to be taken when heart pacemakers or other specific medical devices are found to suffer from initially unforeseen defects. It also mandated confidentiality. For details, see Article 77-5 of the Pharmaceutical Affairs Law.

9. Related Product Categories

Related products include medical goods falling under the "medical devices" covered by the Pharmaceutical Affairs Law (corrective devices, etc.), dental materials (metals for dental use, etc.), and sanitary products (tampons for menstrual periods, contraceptive devices, etc.). Imports of these products require procedures under the Pharmaceutical Affairs Law similar to medical equipment.

For details, see the sections on "VI-2 Contraceptives," "VI-3 Visual Corrective Lenses," "VI-10 Sanitary Articles," "VI-12 Paper Diapers for Adults," and "VI-13 Hearing Aids" in this guidebook. Further, while not falling under the category of medical devices, for wheelchairs and similar equipment, see the sections on "VI-14 Staircase Elevators," "VI-15 Wheel Chairs," and "VI-18 Mobile Lifts."

10. Direct Imports by Individuals

Individuals desiring to import items under this category should note that the methods of import differ depending on the volumes of the items to be imported and the items themselves.

(1) Items able to clear customs through customs check

<For individuals>

When individuals desire to import medical equipment directly for their own use or when they bring it back from trips overseas, the equipment is allowed to pass through customs if within an amount clearly for use by the individual. Medical equipment of just one set (minimum unit) is allowed for home use.

<For individual physicians>

Medical devices used by physicians for the purpose of treatment of patients may be imported in amounts of up to two sets, after submitting a physician's license (photocopy) to the customs authorities. This does not apply, however, to devices for replacing heart functions (pacemakers, artificial heart valves, etc.), dental materials, and items imported repeatedly by the same physicians.

(2) Items imported after receiving *Yakkan Shomei* (pharmaceutical supervision certificates)

<For individual physicians>

When physicians desire to import items listed in the above for the purpose of treating patients or when trying to import more than the above quantities, it is necessary to submit documents (import reports, written reasons for need, etc.) to the Experts for Pharmaceutical Affairs of the Ministry of Health, Labour and Welfare and obtain a *Yakkan Shomei* (pharmaceutical supervision certificates). In this case, it is assumed that the physician will be using the item at his or her own responsibility. Sale of the equipment is not allowed. Note that when individuals directly import medical equipment for use for surgery, etc., it is necessary to clear problems such as after-sales service, recall, etc.

11. Related Organizations

- Japan Association for the Advancement of Medical Equipment (JAAME)
  TEL: 03-3813-8571 http://www.jaame.or.jp
- Japan Industries Association of Radiation Apparatus (JIRA)
  TEL: 03-3816-3450 http://www.jira-net.or.jp
- National Institute of Health Sciences, Pharmaceuticals and Medical Devices Evaluation Center
  TEL: 03-5403-1411 http://www.nihs.go.jp