

# Report on the Medical Equipment Distribution (Overview)

December 27, 2005  
Japan Fair Trade Commission

## I. Investigation Purpose and Method

- Investigation into domestic/overseas price differences in medical equipment (pacemakers, PTCA catheters, MRIs, laparoscopes) and actual situation for distribution and business
- Questionnaire and responses from manufacturers (manufacturers and sellers), wholesalers and medical institutions

## II. Investigation

### 1. Actual Situation for Domestic/Overseas Price Differences

The price in Japan is approximately 1.6 times that in overseas market for pacemakers and approximately twice for PTCA catheters. No such difference is observed for MRIs or laparoscopes.

### 2. Factors for Price Differences - Pacemakers and PTCA Catheters -

#### (1) Costs

Costs for distribution, regulatory applications, presence at operations and inventory control entrusting (for PTCA catheters); No parallel import

#### (2) Competition in the trade

- **Wholesalers tend to be fixed by purchase policies of medical institutions**

Priority tends to be given to purchasing particular products or dealing with particular wholesalers

- **Wholesalers tend to be fixed by sales policies of manufacturers**

Setting advantageous wholesale prices only for existing wholesalers of medical institutions

### 3. Evaluation from the Viewpoint of Competition Policy

Medical institutions need attitudes to purchase based on a high consciousness about costs.

If a manufacturer specifies the customer medical institutions to the wholesaler so that the wholesaler can deal with only particular institutions, or refuses, without any justifiable reason, selling products to the wholesalers who sell the products to medical institutions other than specified, such manufacturer would be possibly in violation of the Antimonopoly Act (trading on restrictive terms, unjust refusal to trade).

If a manufacturer requests the wholesaler to report the retail prices to the medical institutions, such manufacturer would be possibly in violation of the Antimonopoly Act (resale price restriction).

If a manufacturer sets the wholesale prices for each medical institution (advantageous wholesale prices advantageous for only the existing wholesalers of medical institutions) and makes it difficult for other wholesalers to newly start the trade, such manufacturer would be possibly in violation of the Antimonopoly Act (unjustly discriminatory consideration, discriminatory treatment).

For approval of manufacture and sale under the Pharmaceutical Affairs Act, it should be considered to reduce the approval application period.

Contact: Trade Practice Research Office, Trade Practice Department,  
Economic Affairs Bureau, General Secretariat,  
Japan Fair Trade Commission  
Telephone: 03-3581-3372 (Direct line)  
Website: <http://www.jftc.go.jp>

### III. Investigation Overview

#### 1. Overview of the Medical Equipment Industry

##### (1) Market Scale

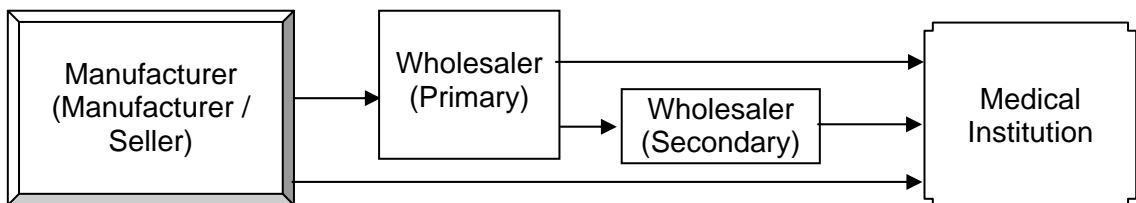
###### Medical Equipment Market Scale in Japan: 2,060 billion yen (2004)

- Market scales for investigated items
  - Pacemakers: 46.5 billion yen
  - PTCA catheters: 29.8 billion yen
  - MRIs: 37.3 billion yen
  - Laparoscopes: 0.6 billion yen

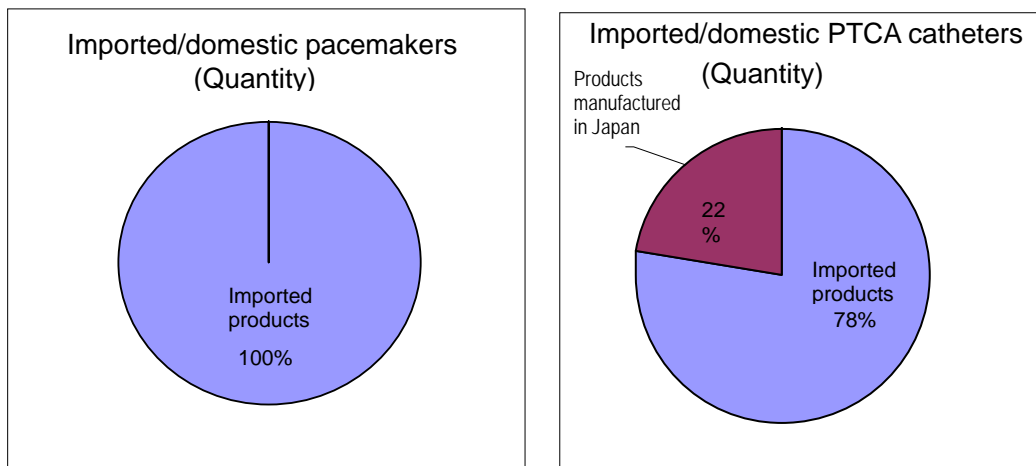
##### (2) Distribution Channel for Medical Equipment

###### From manufacturers via wholesalers to medical institutions

- Most pacemakers and PTCA catheters are sold to medical institutions via wholesalers. MRIs are directly sold from manufacturers to medical institutions in many cases.



- Many pacemakers and PTCA catheters sold in Japan are imported.



Source: "Medical Equipment and Devices Annual 2005," R&D Co., Ltd.

## 2. Domestic/Overseas Price Differences

### (1) Actual Situation of Domestic/Overseas Price Differences

**The price in Japan is about 1.6 times that in overseas market in case of pacemakers and about twice in case of PTCA catheters.**

No difference is observed between domestic and overseas prices for MRIs or laparoscopes.

#### Domestic/Overseas Price Differences for Pacemakers and PTCA Catheters (2004)

	Category	Domestic price	Overseas price (USA)	Ratio
Pacemaker	Single chamber (Type II)	¥1,330,000	¥832,000	Approximately 160%
	Dual chamber (Type IV)	¥1,480,000	¥953,000	Approximately 160%
PTCA Catheter (General Type)		¥172,000	Approximately ¥82,000	Approximately 210%

Note: Domestic price is the **reimbursement price** in Japan (equivalent to the list price) and overseas price is the average of list prices.



### (2) Factors for Domestic/Overseas Price Differences

#### A. Costs

- **Costs required for distribution**
- **Costs required for regulatory application**
- **Costs for presence at operations, etc.**
- **Costs for inventory control entrusting [for PTCA catheters]**
- **No parallel import**

#### B. Competition in the Trade

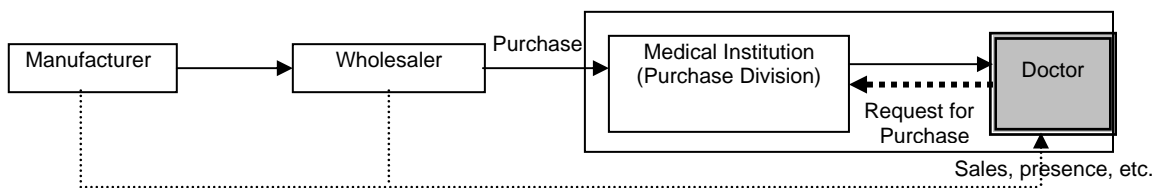
- **Wholesalers tend to be fixed by purchase policies of medical institutions**
  - **Priority tends to be given to continued trade with existing wholesalers**  
Influence of doctors over product selection; attitude of the person in charge of purchase
  - **Method to implement bidding, etc.**  
Bid specifications which limit qualification of bidders; collecting, multiple quotations in a way competition does not effectively work
- **Customers tend to be fixed by sales policies of manufacturers**
  - **Manufacturer's involvement in deciding of customers and sale prices of the wholesaler**  
Deciding customers; report of customers and sale prices
  - **Manufacturer's action on retail prices to the wholesaler**  
Setting of retail prices for each medical institution

### 3. Wholesalers Tend to be Fixed by Purchase Policies of Medical Institutions

(1) Priority tends to be given to continued trade with existing wholesalers

- Requests from doctors at site for purchasing particular products or selecting particular wholesalers based on largely influences determination of equipment purchase by medical institutions and the products or wholesalers tend to be decided by the requests.
- Clerical staffs in charge of purchase at medical institutions also tend to give priority to the trade with particular wholesalers with which they have business relationships from before due to administrative problems etc. and tend to be reluctant to change wholesalers.

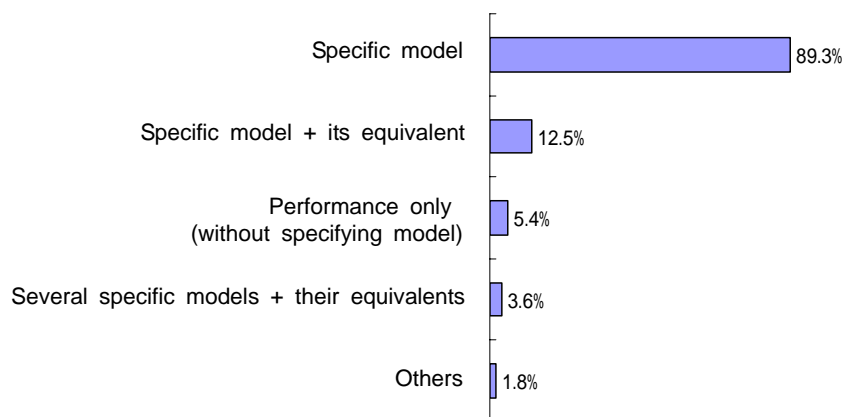
#### Example of Sales Activities by Manufacturer and Wholesaler and Purchase by Medical Institution



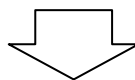
(2) Method to Implement Bidding

In quotation collection or bidding made by medical institutions, excessively limiting qualification for bidders prevents the competition expected by bidding from working sufficiently in the actual situation.

#### Specifications when medical institutions order pacemakers (multiple answer)



Number of valid responses = 56 (Questionnaires for medical institutions)



Medical institutions should have attitudes that show purchasing behavior based on high cost-consciousness.

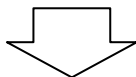
- When requesting purchase of products used in operations, doctors should present several models to the clerical staff for purchase to cooperate in effective purchasing through competition among brands as far as possible.
- Persons in charge of purchasing should collect quotations from a broad range of suppliers and should review the suppliers from the viewpoint of cost-consciousness.

#### 4. Customers Tend to be Fixed by Sales Policies of Pacemaker and PTCA Catheter Manufacturers

(1) Manufacturer's involvement in deciding customers and retail prices

##### -Allocating medical institutions to which the wholesaler sells the products

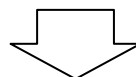
- Problem with finding new customers  
"It takes time to obtain approval for trade from the manufacturer": 53.3% (Questionnaire for wholesalers)
- Reason why they are reluctant in sales activities to medical institutions  
"Customers are allocated by the manufacturer": Over 1/3 (Same questionnaire)



If a manufacturer instructs the wholesaler to sell the products to specific medical institutions to prevent the wholesaler from dealing with other institutions or if it refuses, without any justifiable reason, sale of products to wholesalers selling the products to medical institutions other than specified, then such manufacturer is possibly in violation of the Antimonopoly Act (Unreasonable restraint of trade, unjust refusal of trade).

##### - Report of Customers and Sale Prices

- Report of customers  
According to the questionnaires for manufacturers, 9 companies out of 10 (for pacemakers) or 13 companies out of 20 (for PTCA catheters) have the wholesalers report the customers.
- Report of retail prices  
"Reporting retail prices to medical institutions": 49% (Questionnaire for wholesalers)



If a manufacturer requests the wholesaler to report the sale prices to the medical institutions, such manufacturer is possibly in violation of the Antimonopoly Act (Resale price restriction).

## (2) Manufacturer's Action on Sale Prices to the Wholesaler

**Manufacturer sets the retail prices for the wholesaler for each medical institution**

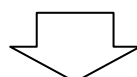


**Manufacturer presents favorable wholesale prices to existing wholesalers**



**Due to this difference in wholesale prices, other wholesalers have difficulty in newly starting the trade with that medical institution**

- "We cannot compete due to difference in purchase prices from manufacturer": 27.5% (Questionnaire for wholesalers)
- Even if a new wholesaler has good trading quantity, it cannot purchase products at special prices from the manufacturer and can only submit quotations higher than those from existing small-scale wholesalers (reported by wholesalers).



If the favorable **wholesale** price set for particular wholesalers and **wholesale** prices for other wholesalers are remarkably and excessively different when compared with the difference in their trade and such differences adversely affect the order of fair competition by directly and seriously affecting the competition for the unfavorably treated wholesalers, then this is in violation of the Antimonopoly Act (unjustly discriminatory consideration, discriminatory treatment).

## 5. Various Regulations on the Sale of Products

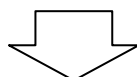
**- Application procedures under the Pharmaceutical Affairs Act: It takes longer time for approval than that in other countries**

The period required for approval is at least 2.5 times (for pacemakers) or 3 times (for PTCA catheters) the one in the U.S. (Questionnaire for manufacturers)

Average period required for regulatory approval

	Japan	U.S.	Europe
Pacemakers	Approximately 16 months	Approximately 6.3 months	Approximately 2 months
PTCA catheter	Approximately 10 months	Approximately 3 months	Approximately 1.5 months

(According to questionnaire for manufacturers)



Various products should be distributed in the market and competition should be promoted. Therefore, approval system of sale under the Pharmaceutical Affairs Act should be reviewed for (ex. a shorter approval application period by reducing the applicant's burden.)