

# **Deregulation of the Medical Equipment Industry in Japan**

## **International Trade Negotiations**

### **INTRODUCTION**

The purpose of this exercise is to simulate an international trade negotiation designed to reduce trade restrictions between two nations.

While the factual scenario is based upon real issues, this case is hypothetical in terms of specific stakeholders identified and certain facts presented.

This case will include country teams, government teams, industry association teams, and various forums including a possible WTO Dispute Resolution Panel.

The goals of this exercise include:

- 1.) Development of research and investigation skills;
- 2.) Development of analytical, planning, and negotiation strategy skills;
- 3.) Development of negotiation, mediation and conflict resolution skills;
- 4.) Development of durable written agreements; and,
- 5.) Development of planning and presentations skills to various governmental and WTO panels and bodies.

# **Japanese Medical Equipment Case**

## **BACKGROUND, FACTS AND ISSUES COMMON TO ALL PARTIES**

### **Parties:**

#### Country Representatives:

Japan

United States

European Union

#### Government Agencies:

Japanese Ministry of International Trade and Industry (MITI)

Japanese Ministry of Health and Welfare (MHW)

Japanese Pharmaceutical and Medical Devices Safety Bureau (PMSDB)

Japanese Pharmaceutical and Medical Devices Evaluation Center (PMDEC)

U.S. Trade Representative (USTR)

U.S. Department of Commerce (DOC)

#### Industry Associations:

Japanese Medical Equipment Association (JMEA)

Japan Medical Equipment Industry

Japan Association for the Advancement of Medical Equipment (JAAME)

U.S. Medical Equipment Industry

U.S. Health Industry Manufacturers Association (HIMA)

American Chamber of Commerce in Japan (ACCJ)

## European Medical Equipment Industry

# **Deregulation of the Medical Equipment Industry in Japan**

**-Expansion of Market Access-**

**International Trade Negotiation Simulation**

**Updated May 2003 by:**

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**This simulation is based on a Master's in Commercial Diplomacy  
Project completed at the Monterey Institute of International Studies by  
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## **Background, Facts and Issues Common to All Parties**

Following is information and assumptions that are common to all parties in this negotiation simulation. They are intended to help set the parameters of the negotiations and give participants an initial point of reference before formulating positions within their respective stakeholder groups.

### **ACRONYMS**

<b>ACCJ</b>	American Chamber of Commerce of Japan
<b>CPAC</b>	Central Pharmaceutical Affairs Councils
<b>CS Japan</b>	Commerce Service in Japan
<b>EBC</b>	European Business Community of Japan
<b>EPA</b>	Economic Planning Agency of Japan
<b>FDA</b>	U.S Food and Drug Administration
<b>GATS</b>	General Agreement on Trade in Services
<b>GATT</b>	General Agreement on Tariffs and Trade
<b>GHTF</b>	Global Harmonization Task Force
<b>HIMA</b>	Health Industry Manufacturers Association
<b>ISO</b>	International Standards Organization
<b>ITA</b>	International Trade Administration of the U.S. Department of Commerce
<b>JAAME</b>	Japan Association for the Advancement of Medical Equipment
<b>JETRO</b>	Japan External Trade Organization
<b>JMEA</b>	Japan Medical Equipment Association
<b>JIS</b>	Japanese Industrial Standards
<b>JMA</b>	Japan Medical Association
<b>MHW</b>	Ministry of Health and Welfare of Japan
<b>MITI</b>	Ministry of International Trade and Industry of Japan
<b>MOSS</b>	Market-Oriented Sector-Selective
<b>PMDEC</b>	Pharmaceutical and Medical Devices Evaluation Center
<b>PMDSB</b>	Pharmaceutical and Medical Devices Safety Bureau
<b>USTR</b>	Office of the United States Trade Representative
<b>WTO</b>	World Trade Organization

## **Market Access and Japan's Medical Equipment Sector**

It is extremely difficult to introduce new, cost-effective medical equipment products into the Japanese market. There are four main reasons for this difficulty:

- 1) Japan's Pharmaceutical Affairs Law is redundant and cumbersome and makes timely approval of new medical equipment impossible. Currently, Japan's approval process is longer than that of any other major developed country. This is particularly troublesome in an era when technology changes rapidly and, therefore, product life-cycles are increasingly short.
- 2) Complex distribution channels impede newcomers' entry to the market and raise the price of medical equipment by 15-25 percent. By simplifying the distribution system, the industry could lower prices and potentially increase its annual sales by over US\$ 849 million—more than five percent.
- 3) The Ministry of Health and Welfare's (MHW's) reimbursement system negates price competition so there is no incentive for hospitals to purchase more cost-effective products.
- 4) MHW has been too cautious in approving new products, especially high-risk products. Its reluctance to approve products that are already in use in other countries causes a significant opportunity loss for the medical industry, as well as patients who could benefit from the new equipment.

Solving these problems is important not only for the medical equipment industry, but also for the Japanese government. Reducing the cost of health care will be crucial to the government's efforts to reduce its budget deficit and pull Japan out of its prolonged recession. Reducing costs is all the more important because Japan's population is aging and, accordingly, demanding more and better health care.

International forces are also putting pressure on the government to deregulate the medical sector. Foreign medical equipment suppliers are lured to Japan because its medical equipment market is the second largest in the world, but they face the same non-trade barriers to market access that Japanese companies do. Since 1986, Japan and the United States have conducted bilateral negotiations regarding deregulation of Japan's medical system. Although some progress was made in the so called "MOSS talks," the United States is still asking for further deregulation. For the purposes of this simulation the following assumptions will be made;

- The Government of Japan has agreed to hold negotiations with a number of interested stakeholders regarding access to the medical equipment market in Japan.
- These negotiations are being held in Tokyo at the request of the USTR and under the invitation of the Japanese Ministry of International Trade and Industry (MITI).
- The goal of these negotiations is to create a Memorandum of Understanding signed by all parties concerning potential changes to the Japanese market for medical equipment.
- While not guaranteed, it is hoped that this MOU will lead to a change in Japan's regulatory environment regarding access to its market for medical equipment.

## Overview of the Issue

Although it is often somewhat overlooked, the 1,520 billion yen (\$11.6 billion). Japanese medical equipment industry is an important part of the overall Japanese economy. It is one of the few industries in Japan that grew steadily during the country's rapid GDP decline from 1996 to 1998, and domestic production of medical equipment has steadily increased. In 1998, GDP contracted 2.5 percent yet domestic production of medical equipment grew, albeit by less than one percent.

Japan's market for medical equipment is second in size only to that of the United States. In 1998, medical equipment sales, including foreign company sales, were over 2,000 billion yen (\$15 billion). By 2025, the market is expected to be around \$73 billion.

MITI has recognized the significance of the senior services market, including the medical industry, by making it a target for enhanced competitiveness in preparation for the next century. Toward this end, the ministry has promised senior services industries that it will finance programs to enhance relevant collaboration between the government, business and academia.

Nonetheless, companies will still have difficulty introducing new medical equipment into the market unless Japan's regulatory and distribution systems are reformed. Because the estimate for market growth over the next 25 years (\$73 billion) assumes current regulatory and distribution systems, the market is likely to grow even larger if reform occurs.

There are four major problems that providers of medical equipment to the Japanese market are facing are the following;

**1. The Pharmaceutical Affairs Law.** This law is redundant and cumbersome. It reasonably requires medical manufacturers to obtain safety approval for all products before they are marketed. However, Japan's approval process is longer than that of any other major developed country. Another problem related to the approval process is that procedures for "me-too" products are redundant. Such products, which incorporate technologies that are already on the market, should only be examined to determine whether they are equivalent to existing products. Currently, "me-too" products are often reviewed as thoroughly as products that incorporate new technologies.

**2. Japan's Distribution System.** This system is unnecessarily complicated and hinders the introduction of new medical equipment into the market. If the current distribution system were reformed, sales of medical equipment could increase by 5.6 percent.

**3. Ministry of Health and Welfare (MHW) Policy.** MHW's approval policies for new products are too cautious and thereby impede market entry. While a certain degree of

vigilance from MHW is vital to ensuring public health and safety, this vigilance needs to be weighed against opportunity losses incurred by both the medical products industries and patients when MHW's policies are too stringent. Indeed, MHW did not approve the Implantable Cardioverter Defibrillator (ICD) until this device has been in use in other countries for ten years. Yet ICD could save \$46,500 per patient, and it offers a better treatment option for many patients.

**4. The National Medical Insurance Reimbursement System.** This system creates a mechanism under which price competition for medical equipment does not work. Because reimbursement prices reflect the cost of a piece of equipment (regardless of its cost-efficiency), hospitals have no incentive to purchase new more cost-effective equipment and manufacturers have no incentive to produce it.

Eliminating these obstacles is an urgent task not only for the industry, but also for the Japanese government. Indeed, the Japanese government will need to adjust its policies to better accommodate the country's aging population. In 1999, the government spent \$264 billion on health care. Estimates indicate that this expenditure will reach about \$600 billion in 2010, and about \$1,240 billion in 2025. To provide adequate services to its aging population without yet further increasing its growing national debt, Japan will need to find a way to reduce the cost of health care.

Japan will also continue to face pressure from other countries (especially the United States) until it deregulates its medical sector. Since 1986, Japan and the United States have discussed deregulation in the medical market under "The Market-Oriented Sector-Selective (MOSS) talks" led by the U.S. Department of Commerce. The two countries have also held regular bilateral meetings under "The U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy" led by the Office of the United States Trade Representative (USTR). USTR has specifically addressed the medical devices sector as part of this second initiative. USTR's main request is that the Japanese government speed up the approval process for new products. According to USTR, Japan's regulatory system, such as its procedures for approving new medical devices, is unnecessarily cumbersome and restrictive compared to other developed countries' systems.

## **Background**

The Japanese market for medical equipment has grown significantly over the last twenty years. It is one of the few sectors of Japan's economy that has grown steadily despite the country's protracted economic recession. Its growth reflects the public's growing interest in health and its high expectations for medical care. It also reflects the fact that Japan's population is aging and that medical professionals are increasingly reliant on new, often expensive technologies and treatments—particularly for previously incurable diseases (such as certain cancers and AIDs).

The Ministry of Health and Welfare (MHW) is the governmental agency responsible for regulating the medical equipment sector by implementing the Pharmaceutical Affairs Law. The main objective of the law regarding medical equipment is to protect and

improve public health by enforcing regulations concerning quality, effectiveness, and safety. The law was first established in 1943 and was amended in June 1994.

In 1996, Japan spent \$290 billion on medical care, or 7.3 percent of GDP, a figure that is relatively low compared to the United States' 14.2 percent expenditure, Germany's 10.5 percent, France's 9.6, or Canada's 9.2 percent. Nonetheless, Japan's market for medical equipment is second in size only to the United States' \$30 billion market.

Japan's demand for medical equipment in 1998 was 2,029 billion yen (\$15.5 billion). The market grew 4.7 percent in 1998, 3.8 percent in 1997, and 12.7 percent in 1996. The growth is due to increases in both domestic production and imports. Domestic production of medical equipment in 1998 was 1,521 billion yen. It grew 0.4 percent in 1998, 4.0 percent in 1997, and 9.0 percent in 1996. Imports grew faster than domestic production, growing 11.2 percent in 1998, 5.8 percent in 1997, and 20.5 percent in 1996. In 1998, imports accounted for a full 41 percent of domestic demand.

Production, Imports, Exports, and Domestic Demand\* for Medical Equipment in millions of yen.

	1995	1996	1997	1998
<b>Production</b>	1,336,551	1,456,136	1,514,015	1,521,376
<b>Imports</b>	588,700	709,396	750,760	834,509
<b>Exports</b>	268,870	299,308	327,517	327,328
<b>Domestic demand</b>	1,656,381	1,866,224	1,937,258	2,028,557

\* Domestic demand = Production + Imports - Exports

Source: "Annual Statistics of Pharmaceutical Industry's Production Trends," MHW.

The largest exporter of medical equipment to Japan is the United States, which accounted for more than 63.5 percent of total medical equipment imports into Japan in 1998. The United States also accounted for by far the largest portion of imports within nine of the top 10 equipment categories of imports. The medical equipment sector is one of the few sectors in which the United States enjoys a trade surplus with Japan, and the surplus has grown since 1991. In 1997, the surplus reached 409 billion yen (\$3.38 billion), an almost 13 percent increase over 1996.

Germany is the second largest exporter of medical equipment to Japan, although its import share declined from 12 percent in 1991 to six percent 1997. Ireland, Switzerland and the United Kingdom followed with import shares of 3.4 percent, 2.8 percent, and 2.5 percent respectively.

## **Regulatory Controls**

Japan's Pharmaceutical Affairs Law was enacted in 1943, and from 1961 until 1994 no fundamental changes were made to it. In 1994, however, the law was amended to reflect the demand for better health care along with recent changes in medical technology.

The law is designed to minimize the risks inherent in the manufacture and use of medical products, to improve general health and hygiene, and to promote research and development of medical products. It applies to medical equipment, as well as drugs, quasi-drugs, and cosmetics.

The law has four main sections:

- definition and names of medical products;
- manufacture and import approval and licensing procedures;
- distribution control; and
- post-marketing surveillance.

### **1. Product approval and manufacturer/importer licensing procedures**

The Pharmaceutical Affairs Law requires manufacturers and importers to obtain a license from MHW in order to sell medical equipment. A manufacturer must obtain a license for each of its plants that will produce an approved product, and importers must obtain a license for each of its offices that will sell an approved product. Licensing decisions are based on an examination of manufacturers' and importers' facilities, personnel and the qualifications of their technical directors.

A foreign manufacturer may directly apply for a product approval. If it does not have a legal presence in Japan, it can obtain approval by using a Japanese in-country caretaker (ICC) that will file an application on behalf of the foreign manufacturer. If necessary, the in-country caretaker has to make itself available for inquiries from relevant parties including MHW.

The standard processing period for obtaining an approval for “new” medical equipment is 12 months. “New” medical products are defined as products that are significantly different from previously approved products or those new in indications, effects or uses. It takes up to four months to approve “me-too” medical equipment—equipment that is essentially the same equipment that is already on the market. These approval periods do not include time spent by the applicant answering questions or supplying additional information during the approval process.

All applications, both new and “me-too,” are first submitted to the provincial government, which forwards the application to the Pharmaceutical and Medical Devices Evaluation Center (PMDEC) of the Ministry of Health and Welfare. PMDEC submits “me-too” applications to the Japan Association for the Advancement of Medical Equipment (JAAME), an independent entity that is responsible for conducting equivalency investigations. PMDEC performs all other necessary evaluations of “me-too” products. PMDEC first reviews new product applications and then consults with the Central Pharmaceutical Affairs Council (CPAC) concerning the application.

PMDEC makes final approval decisions for both new and me-too applications. It then notifies the provincial governor of its decision, and the governor issues the approval to the applicant.

## **2. Medical equipment that does not require approval**

The law also lists medical products for which no approval is necessary. These products are considered to pose only minimal risk to human health. MHW regularly reviews the list and has steadily increased the number of items on it.

## **3. Bilateral Negotiations between Japan and the United States**

The Japanese and U.S. governments began discussing deregulation of Japan's medical equipment market in 1985 as part of the Market-Oriented Sector-Selective (MOSS) talks. The talks were aimed at removing trade barriers that limit market access within specific industrial sectors: medical equipment and pharmaceuticals, telecommunications, electronics, and forest industries.

The MOSS discussions on medical equipment focused on further opening the Japanese health care market. In the United States' view, the Japanese regulatory system was inefficient, inflexible, and prevented new producers and products from entering the Japanese market. The Japanese Government responded that its regulatory system for the medical sector provided equal opportunities to both foreign and domestic companies. Nonetheless, the Japanese also recognized the importance of simplifying administrative procedures, and as a result, took steps to streamline its approval and licensing procedures and reimbursement system.

In 1997, both governments launched the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy (Enhanced Initiative) under the U.S.-Japan Framework for a New Economic Partnership (Framework). The goal of the Enhanced Initiative is to increase efficiency and promote economic activity in order to better serve consumers' interests. Toward this goal, both governments agreed to conduct a serious exchange of views concerning competition policy, distribution practices, and issues related to transparency and government practices.

With the launch of this bilateral dialogue, the MOSS discussion was made into a working level discussion under the Enhanced Initiative. The Initiative includes five expert-level working groups similar to those established in the MOSS process: medical devices and pharmaceuticals, telecommunications, housing, financial services, and competition policy and distribution.

As of May 1999, the Enhanced Initiative had reached agreement on a number of deregulation measures for the medical equipment sector. These included Japan's agreement to:

- improve the consistency and speed of its approval process for medical equipment;

- improve the consistency and speed of its reimbursement process; and
- accept foreign clinical test data for the approval of new medical equipment.

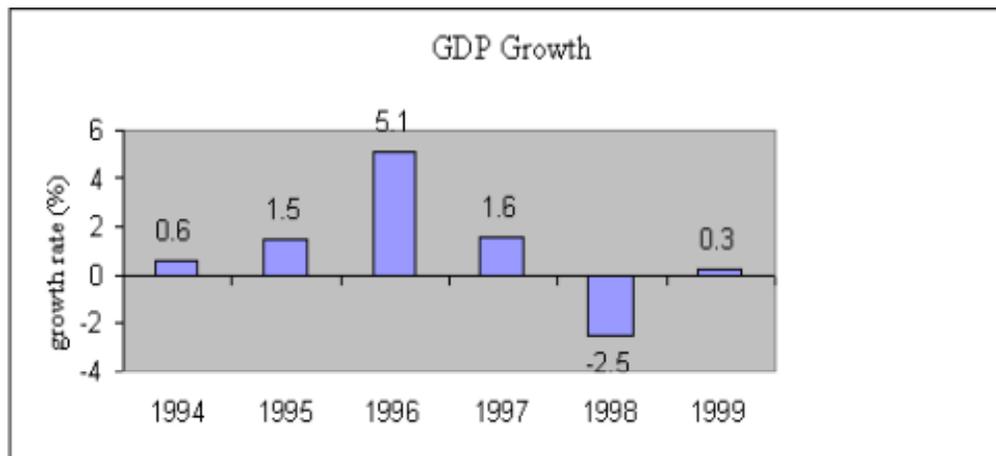
#### 4. The United States' and Other Developed Countries' Regulatory Systems

Prior to 1997, the United States' approval process for medical equipment was considerably longer than that of Japan and certain European countries. It took two to three years to acquire approval for new equipment in the United States, two months to a year in Japan, and even less time in the United Kingdom, Germany and France. Consequently, U.S. manufacturers sometimes received approval for their products in Europe and Japan before receiving approval in the United States. They also began selling their equipment in Europe and Japan before the United States.

In 1997 in response to requests from its domestic medical industry, the United States amended its law that controls medical equipment, and approval times decreased markedly. Currently it takes longer to obtain approval in Japan than in the United States.

### Economic Analysis

The Japanese economy plunged into recession in 1994. It has been slowly recovering ever since but remains weak. Insecurity still prevails in the financial and labor markets. To make matters worse, the government's debt is increasing. Managing health care costs will be important to future economic recovery, particularly because Japan's aging population will demand more health care than ever before in the coming years.



(Source: "Gross Domestic Product: Fourth Quarter 1999 (first preliminary)", EPA, 1999)

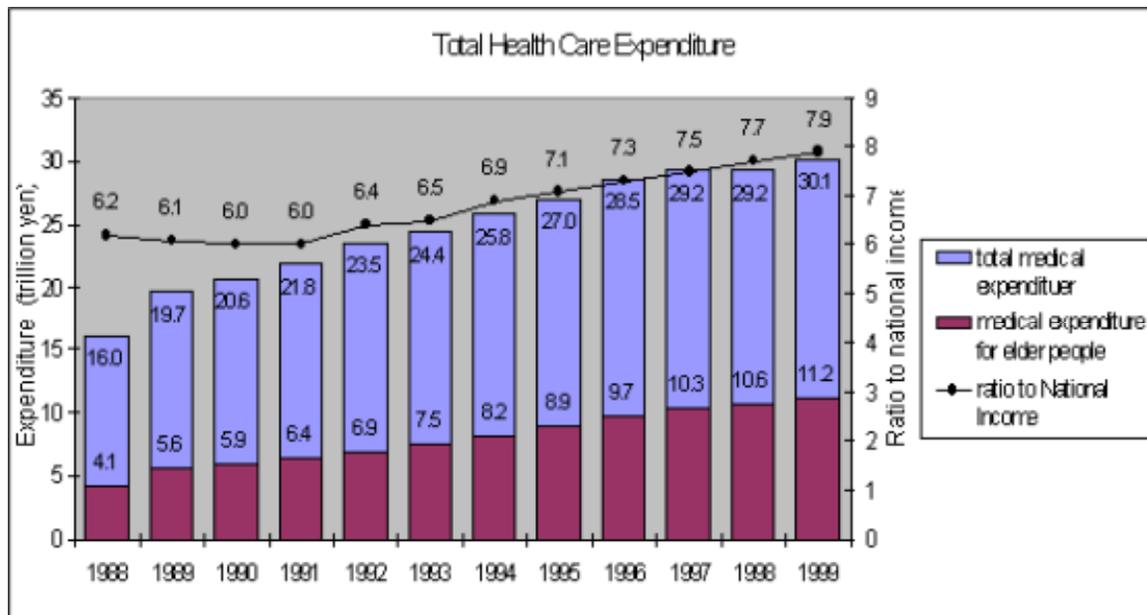
Japan's GDP was 481,865.2 billion yen (\$ 4,230.2 billion) in 1999. Its real GDP growth rate was just 0.3 percent compared to the previous year, and the capital and financial account ran a deficit of 56,148 million yen (\$492.9 million). As of the end of fiscal year

2000, the total long-term governmental debt is projected to reach 645 trillion yen (\$5.6 trillion).

Other 1999 indicators are no more encouraging. The unemployment rate hit 4.7 percent—the worst in modern Japan’s history—and there were 10,249 bankruptcies, which is almost the same level as the previous year.

### 1. Increasing Health Care Expenditures

Japan’s health care expenditures are increasing in tandem with the elderly portion of its population. While total medical expenditures in 1998 were the same as the previous year, the ratio of health care expenditures to national income increased slightly (from 7.3 to 7.5 percent). In 1999, national health care expenditures were estimated at 30.1 trillion yen (\$264.2 billion), and the expenditure to national income ratio grew to 7.9 percent. MHW estimates that health care expenditures will reach to 38 trillion yen (\$333.6 billion) in 2000 and 141 trillion in 2025.

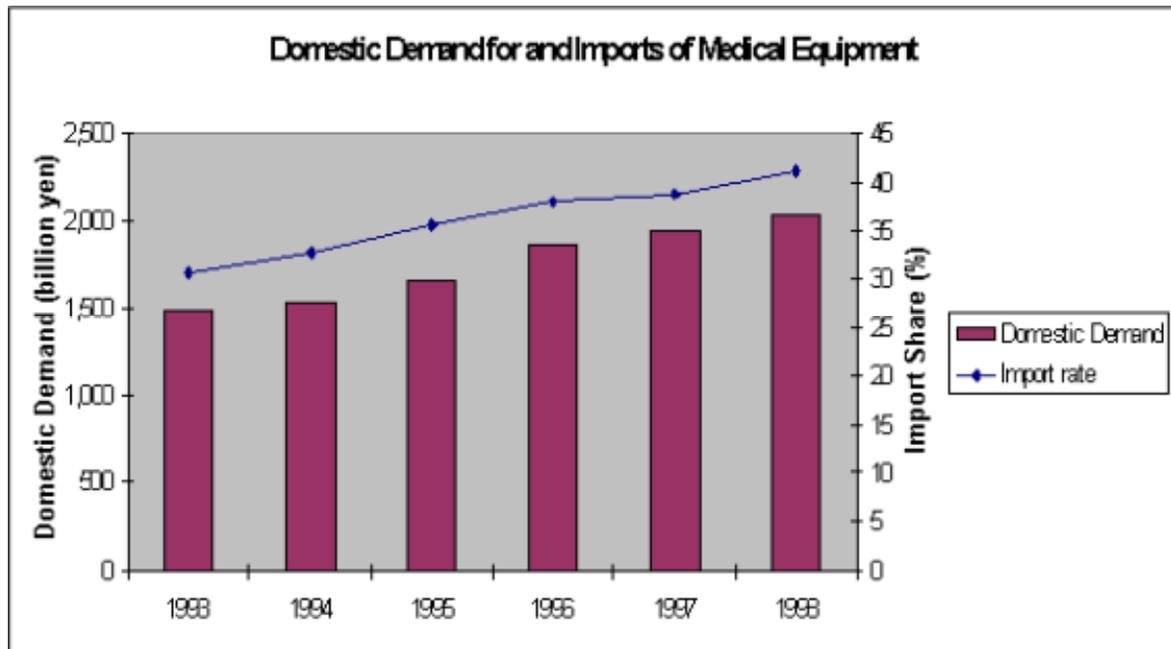


Source: JAAME News, JAAME, 1999 September.

The government is researching various means of reducing health care expenditures. MHW, for example, is conducting studies of how to reform the reimbursement and hospital systems.

## Commercial Analysis

Japan's medical equipment market is extremely attractive to foreign manufacturers because it is large and growing rapidly. In 1995, the cost of medical equipment accounted for 5.9 percent of total medical expenditures. If this ratio were to remain constant (and if MHW's projections for total health care expenditures are accurate), total demand for medical equipment will reach 4,012 billion yen in 2000 and 8,319 trillion yen in 2025. In 1998, the domestic market for medical equipment had already exceeded 2,000 billion yen (\$15 billion).



Source: "Japanese Market Report –Regulations & Practices-: Medical Equipment", JETRO (1998), and "Annual Statistics of Pharmaceutical Industry's Production Trends," MHW (1999).

However, despite the fact that imports in 1998 were valued at 834.5 billion yen (\$6.4 billion) or 41.1 percent of the total market and despite that imports relative to total market size have risen steadily in recent years, foreign governments have often expressed their concern that the Japanese medical industry is relatively closed. In fact, burdensome government regulations combined with Japan's cumbersome distribution system have hindered both foreign and domestic Japanese companies from entering the market.

Japan has reformed some of its medical equipment regulations as a result of negotiations with major trading partners during GATT and GATS reviews of Japanese trade policy. For instance, tariffs on medical equipment were dramatically reduced through multilateral negotiations, and now medical equipment is imported duty free. Bilateral negotiations, notably with the United States, have also been successful in achieving

reforms. The time it takes to gain approval for new medical equipment has been decreased, approval procedures have been simplified, and the number of items that do not need formal MHW approval have been increased. Nonetheless, unnecessary bureaucratic procedures in the product approval process and certain business practices continue to hinder the entrance of new medical equipment products into the market. Both also increase the cost of supplying medical equipment, which means that Japan's total health care bill is larger than it needs to be.

## **1. Unnecessary Bureaucratic Procedures**

In today's world of fast paced technological innovation, some products are outdated almost as soon as they hit the market. The life-cycle of medical equipment is already down to about two to three years.

In this environment, it is crucial to a company's survival for it to get new products to market as quickly as possible and to continually introduce products. Lengthy product approval procedures can significantly diminish a product's profitability, as well as delay the incorporation of new technologies into the research and design of future products.

Japan's approval process is longer than that of any other major developed country; it usually takes a full year to obtain new product approvals in Japan. There are several reasons for this:

- MHW's policies are too risk averse and therefore hurt both medical equipment manufacturers profits and the quality of patient care.
- MHW does not have enough personnel to keep up with new medical product applications.
- Obligatory third-party investigations unnecessarily slow the approval process for "me-too" products, which incorporate technology that is already widely available on the market.

This last problem concerning third-party investigations is actually a result of the U.S.-Japan MOSS talks. It was the United States that asked Japan to commit a certain part of its new product approval procedures to a third party. The goal was to improve transparency and to speed up the procedures by using external sources. However, the situation became worse after the reform.

Before the reform, MHW's Pharmaceutical and Medical Devices Evaluation Center (PMDEC) conducted similar approval investigations for both new and "me-too" equipment. But because "me-too" equipment only incorporates previously approved technology, full-scale new equipment examinations are redundant. "Me-too" products only need equivalency examinations to ensure that they have the same effect as equipment that has already been approved. The redundancy was compounded by the fact that PMDEC was chronically understaffed and lacked transparency.

In 1995, the Japanese government significantly revised the Pharmaceutical Affairs Law with the goal of providing appropriate regulations for each type of what is a growing diversification of medical devices. As part of the revision, Japan established a new institution, the Japan Association for the Advancement of Medical Equipment (JAAME), devoted to examining “me-too” products. JAAME was supposed to review “me-too” applications, make equivalency determinations, and report the results to PMDEC. However the new procedures did not shorten (and in some cases even lengthened) the approval period for “me-too” products because PMDEC still reviewed JAAME’s findings, and it sometimes rejected these findings and initiated its own equivalency investigation.

## **2. Business Practices**

Most medical equipment is sold in Japan through a complex system of distribution channels. Although manufacturers directly provide expensive and high-tech equipment such as CT scans and MRIs, it is common for hospitals to purchase the rest of their products and equipment from just one or two distributors. In both the United States and the European Union, the portion of sales that go through distributors is much smaller and the distribution systems are much simpler—which means that medical products are often much cheaper because dealer systems raise the price of medical equipment by 15-25 percent. A 25 percent drop in prices in Japan could mean a 5.5 percent (\$849.1 million) increase in sales.

## **Policy Analysis**

In addition to the prolonged process for approving new medical equipment, a number of other factors impede access to Japan’s market for medical equipment, including MHW’s overly cautious policies, and both the medical equipment and hospital care reimbursement systems. MITI’s Millenium Project may help the medical equipment industry grow in the coming years, but the industry has until now maintained only weak relations with this ministry—which means that the industry has not benefited from MITI’s industrial policies.

### **1. MHW’s Policy**

One of MHW’s main missions is to improve public health. Since medical equipment directly impacts human lives, MHW is particularly concerned with ensuring its safety. The public holds not just manufacturers but also MHW responsible for any medical accidents that occur due to faulty equipment. It is not surprising then that, even if a manufacturer has a good track record for introducing safe products into the market, MHW scrutinizes all new product approval applications carefully. However MHW has been somewhat too prudent in accepting new technology, and as a result, medical manufacturers, both domestic and foreign, have lost opportunities to introduce new technologies.

A study conducted by the private management consulting firm, Bain & Company Japan, shows that MHW's policies delay the introduction of new technologies. The study found that the industry has missed business opportunities for many years and that patients and the Japanese government have wasted health care dollars because of these delays. For example, the study found that Japan would save 5.3 million yen (\$ 46,500) per patient by approving Implantable Cardioverter Defibrillators (ICDs) for the treatment of tachyarrhythmia (racing of the heart). In April 1996, after the completion of the study, MHW finally approved the product. Other countries had already been using ICD therapy for up to ten years.

## **2. Medical Insurance and Equipment Reimbursement**

Only insurance-approved treatments (including equipment) are eligible for reimbursement. Accordingly, both medical institutions and doctors are only willing to buy and use insurance-approved equipment. Medical institutions also cannot be reimbursed for the use of approved medical equipment until MHW determines what reimbursement price will apply to the use of that equipment. Not surprisingly, it is almost impossible to sell medical equipment for which MHW has not yet determined a reimbursement price.

Under the Health Insurance Law and the National Health Insurance Law, the Japanese government insures medical services (including equipment use fees) for all Japanese citizens. The government collects medical insurance fees from the public and pools the money into a governmental payment fund, such as the Social Insurance Medical Fee Payment Fund. Doctors and medical institutions are reimbursed for their services by the payment agency based on uniform reimbursement prices set by MHW. As previously noted, it is almost impossible to sell products without reimbursement approval because medical institutions do not want to use products for which they will not be reimbursed.

Unfortunately, Japan's reimbursement policy skews competition by creating a situation in which hospitals are price indifferent in their new equipment purchases. Hospitals often do not make cost comparisons when buying equipment because reimbursement prices usually reflect the sale price of a piece of equipment; each brand of products is assigned its own reimbursement price (even though a product has the same function as another product) and the government guarantees to pay back the purchase cost of equipment. Under the current reimbursement system, new, more cost-effective equipment is no more appealing than less cost-effective because the government reimburses more expensive equipment at a higher rate than more cost-effective cheaper equipment.

This system is clearly disadvantageous to newcomers, especially to domestic newcomers because Japanese manufacturing industries have typically grown by producing cheaper versions of foreign products. Japan has the skill and technology to produce cost-effective manufacturing products. However, the current reimbursement system makes it extremely difficult for Japanese companies to get new products into the market.

### **3. Hospital Care Reimbursement**

Japan is famous for its long hospitalizations. In 1996, the average hospital stay in Japan was 33.5 days, whereas in the United States, United Kingdom and Sweden average stays were just 7.5 days, 9.8 days, and 7.5 days respectively. While this phenomenon is largely due to the fact that the reimbursement system rewards hospitals for keeping patients in the hospital as long as possible, increased use of innovative medical equipment would likely shorten costly hospital stays. Shortened stays would result in significant cost savings because the cost of hospitalization accounts for over 50 percent of the remuneration hospitals receive.

### **4. The Medical Equipment Industry's Weak Relationship with MITI**

MHW largely controls the medical equipment industry because medical equipment plays a crucial role in maintaining public health. In order to facilitate product approvals, the industry has concentrated its energies on developing good relations with this agency. However, MHW's interest lies in studying advanced medical technology and protecting public health, not in protecting the industry's commercial interests.

In order to gain more support for the development of a strong industry, the medical equipment sector needs to develop stronger relationships with MITI, the only ministry that promotes commercial interests and industrial competition. MITI has succeeded in enhancing the competitiveness of strategic industries such as the electronics, automobile, and steel industries.

### **5. MITI's Millennium Project**

In 1999, MITI proposed a comprehensive project, the "Millennium Project," to help build Japan's competitiveness in the 21<sup>st</sup> century. The project covers 15 technology areas and is geared toward creating "frontier markets" that will create new market and job opportunities.

One of the primary goals of the project is to build greater collaboration between business, universities and the government. Toward this end, the government will provide generous financial support for research and development and the development of smoother technology transfers from the research phase to the product-engineering phase. The project also includes the elimination of regulatory impediments that prevent business from achieving its full potential.

The senior services market was selected as one of the 15 target areas. MITI proposes to promote the development of technologies that help senior citizens lead rich and fulfilling lives. The project will support research and development within the medical industry and help the industry introduce new cost-effective and innovative products into the market.

## **Legal Issues and International Harmonization of Standards**

Each government in the world regulates the use of medical technology in order to ensure the public's safety. While such regulations provide a valuable public good, they also can act as technical barriers to trade, and such barriers are becoming more and more of a problem as trade expands. Indeed, concern over such technical barriers to trade has become one of the central issues confronting the international trade system, and medical equipment is one product category in which standards differences are a particular problem. To date, there is no international agreement concerning medical equipment standards.

### **1. Standards Systems for Medical Equipment**

In Japan, the Pharmaceutical Affairs Law requires medical equipment to meet the Japanese Industrial Standards (JIS) of the Industrial Standards Law. Japan is working toward harmonizing JIS with international standards, such as those of the International Standard Organization (ISO) and the International Electronic Commission (IEC), in order to comply with the WTO (TBT) Agreement.

The Pharmaceutical Affairs Law also requires manufacturers to meet the standards for manufacturing control and quality control of medical devices under the so-called Good Manufacturing Practices (GMP) standards. The United States uses 21CFR820GMP as its standard for manufacturing control, and the European Union uses EN46001~2. ISO 13485 is considered to be the international standard for regulating the manufacture of medical devices. There is a growing movement toward harmonizing each country's GMP with ISO 13485.

The Uruguay Round trade negotiation yielded considerable success in reducing market access barriers raised by tariffs, rules of origin, custom valuation, import licensing procedure, and pre-shipment inspection. Now some WTO members are considering whether Japan's distribution systems constitute market access barriers. At this stage, there is no agreement as to whether these systems violate any WTO agreements. However, it is true that the business practices that currently prevail in the medical equipment industry make market entry difficult for both domestic and foreign manufacturers.

### **2. International Harmonization: The Global Harmonization Task Force (GHTF)**

In recognition of the increasing need for international harmonization of regulatory controls for medical equipment, representatives of the governments and private sectors of the United States, the European Union, Canada, and Japan formed the Global Harmonization Task Force (GHTF) in 1993. GHTF's primary goal is to harmonize regulatory systems, promote technological innovation, and facilitate international trade.

Members are divided into categories. Principal members are representatives of a national government or relevant industries from the European Union, the United States, Canada,

Australia and Japan. General members are any persons, representatives of a governmental body or relevant industries from non-principal countries or NGOs.

GHTF has established four study groups with the following responsibilities:

#### *Study Group 1*

- To compare present regulatory systems around the world;
- To identify the essential elements/principles for harmonization;
- To identify obstacles to uniform regulations; and
- To develop a standardized format for pre-market submissions and common labeling.

#### *Study Group 2*

- To harmonize data collection and reporting systems such as post-market surveillance.

#### *Study Group 3*

- To examine existing quality system requirements; and
- To identify areas for harmonization.

#### *Study group 4*

- To examine quality system auditing practices; and
- To develop harmonized medical device auditing process.

GHFT has conducted a series of discussions and information exchanges among its members. To date, however, no specific harmonization measures for medical equipment have been established.

Participation in GHTF is beneficial to the Japanese medical industry for three reasons:

- GHTF will help Japan reform and simplify its regulatory system by providing a forum in which government officials can learn about other countries' regulatory systems.
- GHTF will help Japanese manufacturers promote exports because by harmonizing its standards with other countries' standards, Japan can reduce the additional production costs associated with adjusting products to meet each individual importing countries' standards.

GHFT will help individual medical device manufacturers gain international recognition because private companies and associations are allowed to participate in GHFT meetings as general members. To date, however, few medical device companies have attended the meetings.

## **BACKGROUND ON CONDUCT AND ORGANIZATION OF SIMULATION**

### **THE NEGOTIATION PROCESS**

The parties to these negotiations will be provided with individual team instructions and facts common to each country team's interests.

Individual interest groups (e.g., associations, government agencies, etc.) will meet first to review facts, develop team negotiating goals and strategies, assign research and negotiating roles, and to document all negotiating sessions.

All interest groups will then meet with their country team members. (Country team members may or may not share common interests, goals, etc.) Lead government agencies will seek to reconcile differences and to advance a unified voice in the bilateral or multilateral sessions.

All teams will seek to advance specific negotiating goals and interests. For example, it can be assumed that China seeks acceptance **in the** international trading community, that it would like to avoid a dispute in the WTO, and that it is committed to an increased level of enforcement in the area of intellectual property rights. Similarly, it can be assumed that the US, EU, and Swiss governments and constituent manufacturing groups seek enforcement of IPR laws in China and greater access to the Chinese market. Interest groups may differ, however, on appropriate timetables, implementation mechanisms, and enforcement.

All parties will want to consider some or all of the following:

- 1) Documentation of the scope of the problem;
- 2) Specific agreements to implement reforms including, but not limited to rules, regulations, monitoring devices, enforcement mechanisms, legal remedies, etc;
- 3) Timetables for implementation of agreements reached;
- 4) Criteria in the field of IPR for Chinese accession to the WTO.

It will also be important to determine the interests of your counterparts including adversaries and allies. You will want to try to build alliances within your country and with other country governments or individual interest groups.

### **CONFIDENTIAL PARTY INSTRUCTIONS**

Each individual team (interest group) will be provided with further confidential instructions issued from the perspective of a superior corporate, governmental, or military officer. You are to design your negotiating strategy in accord with the instructions. Questions regarding instructions or the terms of agreements reached can be reviewed with one of the instructors.

## **NEGOTIATING SKILLS AND TECHNIQUES**

- 1) Teams should engage in "brainstorming" sessions to identify and articulate your interests and those of your counterparts including the listing of potential **OPTIONS** for an agreement and the use of **OBJECTIVE CRITERIA** for the structuring and implementation of agreements;
- 2) Teams should elect a **LEAD NEGOTIATOR** for each negotiating session. It is important for team members to defer to a lead negotiator and to **SPEAK WITH ONE VOICE**. Lead negotiators may invite the participation of team members on specific issues, areas of expertise, etc.
- 3) Teams should use **CAUCUSES** (private team meetings) to review proposals, formulate counter-proposals, or to review the status of the negotiations; Remember to **LISTEN** to your counterparts and **ASK QUESTIONS** to learn what their needs are. What do they want? Can you fashion an agreement or the provision of an agreement that will meet some if not all of their needs? Are your sessions **CONFIDENTIAL** or open to the press and public? Craft and utilize **SINGLE TEXT DOCUMENTS** to introduce proposed language on agreements, to capture agreements on procedure and/or substance that can be added to the text of a final agreement; Obtain **SIGNATURES** of counterparts on documents reflecting interim or final agreements; Consider future meetings, working groups, investigative teams, etc as means to keep the process moving forward and to avoid stalemates. Remember you are dealing with people. What are their needs within their organization, bureaucracy, company, etc. Can you help them to meet their needs? Establish a personal rapport. Be hard on the problem, be soft on the people. Consider a **JOINT MEDIA RELEASE OR CONFERENCE** to announce progress or a final agreement. Use the media to help solidify the parties' public commitment to the agreement.

## **RULES TO ENHANCE THE LEARNING GOALS OF THE SIMULATION**

Because time is extremely limited, the instructors request that students abide by the following rules which have proven effective in other negotiation simulations:

- 1) Limit caucus sessions and breaks during negotiations to no more than five (5) minutes;
- 2) Country teams will have to negotiate an internal consensus among all interest groups **BEFORE** the commencement of official bilateral negotiations with national counterparts.
- 3) The parties will not be authorized to "walk-out" or otherwise boycott a negotiation session;
- 4) If negotiating teams reach an "impasse" (stalemate, dead-end, end point) they should work on another issue and/or seek the instructors' intervention;
- 5) No name calling, personal attacks, or insults will be permitted. (This is not good style in real world negotiations and is usually the result of ego, loss of emotional control, etc.)
- 6) Make use of charts, note-taking, printed exhibits, and printed documents to facilitate the recording of interim and/or final agreements.

## **LOCATION OF THE NEGOTIATIONS**

As negotiating sessions are established, a home country will be identified. The home country should serve as the host of the negotiations. Hosts should welcome guests to their country and to the negotiation session. Introductions should be made before the parties proceed to substantive matters