

## Keeping Up with Changes in the Japanese Medical Device Market

For manufacturers exporting medical devices to Japan, understanding the recent regulatory developments there is essential to success.

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Although Japan has experienced a recession since the early 1990s, its medical products market has continued to expand. In 1995, for example, this market grew 3% to \$21 billion. In 1996, the Japanese spent \$290 billion on health care, or about 7% of their national income.<sup>1</sup> The U.S. share of this market is also increasing. Between 1990 and 1994, the U.S. market share rose from 13 to 20.3% and accounted for 62.3% of all medical product exports to Japan. According to the Health Industry Manufacturers Association, U.S. medical product exports will continue to grow as Japan opens its market to the West even further.

This growth has magnified the economic, political, and other types of pressures facing the Japanese government, and has spurred dramatic reforms of several aspects of the government's policies on medical products. The pressures include upwardly spiraling health-care costs, a rapidly growing aging population, and ongoing international trade negotiations. Some of the economic pressures are unique to Japan, and some resemble those that have plagued the U.S. health-care system for some time, although Japan's government-sponsored, single-payer system is very different from that of the United States.

Some of the most important areas in which changes have been made are in pricing, reimbursement, and in the requirement of postmarket safety assurance. In addition, the government has begun large-scale restructuring of the organizations that are responsible for overseeing the medical device market.

### RESTRUCTURING

An immediate catalyst for the restructuring of Japanese regulatory bodies has been the recent scandals that involve HIV-infected blood and nursing home subsidies. These scandals have led to greater separation of regulatory and industry interests within the government.

**Tainted Blood.** In 1995 and 1996, public outcry followed reports that both the Ministry of Health and Welfare (MHW) and industry a decade earlier had concealed findings showing the grave and imminent health danger of unheated blood products. This bureaucratic inaction caused more than 400 HIV-related

deaths, and uncovering the scandal resulted in the arrest of an expert on the treatment of hemophiliacs, three presidents of leading domestic manufacturers of blood products, and one high-ranking MHW official.

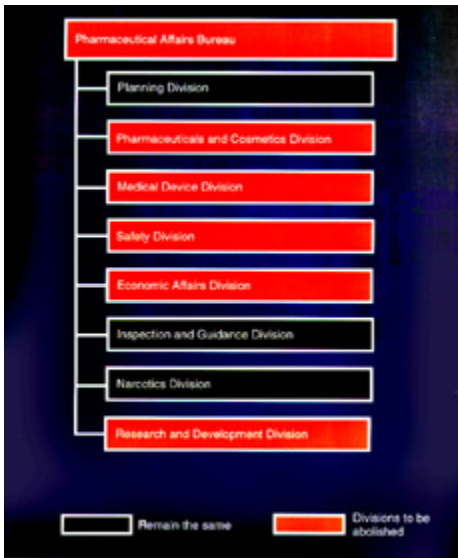


Figure 1. Ministry of Health and Welfare reorganization chart--present system.

In the mid-1980s, despite well-known international evidence that HIV can be transmitted through unheated blood products, MHW and some pharmaceutical companies failed to issue warnings in Japan. At that time, HIV was still largely unknown in Japan, and some facts about AIDS transmission were still in question. One MHW official said that the Japanese government, in principle, could not take any action before all information was confirmed. On the basis of this principle, MHW delayed issuing warnings for almost a decade. When Japanese victims of the virus, most of whom remain anonymous because of the continuing general perception that AIDS is shameful, finally brought the matter to court in 1995, the public was outraged. By the time a settlement was reached in March 1996, information had been revealed that caused public condemnation of the government in general and of MHW in particular.

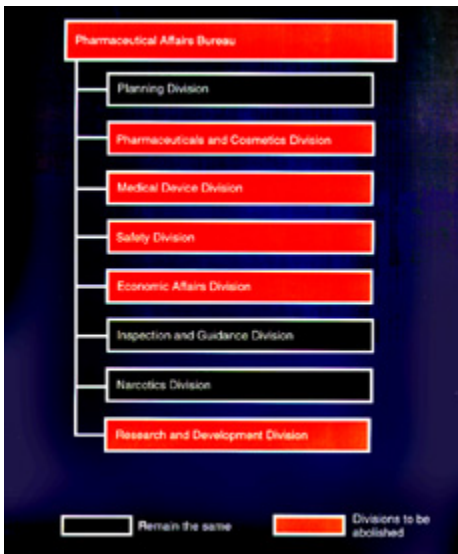


Figure 2. Ministry of Health and Welfare reorganization chart--proposed system.

Many in Japan felt that the organizational structure of the regulatory authority involved was to blame for the scandal, and in 1996 the government began to address this problem. In Japan, new drugs and medical products are not only inspected and controlled, but also promoted by the MHW's Pharmaceutical Affairs Bureau (PAB). This inherent conflict of interest, charging one government office with both regulation and promotion, is considered by many to have caused the delay in introducing heat-treated blood products for hemophiliacs and to have prolonged the use of unheated blood products even after the official approval of heat-treated products.

As a result, MHW plans to abolish the PAB, replacing its safety functions with a pharmaceutical safety bureau and shifting its promotion functions to the MHW's Health Policy Bureau (HPB), which currently oversees medical institutions and related matters, including Japanese hospitals and their operations (see Figures 1, 2, and 3).



Figure 3. Reorganization of the Health Policy Bureau.

Under this plan, the Safety and Pharmaceutical and Cosmetics divisions within the current PAB would also be eliminated and an Inspection and Management Division would be created within MHW. MHW officials believe that the new Inspection and Management Division would result in better premarket oversight of medical products. In addition, the Inspection and Guidance Division of MHW would be responsible for postmarket inspection of drugs and medical products. Medical firms, therefore, would have to remain alert about their products even after successfully releasing them into the market.

Also, a National Food and Drug Evaluation Institute (NFDEI) would be created under the existing National Institute of Health Sciences, and much of the work related to evaluating drugs and medical devices would be transferred to this new NFDEI in order to increase the efficiency and accuracy of inspections. According to one industry observer, however, "transparency in and acceleration of the approval process for the manufacture and import of drugs and devices remain to be monitored."<sup>2</sup>

The government also plans to create a Blood Products Policy Division, and the Red Cross, which supervises a major portion of the blood supply, would have a key role within it. The new rules to be implemented by this division are still unknown. Additionally, a new AIDS Policy Division would be instituted under the Health Service Bureau, which now oversees disease control.

Not only does the government intend to redistribute oversight duties, but it also plans to triple MHW's pharmaceutical examination staff by the year 1999, from 60 people today to more than 200, which would approximately match European and U.S. regulatory agency levels. This increased staff would shorten not only the drug approval process, but also, according to one MHW official, the approval process of medical devices. This process, which now takes up to two years, could be shortened to less than a year.

All of these changes, of course, are dependent upon whether MHW's 1997 budget request is granted. MHW has requested a 74% increase in the current PAB's funding to 16,800 million yen, or about \$150 million.

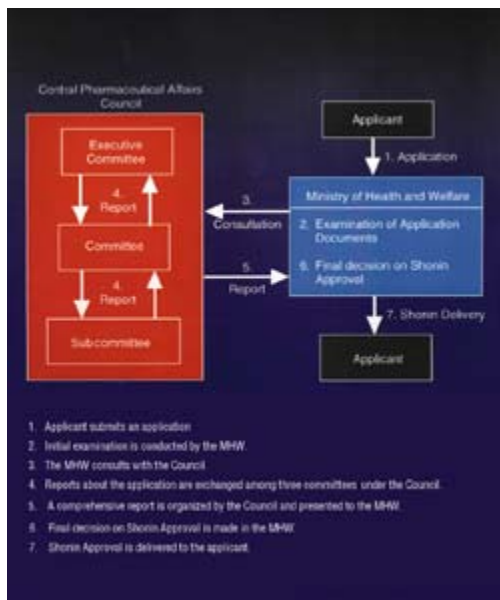


Figure 4. Shonin approval process--present system.

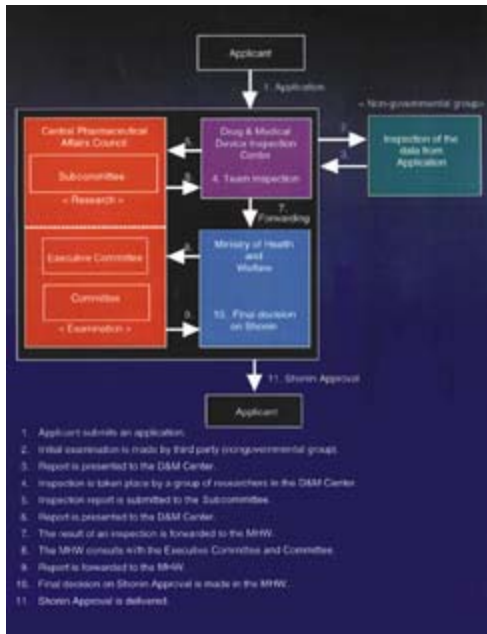


Figure 5. Shonin approval process--proposed system.

**Subsidized Nursing Home Bribes.** Another government scandal was uncovered when MHW's former deputy section chief, Shigeru Chatani, resigned last November after admitting that he had accepted bribes of 60 million yen, or about \$60,000, in cash and membership at an exclusive golf club from a businessman who ran several government-subsidized nursing homes.

The businessman, Hiroshi Koyama, a representative of the Aya Fukushi Group, had already been arrested the day before for allegedly bribing other ministry officials. MHW intends to punish more than 10 of its bureaucrats involved in this episode.

In Japan, a social welfare corporation that establishes a nursing home for the elderly is eligible for subsidies from the central and prefectural governments. The central-government subsidies alone can amount to half of a project's construction cost. Koyama had set up six social welfare corporations between 1993 and 1996 under the name of Koyama Group Co. The company obtained 3.6 billion yen, or about \$36 million, in subsidies, including 2.1 billion yen, or about \$21 million, in prefectural subsidies, after receiving advice from MHW officials.

While bribes to government bureaucrats for business favors are not unusual in Japan, this incident focused public awareness on the links between business and government. As a result, MHW decided to implement a strict ethics code. For example, any entertainment for government bureaucrats from companies directly supervised by MHW is now prohibited.

The subsidies incident has hastened the separation of business and government interests within MHW, a process that was begun as a result of the tainted blood scandal.

## HIGH PRICES AND REIMBURSEMENTS

In addition to the government reorganization described above, the pricing and reimbursement systems for medical devices sold in Japan are also changing.

**Medical Equipment Pricing.** According to the *Nihon Keizai* newspaper, the high price of medical equipment in Japan has been a factor in the country's ballooning medical expenses. These prices are actually higher than those of both Europe and the United States. The price differential is greatest for foreign-dominated product areas, such as pacemakers and MRI machines. Japanese prices for these types of medical devices are often three to five times greater than those for U.S. and European products. Also, as in the United States, large numbers of expensive diagnostic equipment, such as MRI machines, can lead to unnecessary tests that are conducted in order to recover the costs of the devices.

According to the *Daily Yomiuri*, MHW plans to launch an investigation into possible reasons for the price differences between domestic and imported products and equipment, including distribution channels. As part of this investigation, MHW will hold hearings on sole-import agents for medical equipment and conduct a survey of international prices. Once the investigation is finished, MHW plans to provide guidance to vendors in order to improve the situation and reduce prices. In the meantime, a medical equipment trade association will establish a panel on fair trade, after coordinating with the government's Fair Trade Commission, which regulates antitrust laws in Japan, as the Federal Trade Commission does in the United States. The new panel will check distribution channels independently of MHW.

The Japanese Federation of Medical Device Associations, which includes medical equipment manufacturers and sales agents, also plans to establish a fair trade advisory panel. This panel will review regulations that unduly restrict entry to the medical market. It will attempt to prevent misleading or overblown advertisements and the enticement of customers through premiums or kickbacks. The federation's goal is to promote transparent price formation through free competition among vendors.

**Reimbursement Practices.** Another area of changes in the Japanese medical market is reimbursement. A medical product is technically qualified to be brought to market only after a firm has registered it and obtained the various necessary government approvals, called *shonin* (approval) and *kyoka* (product license). This system was originally enacted as part of the Pharmaceutical Affairs Law to ensure the safe supply of medicines.<sup>3</sup> In 1948, the law was expanded to include

regulations for medical equipment in response to a proliferation, at that time, of defective and inferior devices.

Despite this careful government approval system, a product's sales in Japan actually depend largely upon the completely separate reimbursement policy conducted under the National Health Insurance System, which is a single-payer plan covering virtually all of the population. A manufacturer must obtain an appropriate price listing under this system or there can be no reimbursement for purchase or use, whether or not the product has been approved for sale. Each medical examination or treatment using a product in question is awarded points that correspond to a value chart issued by MHW. In this system, which is known as the *piecework payment system*, one point equals one yen.

Actual reimbursement is given by the insurer via a screening and payment agency. MHW consults the Chuikyoku, or Central Social Insurance Medical Council, to obtain a range of opinions on the reimbursement apportionment points. This council has 20 members representing medical practitioners, those who pay fees, and the public.

For reimbursement, the MHW's Health Insurance Bureau places products in one of three categories: technical fee, special treatment materials (STMs), or highly advanced medical technology system (HAMTS).

For products in the technical fee category, hospitals receive payment per procedure rather than per product.

The STM category includes such products as guidewire angiography catheters, foley catheters, and orthopedic accessories. Reimbursement for the products in this category is on a per-product basis according to device function. Prices are revised every two years based on a weighted average of all brands in a functional group, as well as on a price survey. This functional approach is different from the previous system, which was in effect until 1995. Under that system, products were classified according to their brands rather than their functions.

The STM reimbursement category's main shortcoming is in determining the functional classification to which each product belongs, which rapid technological innovation makes difficult. The price differentials between domestic and imported products is another problem with the STM category. Because of these problems with STM product pricing, MHW has selected two products from the category for a distribution survey. The ministry hopes that the results of the surveys will help correct the high prices of imported STM products in Japan.

Other aspects of the overall reimbursement system, such as piecework payment to hospitals and official STM price setting, also hinder competitive pricing and, in turn, lead to price differentials.<sup>3</sup>

The HAMTS category covers breakthrough technology. In this category, hospital reimbursement is given only for procedures and related procedure costs, not for products. The major difficulty in setting prices for HAMTS products is that clinical trials can be long, and there is no defined schedule of when reimbursement will be approved, which can discourage producers from bringing advanced technologies to Japan. This system creates difficulty in obtaining a higher price for improved technology, providing little incentive for new technological development. Because most HAMTS products come from foreign manufacturers, the difficulties with this category create an obstacle to foreign producers entering the Japanese market. It is important to note, however, that from MHW's perspective, it is difficult to approve expensive products that are used by only a few patients because all citizens are supposed to receive the same level of treatment in Japan, and not many can afford highly expensive technology.

The current medical product reimbursement system encourages the use of products that do not contain advanced technology because new technology takes a long time to gain approval and may not be profitable at the beginning. Moreover, the system focuses on the cost rather than the quality of medical products. In some respects, it is sending the message to foreign manufacturers not to introduce products that might make health-care delivery more efficient.

## **POSTMARKET SAFETY ASSURANCE**

Manufacturers should also be aware of the need to gain postmarket safety (PMS) assurance, which an in-country caretaker (ICC) may not mention up front.

The Japanese ICC system works in the following way. If a foreign medical company does not want to set up an office in Japan and instead decides to export its products, allowing a Japanese distributor to sell them, the manufacturer must choose whether to register its products directly in its own name via an ICC or to allow the Japanese distributor to register the company's products in the distributor's name.

If a foreign manufacturer chooses to have the distributor register the products in the distributor's name, the manufacturer usually does not have to pay all the registration fees or handle ongoing safety responsibilities. However, without direct registration or shonin, changing distributors can be difficult, time-consuming, and costly. If the current distributor is doing a poor job or is otherwise no longer suitable, and is not willing to relinquish control over shonin, the foreign medical manufacturer may have to begin the shonin process all over again to obtain a new approval and find a new distributor.

In contrast, registering products directly in the foreign medical company's name with an ICC enables a foreign medical manufacturer to retain more control over its products and marketing strategy in Japan. With direct registration or shonin, a foreign medical manufacturer can change Japanese distributors easily. A second

major advantage of using an ICC is that a foreign medical manufacturer can arrange for multiple product distributors.

A new regulation applicable to the ICC system now mandates that all unique medical products that are introduced into the Japanese market and that require clinical studies for registration approval will also require PMS assurance. In effect, MHW requires that the ICC continue to collect data after the products are marketed, because certain safety problems may become evident only during actual use in the marketplace.

For PMS assurance, MHW requires that an annual report be submitted for three years following the introduction of a unique or new medical device into the Japanese market. After the final annual report is submitted to MHW, the medical product manufacturer must also submit an application for a reevaluation of the original approval that takes into account the new data.

The PMS procedure is an important aspect of an ICC's work and should be considered when contracting with an ICC. An ICC's initial proposal to a foreign medical manufacturer often does not include the PMS process and fees, although the ICC's PMS work can add \$25,000 to \$50,000 in fees to the medical device manufacturer's overall direct registration costs over a three-year period.

## CONCLUSION

Japanese medical product regulations are evolving every day. In the wake of government scandals, MHW has begun a sweeping internal reorganization. In addition, pricing and reimbursement practices have changed. New requirements for PMS assurance mean higher costs for devices that require clinical trials. Recently, along with these other developments, MHW has also changed the registration process for new drugs. According to one MHW official, this change will soon lead to a reform of the registration process for medical devices as well (see Figures 4 and 5 for an overview of the changes). Medical firms must stay alert to all such regulatory changes in Japan if they hope to succeed in the world's second-largest medical market.

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