



## Medical device exports to Japan require long-term commitment

Japan is a country rooted in tradition, uniformity, and subtlety. These characteristics have sometimes created problems for U.S. medical device manufacturers, which historically have encountered closed doors and hidden barriers when attempting to penetrate the Japanese marketplace. Japan is far too attractive for U.S. firms to ignore, however: The Japanese market for medical devices is worth an estimated \$20 billion, second only to that of the U.S.

The well-publicized trade imbalance between the U.S. and Japan for consumer goods is also found in the medical device industry. The situation has been exacerbated by the recent 60% devaluation of the yen, which makes U.S. medical devices more expensive in Japan and Japanese products cheaper in the U.S. Comparing the first five months of 1998 to the same time frame in 1997, U.S. medical device exports to Japan are down 8%, while Japanese imports to the U.S. are up 13%, (source: Health Industry Manufacturers Association).

Recent developments in the Japanese health care sector, however, signal some headway in removing traditional barriers to entry. First, U.S. firms must unravel the web that is the Japanese medical device market.

### Fixed pricing

For a U.S. firm to sell a medical device or pharmaceutical in Japan, an approval (shonin) and a license (kyoda) must be granted by the Japanese Ministry of Health and Welfare (MHW). This can take from 90 days to two years or more, depending on the product. Firms wishing to sell in Japan must be prepared for a long-term commitment.

Further, the return on investment may take years to realize. As a result of Japan's public-sector procurement market, U.S. manufacturers are reimbursed for their products under the Japanese National Health Insurance Program. U.S. firms obtain pricing for their product via the Chuikyo (Social Insurance Medical Affairs Council). This process is particularly troublesome for manufacturers who feel that they are not adequately and fairly reimbursed for innovative technology.

### "Hospitals have become de facto nursing homes"

Language requirements begin at this initial stage. Frank Vaughan, head of HIMA's new Tokyo office, comments: "In principal, all documents submitted to MHW as part of the shonin application must be in Japanese."

For pharmaceutical firms, only the "gaigo" or summary of submissions, both clinical and pre-clinical, must be translated into Japanese if the original documents exist in English, pursuant to MHW notification 256 issued in March 1998. However, if the original documents are in a language other than English, the entire dossier must be translated into Japanese, comments C. Michael Lutz, Director of Global Drug RA at Hoechst Marion Roussel in Bridgewater, New Jersey. Furthermore, once a product is approved, most product documentation typically is translated into Japanese throughout the product's life cycle. Without a proper budget, translation can represent a barrier for U.S. firms.

### "Necessary" vs. "convenient" devices

Another potential roadblock is the traditional Japanese approach to medical technology. Yoshiaki Mizutani of Nishimoto Sangyo Company, a medical distributor in Tokyo, notes that the Japanese divide medical devices into two distinct categories: products considered "absolutely necessary" and those dubbed "convenient if owned."

Innovative technology may not be purchased by Japanese hospitals because it is not considered "absolutely necessary." Moreover, doctors may not have proper training to use the new technology and/or may not have the additional space to store and maintain the equipment.

To navigate through such tricky waters, U.S. firms must establish a presence in Japan and learn as much as possible about local market conditions. Many firms opt to work with a Japanese distributor who understands the nuances of the marketplace. Mizutani-san suggests that U.S. manufacturers begin distribution of new technology in the western region around Osaka, where doctors tend to be less trepid in their approach to new technology than their colleagues in Tokyo.

All too often, small and medium-sized manufacturers fail in Japan as a result of not understanding the marketplace. "The distributors may lack direct coverage for the Japanese market and the in-house capabilities to

**"Too many times the channels/distributors lack direct coverage for the Japanese market and the in-house capabilities to march the product through the government approval process."**

march the product through the government approval process. Moreover, the distributors can be too generic to reach the potential niche or market segment," says Dick Howell, a consultant in Gilroy, California who helps U.S. companies locate appropriate Asian channels.

### Health care problems encourage new device demand

In spite of such barriers, firms can and do sell successfully in Japan. Recent trends in the health care sector point to a gradual easing of trade barriers for U.S. firms. The MHW has been working with the U.S. Department of Commerce and the FDA to overcome trade barriers that discourage U.S. importers from entering the Japanese marketplace.

One reason motivating the MHW is a long-standing problem in Japanese hospitals. "Japan has the oldest and most rapidly aging population, the most hospitals per capita, and the longest hospital stays in the world," says Ed Rozynski, HIMA's Executive Vice President. Hospitals have become de facto nursing homes, and the drag on the economy is extreme.

In view of both the MHW and the FDA, relaxing regulations and creating a competitive marketplace should bring in new technology that improves overall treatment and thus reduces hospital stays. It also promises to allow the open market to dictate device and drug prices.

These changes, however, likely will proceed at a very slow pace. In the meantime, a U.S. firm must do everything it can to learn about the Japanese marketplace, choose a reliable, knowledgeable Japanese partner, commit a budget adequate to establishing a presence and localizing the product, and, most importantly, have the resolve and patience for the long haul. Only by adhering to these guidelines does a manufacturer have a chance of succeeding in the Japanese marketplace.

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