

Strategies for Success in Japan's Medical Device Market

It's critical to understand the characteristics of this country's market to determine the most effective steps.

Japan is a large country with more than 125 million people, and it is still the second largest medical device market in the world—even if China is catching up. Entry into Japan's market can be very difficult to navigate. The following tips cover some of the most important issues that you must consider in order to maximize the chances of success for your medical device product.

Japanese Healthcare: Understand Japan's Healthcare System and Business Culture

Japan has an advanced healthcare system, although it is very different from the healthcare system in Western countries. Japan has a single payer system where the government is paying out a great deal of money for healthcare via reimbursements. While some drug prices will be slashed in 2018, medical device prices will mostly stay the same. The average hospital stay in Japan is 27.5 days and the average time a woman will spend in a Japanese hospital for giving birth is about one week. In contrast, in the United States, once you deliver your baby and everything is normal, generally you will not spend more than two nights in the hospital.

While health economics is becoming more popular in Japan, it is still not as prevalent as in the West. Japanese business culture is very conservative and generally attempts to avoid risks. Competition is fierce throughout the medical world, but is especially so in all aspects of business in Japan. For example, a number of years ago I had an employee who had worked at a wasabi manufacturing company in Japan prior to joining my firm. While most of us would assume that wasabi is just wasabi, for Japanese people, the quality and taste of the product is a key competitive issue. Her previous job was to travel to more than 2,000 Japanese restaurants a year to check the quality of her company's wasabi product and competitor's products, and determine how to get an edge.

Market Research: Ensure There Is Demand

As a foreign medical device manufacturer, determining the demand for your product before trying to enter Japan's market is crucial. While some of the same strategies you use in Western markets will still be applicable, you must remember that Japan is a very different market. In most cases there will already be competitive devices already on the market—so how will your product break in? Japanese buyers usually prefer domestic Japanese products when they are available.

If you have a new device that has succeeded in Western markets but has not been introduced to Japan yet, there are several steps you should take to ensure there is demand for your product. Asking Japanese key opinion leaders (KOLs) about your new product in Japan can be very helpful, especially if these KOLs have connections to a local Japanese researcher. However, it can be troublesome for Western companies to ask for feedback from Japanese KOLs since many Japanese people will always be more polite and less direct to foreigners, and therefore will not give their true opinions about the product. Also, please keep in mind that while Japanese KOLs can provide important help in the registration and reimbursement process, they themselves do not register or reimburse products. Besides KOLs, there are serious trade associations in Japan whose support can make or break you there, too.

Registration Strategy: Determine the Need for Marketing Authorization Holders and Clinical Trials

Once you have done lots of homework and are convinced there is a demand for your product in Japan, you need to determine the best registration strategy. Big companies oftentimes have their own subsidiary or team in Japan, but small- to mid-sized foreign device companies need to have their distributor register the product or utilize an independent Marketing Authorization Holder (MAH) or Designated Marketing Authorization Holder (DMAH). This independent entity is usually a regulatory affairs (RA) consulting team that has registered with the Japanese government to perform marketing authorization holder functions.

There is a number of RA consulting companies offering DMAH/MAH services in Japan, but how do you choose the best one to help you? This requires extensive research and due diligence. Just because the RA consultant's team in Japan is big does not mean they will be able to allocate the necessary time to your product.

Perhaps the most important registration issue is whether there is a requirement for local clinical testing, which is expensive in Japan. Foreign companies will generally need to attend a free Pharmaceutical Medical Devices Agency (PMDA) consultation session to determine if local clinical studies are needed. Normally, no decision is made during this free consultation session, but the PMDA officers will direct you to one of the more formal PMDA consultation sessions, where the applicant will need to prepare information to be submitted to the PMDA for their review. Putting together this dossier takes time and money, and so do the formal PMDA consultation sessions. If the PMDA determines that Japanese clinical testing is required for your product, they will give you direction on next steps.

Small- to mid-sized device companies that do not have the resources to pay for local clinical trials may be able to get a Japanese partner or distributor to help foot the bill if the product is attractive enough.

Reimbursement: Obtain a Higher Rate for New Technologies

Another key issue is reimbursement. In Japan there are reimbursement codes A, A1, B, B1, C1, C2 and F. If you have a new product or technology, you do not want your product to be placed in an existing category where your new technology will be devalued to the reimbursement level of inferior competitors. Products with new technologies will normally be in reimbursement codes C1 or C2. However, obtaining the increased reimbursement value that these codes offer is not easy. Using good health economics data and getting the right KOLs and associations to support you will all help. But there is no guarantee that you will obtain the higher reimbursement rate that you need to make a profit in Japan. Furthermore, the reimbursement will only be negotiated about nine months after your product is approved. The risk involved in obtaining a higher reimbursement for your product leads to an uncertain, complicated and lengthy process.

Distributor Search: Do Not Take Shortcuts

On the business front, choosing the right partner or distributor (if you do not have your own office in Japan), is crucial. It takes time to identify and sign up the right distributor, and many serious meetings are needed to make sure the business will be set up right. Most Western device executives want to find a shortcut for the process, but this will usually come back to haunt them later on. One well-known company I had as a client chose to work with a large Japanese trading company and its subsidiary device distributor without conducting the necessary due diligence to determine whether these companies were qualified. The impetus for choosing this Japanese trading company

was the fact that this trading company was going to invest \$5 million in the client's company, where cash was needed. Several years later, the subsidiary distributor failed at conducting acceptable clinical trials, and the U.S. client's Japan business was delayed a number of years—resulting in lost sales and a huge opportunity cost.

It is critical to take steps to understand the unique characteristics of Japan's medical device market and determine the most effective and cost-efficient strategies for registration, reimbursement and distribution, in order to ensure your product's success in Japan.