DO BUSINESS IN (NOT TO) JAPAN

By P Reed Maurer

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Forty-five years ago, Japan eliminated strict limits on the percentage ownership permitted for foreign pharma companies in Japan. The path was cleared for 100% ownership of a Japan entity, writes long-time Japan pharma watcher and president of International Alliances Limited P Reed Maurer in his exclusive column for The Pharma Letter.

Since then a generation of foreign executives have come and gone. And yet there are those who still consider Japan a type of black hole. They build businesses in Europe and the USA but approach Japan as a mysterious market best attacked by licensing out their drugs to local companies.

For a moment let us consider the characteristics of the Japan pharma market. It is the third largest in the world with strong patent protection and various policies that promote innovation. There are very few restrictions on usage once a drug is approved, thus uptake is rapid. Everyone is covered by some form of insurance and the benefits are universal. Access to healthcare is convenient and available to everyone. Of course, success in building a business in Japan is not guaranteed, but neither is it denied.

The first step – regulatory approval

The first and most important step of doing business in Japan is to obtain marketing authorization for your drug or device. This is ownership of your asset. It simply does not make any business sense to cede your asset to a third party because by doing so you will never get it back.

Companies often make this mistake because of a short-term focus on the fees received or a decision to not enter the market. After the fee money is long gone and new management decides to enter Japan, there is no product to build on.

Getting approval for a product is not a mysterious process. In fact, the Pharmaceutical Medical Device Agency (PMDA) is very eager to assist companies in navigating the approval process.

There are two paths to follow. One is to recruit your own people to carry out the development and regulatory submission process. The time it takes to complete the requirements and review the new drug application depends on the type of drug. But in general, there is no drug lag in Japan. Approval times are in line with those in the USA.

Another more recent option is to solicit the services of a contract research organization (CRO) which can act as an in-country caretaker and take your product through the entire process and receive approval on your behalf. Either way, at the end of the day you are the owner of your product and can decide how you want to optimize sales in Japan.

The next step – sales and marketing

Now you have three options to get your drug prescribed for patients. The first is to build your own sales and marketing organization. The magnitude of this task depends on the number of target patients and doctors. Many more people will be required to sell a drug for hypertension versus an orphan drug.

A hybrid model would be to co-promote with a pharma company, particularly one that is familiar with the therapeutic area of your product. It would not be wise to allow a third party, ie, a pharma company or a contract sales organization to take full responsibility for sales. By doing so you would not have any contact with the customer, always a bad strategy.

To repeat the options. One is to build an organization that can assume full control of promotion to doctors. Second is to co-promote with another party. And third is to assign full control of sales promotion to a third party.

Whichever option you pursue it is necessary to build certain compliance functions in house. This includes quality control and side effect reporting. Also, there are other activities that must be done internally, not the least of which is to keep the home office informed of your successes and frustrations.

What about manufacturing?

Two issues are clear. Manufacturing active ingredients in Japan is not cost effective. However, importing a finished product is difficult given the very high-quality standards in Japan. A blemish on a tablet, a hard to see scratch on a vial, or a crease in the package are unacceptable defects. You might argue that none of these affects the integrity of the product. But your finished package will be returned with a demand for a replacement.

You have two options. One is to build an internal capability to import bulk product and do the final finishing and packaging in Japan. Or to use a local contract manufacturing organization (CMO). The second is likely to be the most cost effective.

A virtual Japan presence

The outsourcing services described above are recent players in the system. In fact, the CROs, CMOs, and CSOs are still struggling to get business from Japanese companies who want to keep everything in house.

But the virtual company is no longer a dream and can be implemented quickly. A company thinking about entering Japan need not burden itself with recruiting a large staff with the concomitant costs, both direct and indirect.

Options for a presence in Japan are not only available but are cost effective. This is the new Japan that is unfamiliar to so many companies outside Japan. Staying outside and licensing a product to a local company should be given the lowest priority among the many options available.

Lack of familiarity is no longer a legitimate excuse for not establishing a presence in Japan.

To conclude

The payback from establishing a Japan presence is far greater in the long term than licensing out your asset to a third party. There is no logical reason to delay entry. In fact, many companies are now conducting their development and regulatory activities in Japan simultaneously with those in the USA and Europe.

By not doing so you leave a lot of money on the table for others to collect. Yet these people did not spend one yen to discover the product but reap the rewards in the worlds' third largest market. It is time to level the playing field.