WHITE PAPER

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Don’t stay outside!

How overseas medical device and pharmaceutical companies can successfully cross the US border

Many non-US medical device, diagnostic and pharmaceutical companies have products that would sell well in the United States, but they hesitate to enter the market. These companies market in many countries outside their home nation but don't cross the US border.

Why avoid the largest market in the world? First, they perceive that the FDA is too tough and will cause significant difficulties and costly testing to get their products approved. Second, they are afraid of the legal system and worried that frivolous US lawsuits could put them out of business. And, third, they imagine their company would have to build a large, expensive sales force to cover the vast US market. In previous publications and webinars, we have discussed ways to reduce regulatory delays as well as costs by using experienced FDA experts and specialized filings (like the 510k or ANDA processes). Likewise, there are straight forward ways to set up separate corporate entities and obtain insurance coverage that will minimize the legal risks.

300 million citizens in 50 states

We've discussed this topic in previous articles citing the ways you can select and establish productive partnerships with larger US firms, but let's take a closer look at distribution options if you want to retain more control over your products. In many cases, this is the smartest way to break into the US market by plugging into this country's existing distribution network calling on the many types of health care providers (HCP). There are hundreds of experienced distributors covering virtually all healthcare specialties and regions of the United States. By engaging the right distributor to sell your product, you can limit sales expenses, reduce your hiring needs and have less risk than a direct market entry would entail. In fact, using a network of regional distributors who are already connected to the target customers may be the best strategy depending on the product and market characteristics. Even for specialized new medical products that need clinician/technical education, you can always form a small team of technical sales specialists who can support the distributors' network and attend key medical meetings.

"Marriage rules" with distributors

But you first have to search and select the right distributors for your product as it fits into the American healthcare marketplace (based on a detailed US opportunity assessment). Once the distributors are selected, you need to develop a strong relationship with each one on an individual basis, using all of your consultative relationship skills. A common mistake we see with overseas firms is that they sign the first distributor who shows an interest and don't consider all the needs to ensure long-term market success. As in other areas of life, rushing the task can lead to an adversarial, hellish relationship with lots of finger-pointing and no mechanism to give the parties a graceful way out. The new US business languishes with both sides thinking that "Well, the market is too small or the product just does not fit properly in the US."

Rule #1: Understand that your "real" customer is the distributor

You are the developer and manufacturer but a marketing mindset is required at this point of US launch. Good marketers learn to anticipate their customers' unspoken needs beforehand and it's no different here. What do they need to be successful in a competitive HCP office or institution?

Distributors look at your product primarily through their customers' eyes: How are my customers going to react to this unique drug or medical device? Is it priced right?

In the case of a medical device, is it reliable and simple to use? Does the product require staff training and education and if so, who will give it? Will my customer be comfortable with my level of product knowledge or could I lose some credibility in this field?

If you have a sophisticated or expensive product, you need to be prepared to give important support – sales materials, published studies on product benefits, training on key aspects and maybe even technical specialists who will work with the distributor's reps to educate their customers. You need to show them that you understand their needs and communicate clearly.

Under pressure: Distributors try to look at your products through the eyes of their customers.

Rule #2: Know what motivates the distributor's sales reps

You may sign up an experienced distributor, but it is the individual reps on the street that will make you successful in the US. Their day-to-day needs are where to spend most of your time to achieve and exceed your sales goals. A distributor's representative for individual HCP offices typically makes 15 to 20 calls per day. Each call on a particular group is probably only 20-25 minutes. The first part of a call is old business – checking inventory/billing and how the last product sold is performing along with any customer questions. It's only in the last few minutes of the sales call that the sales rep has an opportunity to present new products assuming that the target user is available to listen.

As the manufacturer, you have to make it easy for the reps. They are paid to move product, so they have to see how easy it is to make money with your product. Beyond meeting the minimum price point set by your transfer cost, they should have some freedom in setting the price for their customers since many US sales reps are compensated based on a percentage of the profit of the sale, not a percentage of the sales price. They could get 50% of the price they negotiate over the threshold price point, so they are thinking about price as well as volume and how long it will take to make the sale. If it takes up to three visits to sell your product, and provides the sales rep with the same commission as he can earn on a product that can be sold in one visit, you know which product will get those precious last three minutes of the call! You also need to show them that your product is going to be reliable and popular with HCP customers. They don't want to spend 45 minutes on the phone with an unhappy customer. Your role is to supply the distributor with easy-to-use selling materials and to avoid any surprises.

The relationship starts with your attitude. There are manufacturers, and even some marketers, who think of distributors as "necessary evils" or, worse, as "parasites on the system taking all their profits." But the wise way to view them is as your customers as well as your business partners in the area where they operate. There is a lot of value in taking that approach. Business partners renegotiate contracts to win-win solutions when market and industry conditions change. A true partnership helps you through the cyclical ups and downs that are inevitable in this industry. If you have a great relationship, your distributor is more inclined to work with you if you face difficult times, particularly if you have supported the product and helped them be successful in the challenging launch period.

Rule #3: Select your distributors carefully and develop well-defined contracts.

These efforts to understand US distributors take time but it is critical to find the best matches for your product (and this can be done concurrently during the 6-12 months while you compile and file your 510k or other application with the FDA). Once selected, you want a US lawyer to carefully craft the contract terms covering all the basics and contingencies, so there will be no misunderstandings and there are clear ways to sever market ties if unforeseen difficulties arise. Key items include:

- Length of contract.
- Distributor's rights in setting price.
- Manufacturer's rights to customer information.
- Dispute resolution.
- Sales guarantees, minimums and milestones.
- Exclusivity in specific types of institutions and territories.
- Marketing and training responsibilities (brochures, meeting coverage).
- Methods for increasing or decreasing prices to meet market conditions.
- Non-compete clauses identifying product categories.
- Liability and indemnification of each party – handling any lawsuits.
- Intellectual property rights.
- Disposition of remaining inventory at end of term.
- Methods for managing exchange rate fluctuations.

While the contract serves as the legal foundation, remember as noted above, it is the relationship that you build before and after the signatures that is critical.

Follow these rules to success

Follow these basic guidelines to show your distributors and their reps that you are working hard for them in the US and helping them close deals with a reliable product they can make money on. They will repay you with sales, loyalty and a heavenly partnership. And their help will increase the success of your US product launch.

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