

Preventing Cold Feet and Bloody Noses

What European Life Science Companies should know about U.S. Marketing

By Dr. Robert C. Keefer

Picture yourself at the edge of an Olympic-size pool on a hot summer day. The water looks inviting. No reason not to dive right in. But instead you get cold feet and just sit on the edge of the pool. Or you get overconfident and dive off the high board and get a bloody nose.

The U.S. market is like that swimming pool for many European medical device and pharmaceutical companies that have successfully marketed products in Europe and the rest of the world — big and inviting. But there's a right way and a wrong way to dive in. We have found that companies whose U.S. product launches have failed made major mistakes they could have avoided. In general, they:

- Started out making all the right decisions, but when surprises happened they got cold feet and took shortcuts that delayed their success, or
- Jumped to conclusions about the best way to market in the United States based on their experiences elsewhere and then got a bloody nose, costing them further delays plus a lot of money.

Here are a few proven ways to avoid those mistakes in the U.S. market:

1. Step — don't leap — to a successful U.S. product launch

Many smaller companies tend to leap over important steps in a U.S. product introduction and just go directly to a distributor — who may be good at sales but does not really have the resources or intimate knowledge to do a good job of marketing. Two years later, when they realize the distributor couldn't get the job done, they get cold feet on the U.S. market because the competition has given them a bloody nose in sales.

Therefore, the first step is to understand the market and know what kind of distributor network you really need for this market. There are hundreds of distributors covering all healthcare specialties and regions of the United States. Employing the right distributors to market your product can mean very limited expenses on your part and only a fraction of the cost of direct market entry. Learning the market your self would be best if you have the time and are willing to learn from mistakes. On the other hand, doing it with a United

States partner who has done it before gets you faster results. Whichever way is right for you, just do *not* leap over the critical first step of thoroughly understanding the U.S. market in your rush to choose a distributor.

2. **Don't assume you know who your ideal customer is**

Many companies fall into the trap of thinking that their target audience — the buyer — in the United States will be the same as it is in Europe. This assumption may automatically put them on the wrong path right from the start. Let me give you a real-life example with the names changed to protect the “innocent”:

ABC Company had a great product that helped physicians more accurately and cost-effectively determine the exact treatment they should give to their patients undergoing a crucial life saving surgery. The product was marketed very successfully in Europe and was superior to the U.S. competitor's product. The company decided to introduce it in the United States. The process started out well enough, with FDA approval on track, but the product launch ran into difficulties when it came to determining how, when and where the marketing dollars should be spent to reach the buyer.

In Europe, the product is sold directly to physicians. The culture is such that the physician has a strong voice in buying decisions. In the United States, however, the physician is the end user for this product — he or she only *influences* the buying decision but is not the decider. The actual decision is made by other personnel in the hospital charged with testing all new products against the current standard of care.

This came to light *after* the business and marketing plans had been developed which caused confusion and, even worse, cold feet. Instead of a course correction, ABC Company over-reacted and went to an entirely new business plan employing a distributor who wasn't ideal for the market conditions. There was a safer and more cost-effective option available.

Determining the ideal customer *before* committing to a marketing plan makes a huge difference in how the product is marketed and sold. Marketing to the end user (in this case, the physician) calls for different messages than to nurses, laboratories, purchasing departments or thought leaders on the institutional review board (IRB).

For example, if an over-worked laboratory director is the decision maker, the marketing messages need to include benefits to quality control parameters, information system connectivity and clinical research protocols. In contrast, the physician pays less attention to those benefits and is more interested in the benefits to the patient, as well as his or her reimbursements. Nurses are mostly interested in how the new process or medical device will fit with their work processes.

ABC Company's lack of initial research to understand how buying patterns are different in the U.S. market than their home market in Europe resulted in its loss of confidence and cold feet. Their resulting decision made the situation worse. To rely on a sales channel with little or no marketing experience increased the risk of the next bloody nose.

3. **Thoroughly research how your product will be viewed by insurers and providers**

Another aspect of the U.S. market that contrasts sharply with the European market is product pricing and reimbursement. Not understanding these dynamics will surely create a bloody nose for any new entrant into the United States.

In Europe, there is a good amount of negotiation on a hospital-by-hospital basis to determine product price. In contrast, payors in the United States (federal, state and private health insurance companies) really dictate how much hospitals and pharmacies will pay for pharmaceuticals, diagnostic tests and medical devices by what they will reimburse.

There are about 100 payors in the United States, including Medicare, Medicaid (government health insurance programs) and all private insurance companies. Once you have convinced one or two of the leaders of the value of your product and they add it as a preferred product in their formularies, any hospital can bill for it. That makes your sales job with the remaining payors possibly easier than in Europe where pricing is negotiated with every provider.

However, the key to convincing that first payor is having the data to demonstrate your product's value and cost justification. Let's say you have a new dressing for burns. Current treatment involves a lot of physician and nurse time, charges for every bandage, infection control, hyperbaric chambers, etc., totaling \$2,000. The price for your bandage is \$1,000, considerably more than any other bandage on the market, but it reduces physician and nurse time and other costs.

You've researched health outcomes data and modeled the total costs. You know what insurance companies are paying in total to treat burns. You can present an economic case that insurance companies should reimburse \$1,000 for your new revolutionary bandage, because your product will cut the total cost of the cure in half.

This is what every successful marketer of innovative products in the United States will do. Whatever the product, you need to understand how reimbursement issues will affect your product's success, and ensure that the value of your product is recognized by the payors. If you don't, you will pay the price with slow — or no — market uptake. You can recover just like you can recover from a bloody nose, but it is a humbling experience. Doing it right the first time will save you time and money.

4. **Most importantly: know — really know — the costs and timetable of your U.S. product launch**

It isn't as expensive to enter the U.S. market as some European companies might think. Depending on your product, you can leverage a vast existing sales and marketing infrastructure to your advantage. That's the good news.

The bad news is that it is not cheap, and there are a number of things that could add costs and time to your product launch if you don't have contingency plans. Examples include unanticipated costs and delays in the FDA approval process or in working with the payors and U.S. thought leaders. Surprises like these, especially unbudgeted surprises, usually result in cold feet and bloody noses for non-U.S. companies. The antidote, of course, is good planning and budgeting.

More good news is that costs can be managed to fit within your budget, because no one needs to conquer the entire U.S. market all at once to be successful. To help you develop the right budgets and plan, you need someone who first and foremost knows the U.S. market. Using someone who speaks your language and knows your culture is nice; but it is not as important as having someone with U.S. marketing experience — someone who knows the U.S. medical market culture and nuances of the language. The cultures, the business practices and decision processes are too different.

The most crucial point to remember in all of this is that an intimate knowledge of the players and decision pathways is critical. The only way to avoid a bloody nose from an unsuccessful U.S. product launch is to understand all the market dynamics and not assume *anything* is the same as in the European market.

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SPECIAL ANNOUNCEMENT FROM TCG:

If you have a medical technology or medical device you need to license to a European company for commercialization, please call TCG at 919-354-4204 (US). We are attending EuroMedtech in Düsseldorf, Germany, on June 3-4, 2009, and may be able to assist you in your partnering efforts at this excellent event. For more information on the event and its participants, please see details below.

UPCOMING EVENTS:

EuroMedtech

June 3-4, 2009, Düsseldorf, Germany

Join Executives from J&J, Phillips, Medtronic, Covidien, Sorin, Abbot, B.Braun, Baxter, and other firms who will be seeking new products and collaborators at the EMT Partnering conference in Düsseldorf, June 3-4. The pre-conference software match system and one-on-one meetings will give your company and products maximum exposure to potential distributors and new investors. EuroMedtech will also provide opportunities to hear presentations on the latest developments in cardiovascular, imaging, diagnostics and regenerative/orthopedic products.

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