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WHITE PAPER

Preventing Cold Feet and Bloody Noses

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

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. From dozens of US product launches, we have found that unsuccessful projects made 3 major mistakes that could have been avoided, they:

- Based a full US launch on the limited experience of one or two company execs.
- Jumped to conclusions about the US market from their businesses in other countries causing delays and extra costs.
- Started following a good plan, but when US surprises happened they took shortcuts that impacted their success.

Here are a few proven ways that we have found to avoid those mistakes.

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 partner or distributor — who may be good at sales in one category but does not really have the resources or intimate knowledge to do a good job for them. Two years later, when they realize the partner or 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 US market and know what kind of user needs this product. Then match up the strongest marketers and distributors covering the most relevant health-care specialties and regions of the United States.

Working with the right partner and distributors to market your product can mean limiting your expenses to a fraction of the cost for a direct market entry. Learning the market by yourself could work if it is a specialized area with clinical practices like Europe and you have the resources to sustain a slower sales build.

A US partner who has done it before can get you faster sales but less control. Decide which way is right for your company at its current stage but do not skip the critical first step of thoroughly understanding the U.S. market before deciding on a partner or distributor.

2. Don't assume you know who your best U.S. 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 from our experience: ABC Company had an excellent product that helped physicians more accurately determine the best treatment during critical life saving surgeries. The product was successful and growing in Europe and considered superior to the leading U.S. product. But the company focused on selling only to surgical teams during its US pre-introduction. Plus part of its FDA clearance was delayed giving its competitor extra time to defend their franchise. Marketing dollars were spent on the OR physician users assuming that they had the strongest voice in buying decisions.

However, an expensive hospital purchase has many people impacting the buying decision including lab directors, OR managers, financial directors and those charged with testing new products against the current standard.
This challenge came to light after the busi-

ness and marketing plans had been developed which caused confusion and, even worse, cold feet. Instead of a course correction, ABC Company stuck to their plan and did not increase marketing to these important decision makers which delayed sales commitments. This led to quarterly sales misses and replacing US sales management which further delayed marketing investment giving competition more opportunity to tie up long term hospital contracts.

Marketing correctly to the end user calls for different messages to physicians, laboratories, purchasing departments or key leaders on the hospital buying committees. For example, the marketing messages to lab directors need to include benefits to quality control parameters, information system connectivity and current hospital protocols.

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 poor decisions, loss of confidence and cold feet making the situation worse.

3. Research how your product will be viewed by payors and providers

Another aspect of the U.S. market that contrasts sharply with the European market is product pricing and reimbursement. The processes have become much more complex and require a thorough knowledge of the system. Not understanding these dynamics will surely create a bloody nose for any new entrant into the United States.

There are several key aspects of learning how your product will be paid for and how to qualify.

- Determine whether there is a CPT code in which your product would be used. If not you need to know how to apply for one and the timeline involved. The US is moving to a system under which products and services will receive a bundled payment for a given procedure.
- Payment approvals and process vary by the treatment venue. Is your product used in a hospital, an outpatient clinic, in a physicians office or at home? Eligibility for reimbursement and amount can depend on venue.
- Is your device used predominantly in an elderly population? If so, payment is determined by Medicare Administrative Contractors (MAC's) who will determine under what medical conditions or criteria the product will be reimbursed.
- Commercial payors – insurance companies – cover the majority of the US population and independently decide how much they will pay for a procedure. At times they will work (informally) in concert with the MAC's in determining eligibility for payment.
- No matter who the payor is you must present both clinical data demonstrating efficicacy superior to currently-approved products and/or a substantially lower price. "Me too" products have little or no chance.
- If you are selling into hospital systems you must be prepared to present your case, again, in both clinical and economic terms to what are called Group Purchasing Organizations (GPO's) in a competitive bidding process to secure a contract. Over 70% of all products sold into hospitals go through the GPO's.
- If you have a product that can be sold directly to large hospitals expect tough negotiating by the hospital – they will be looking for a 30-40% discount off list price, bundling with discounts across a range of products and demonstrable ability to supply large volumes.
- In many cases hospitals in the US now require vendors of high priced items to bear the inventory cost. That is, you will supply your products on consignment and will be paid if and when they have used the product.

However, the key to convincing any payor is having the clinical data to demonstrate your product's value and pricing justification.

Especially with a new technology the clinical data that you present must be compelling and may have to include data from several different clinical trials. A single study may be insufficient even if it was adequate for achieving FDA clearance. The real danger is that your product becomes labeled "experimental, therefore not medically necessary." In such a case all payors will take the same position: no reimbursement.

On the pricing side you must know what your competitors charge and be able to offer the same/lower price or provide broad economic data that can show overriding system savings. An example would be a product that can be shown to reduce costly complications or that would allow for a reduced hospital stay.

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.

4. Plan well for the cost and timetable of your U.S. product launch

It isn't as expensive to enter the U.S. market as you might think. Depending on your product, you can leverage a unified existing sales and marketing infrastructure to your advantage. That's the good news. The bad news is that it is expensive, and it can be even more costly if you do not plan well and do not include contingencies for key milestones. Examples include unanticipated delays in FDA approval or the slow pace to gaining reimbursed pricing. But you can use these delays to your advantage by gaining additional U.S. opinion leaders and engaging with more potential buyers at key conferences.

Delays and unexpected costs can be managed if a sufficient multi-year budget is planned recognizing the long term ROI that the US market offers. Alternatively, you can reduce costs by doing a regional launch or by partnering with an experienced medical marketer in your field. These approaches help build your product profile in the US with less investment but with reduced control.

To develop a practical budget and plan, you need to include someone on your launch team with direct experience in the U.S. market. An executive who knows your company's culture and has some US background is not as useful as one with recent contacts and experience in your therapeutic category.

The most crucial point to remember is that an intimate knowledge of the trends, players and decision pathways is critical for a successful launch.

These four important steps should reduce cold feet and bloody noses as you bring your European product to the large American market.

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