TCG

WHITE PAPER

Hello, Europe. Be the first to meet my new product.

When is crossing the Atlantic the best way to introduce your pharmaceutical or medical device?

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In many Pulse articles, we have focused on "how to" and other issues of launching a pharmaceutical or medical device in the United States. Now, we'd like to reverse that and talk to companies in the United States about launching their products in Europe.

There are good reasons to do so for certain products and in certain situations but, as always, you need to look before you leap. Even though Europe is becoming a more unified market, there are certain country-to-country market differences. Knowing these will help you avoid some pitfalls, as well as take advantage of the differences.

Although the United States is universally recognized as the holy grail of markets for pharmaceuticals and medical devices, many companies lose sight of the incremental opportunity for sales of their product in Europe. Europe – and certain European countries, in particular – can offer great advantages depending on the situation. This is true whether you've already launched your product in the United States, or you are considering Europe for the initial launch. Here are four reasons why:

1. Less costly clinical trials

Many countries from Central and Eastern Europe joined the European Union (EU) in 2004 and 2007: Estonia, Czech Republic, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia, Bulgaria and Romania. Together with the implementation of the European Clinical Trial (EU CT) Directive, this created one pan-European clinical research market and unified the legal environment. Among the cost/quality advantages to placing clinical research studies in these areas are:

- a large population of over 300 million
- centralized healthcare systems with large, highly specialized hospitals, especially in oncology, cardiology and rheumatology
- High quality of medical care and clinical data confirmed by audits and inspections
- Lower cost per completed case report form, due to fewer days needed to recruit one patient, low percentage of rejected recordings, and low number of queries per 100 case report form pages

2. Easier approval

For medical devices, there is no European approval authority like the FDA (Food and Drug Administration). Instead, EU countries require medical devices to be issued a CE (Conformité Européenne) Mark by the European Commission before they can be marketed. The CE Mark certifies that the product meets EU standards for health, safety, quality and the environment. Once a product has received CE Marking, it can be marketed in all the EU countries (currently 27) without undergoing additional scrutiny or requirements from individual countries.

The first step is to determine your product's risk class: Class I are considered low risk (e.g. wheelchairs), Class IIa are low-medium risk (hearing aids), Class IIb are medium risk (ventilators) and Class III are high risk (prosthetic heart valves, for example).

You can determine your product's risk class by consulting the Medical Devices Directive (MDD), the Active Implantable Medical Devices Directive (AIMDD) or the In Vitro Diagnostic Medical Devices Directive (IVDD).

The requirements and standards for each class are outlined in the directives. ISO certification is not mandatory to meet CE marking requirements, but compliance with ISO 13485, which outlines a comprehensive management system for the design and manufacture of medical devices, is certainly a plus.

Low risk devices can be "self certified" meaning that once you have determined that your device is low risk and you have met the re-

The European Union consists of 27 states with a total population of 0.5 billion (darker blue). Main markets are Germany, UK, France, Spain and Italy.

quirements of the relevant directive, you can place the CE mark on your device. Higher risk devices require that a "Notified Body" audit your quality system to certify that you have complied with all requirements as laid out in the applicable directive. A Notified Body is an organization recognized by the European Commission to approve medical devices covered in the directives.

A well-designed European Opportunity Assessment will help you understand how your device should be classified, whether a Notified body audit is required, and how to certify your medical device and implement and manage your quality system in a way that maximizes your market opportunity.

For pharmaceuticals, the route to approval depends on the novelty of the product. The majority of existing medicines throughout the European Union's member states can be authorized more quickly because the decisions are made on a national basis. Novel medicines are authorized through the EMEA. If the relevant Committee for Medicinal Products for Human Use (CHMP) or Veterinary Use (CVMP) concludes that quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. This is sent to the European Commission to be transformed into a marketing authorization valid for the whole of the European Union.

3. Well-funded healthcare systems

European insurers cover a broader range of diseases than in the United States. Fibromyalgia and chronic fatigue syndrome, for example, are controversial diagnoses in the United States, while in Europe they are recognized illnesses. If your diagnostic test or therapeutic treatment targets a condition that is not fully recognized in the United States, you may find better market acceptance in Europe.

European reimbursement policies generally cover more conditions, but it is important to know the specific reimbursement policies and procedures on a country-by-country and

Specialty centers with high throughput are easier to adress than decentralized specialists. One example is diagnostics for viral diseases.

organization-by-organization basis. And, of course, it is key to understand any pricing constraints, such as government controlled pricing, and how it differs by country.

4. High-quality specialty centers

Although there are specialty healthcare centers in the United States - for pain or cancer treatment, for example - they are much more prevalent in Europe. By nature, Germans are organizers; so it is possible to find many specialized healthcare-related centers within its borders. For example, there are at least 50 centers that specialize in the treatment of tinnitus. It is important early on to identify the specialty centers that are most relevant to your product and where it is most likely to be used.

The existence of centers specializing in your therapeutic areas can give you several advantages to launching a pharmaceutical or medical device in Europe. First, recruiting candidates for clinical trials and tracking results is easier and more efficient if there are centers specializing in that condition or disease. The key opinion leaders (KOLs) at these centers can give you crucial feedback on current practices and the medical need for your product. In fact, KOLs may be even more important to a successful product launch in Europe than in other markets.

Second, if you are trying to get a foothold in the marketplace with a new product, selling your product first to a recognized center of excellence can lead to a more effective product launch. Let's say you have a medical device for the treatment of tinnitus. Targeting a few key specialty centers could generate word-of-mouth advertising as the physicians in those centers publish papers and give presentations to the wider tinnitus community. Marketing that same product in the United States would be more difficult because physicians who specialize in tinnitus are not centralized.

Even with these advantages, a European launch is not without its complications, which means potential pitfalls if you don't know the individual geographical and customer markets and develop the right strategy for each.

Differences among the countries

Despite the EU, Europe is still very fragmented. The centralized European Commission administers the CE Mark for medical devices and approves pharmaceuticals for marketing; but questions of insurance, pricing, reimbursement and other healthcare issues are handled differently from country to country.

In Germany, for example, the authority for health insurance and reimbursement is separate from the German Ministry of Health; while in France, the Ministry of Health deals

with all healthcare issues. It can take twice the time to resolve an issue in France as in Germany, because you are dealing with a government entity interested in multiple issues along with pricing. In Italy and Spain, it's even more fragmented with regional healthcare authorities influencing decisions. For example, reimbursement can be different in Lombardia, in northern Italy, than it is in Sicily.

In each country, the specialists who treat patients may not be the same as in the United States. For instance in Germany, office specialists operating in the public sector, who give injections of hyaluronic acid for early stage arthritis, predominantly use multiple injection treatments; whereas orthopaedic physicians in Spain mostly operate in the private sector and use the more effective single injection therapies.

The differences are driven by the different reimbursement policies in Germany and Spain – policies that apply to the physician as well as the product. Other European countries not in the EU (Switzerland, for example) do not recognize the CE Mark and have their own systems for approving products for marketing. If you are thinking about launching in Europe, you have to know these dynamics and select countries that allow you to get your product on the market more quickly and with the highest generation of revenue and profit.

Critical first step

An Opportunity Assessment, however, is a critical first step. We've said this before in discussing U.S. launches, and it's just as important with European launches. Surveying health care providers on a country-by-country basis will provide information that can be factored into the clinical trial protocols and product launch plans. Small differences in how a product is used or prescribed by providers can make a huge difference in where, and how big, the opportunity is and how the product is marketed.

Information from the Opportunity Assessment will allow you to: a) decide which European countries to target for your launch, and in what order; b) build a country-by-country forecast of unit volume, revenue and profit; c) make a well-informed decision on whether to "go it alone" in marketing your product in Europe, sell your product through European distributors, or partner with a company already well established in Europe; and d) negotiate better performance-driven contracts with qualified distributors, if that is the chosen strategy.

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