SELECTION OF MEDICAL DEVICE DISTRIBUTORS IN EUROPE
How to evaluate EU distributors to determine the best fit for your device.

Author
Edgar Kasteel
Manager Distribution Division
(Netherlands) The Hague
www.EmergoGroup.com

18 February 2014
You will learn:

- How to evaluate EU distributors to determine the best fit for your device
- Contractual considerations and preparation
- How to manage payment arrangements with your distributor
- Meeting documentation and shipping requirements

Manufacturers focus substantial time and effort on their product development and CE Marking compliance, but sometimes do not take enough time to properly research and evaluate medical distributors that play a key role in successful European market sales. This can and does result in lost business opportunities and disappointing sales rates.

Companies wanting to sell their devices in Europe should consider not only where they want to sell, but what they need to accomplish. Loading up a crate of goods, calling UPS and crossing fingers do not make a viable business plan.

Before you begin your search for medical distribution partners in Europe, ask yourself the following questions:

- Who are your current competitors in your selected markets?
- Where are your competitors concentrated?
- How does your device compare to competing products in terms of quality and cost?
- How simple or complex are reimbursement processes in the markets you’re targeting?

Points of entry

Of course, Europe is a highly attractive market for medical device manufacturers, but it is essential to appreciate that the EU now has 28 member states with more than 20 different languages—and don’t overlook Switzerland, Norway, Liechtenstein and Iceland, which do not belong to the EU. Although EU member states have made substantial efforts to harmonize regulatory systems and ease transportation of goods between territories, each EU member still maintains its own language, laws and business customs.

As a first point of entry, most firms choose Germany, Europe’s largest single medical device market, as well as the UK and France. Together, these countries contain roughly half of the European Union’s population.

But although Germany, the UK and France are Europe’s biggest medical device markets, they are also highly competitive and saturated. Depending on your device’s target patient population and business strategy, you may also find it worthwhile to consider smaller-tier European markets such as Spain, Italy, Poland or the Czech Republic.
Which type of medical distribution partner?

Once you have identified where in Europe you plan to market your device, you must identify distributors best suited to support your business plan. Key considerations include:

- Is your device relatively simple or complex?
- Will service and maintenance be required often?
- Are you initially targeting only one or two countries, or multiple EU markets?
- Is your device new to the EU market, or is it more of a high-volume, low-margin product?

Companies sometimes skip due diligence of potential distribution partners due to time constraints, opting instead for a simple list or directory of medical distributors active in Europe. This can lead some firms to enter into agreements with the first distributor they come across.

But really, the process of finding a suitable distributor should be undertaken carefully and deliberately. Yes, the Internet has proven an amazing tool for market research, but there is sometimes no substitute for talking to a potential partner over the phone or face to face.

Determining which medical distribution partners to evaluate depends on your answers to the questions at the beginning of this section. Smaller regional distributors may make more sense if you plan to focus on one or a few countries with a relatively simple product; more complex, high-margin devices to be marketed throughout the EU may require a larger distributor able to support you with a pan-European network.

While “master” distributors can offer international networks through which you can sell your device, you should first ensure that your margins can cover additional costs associated with larger distribution networks. One distributor for each European country is ideal; German distributors can often cover Austrian and Swiss markets, but should have branch offices in both countries, not just sales staff supported by their headquarters in Germany. Scandinavia, too, can sometimes be covered by a pan-Scandinavia distributor, but again, you should ensure that such a partner maintains actual offices in each market to support business development. Swedish and Danish distributors often organize sales forces in all Scandinavian markets.

Distribution companies are rarely pan-European, although some claim to be. You should ensure that each country the “master distributor” purports to cover is not simply a sub-distributor, adding another layer to the end-user cost and diluting the information you want sales people to master. Original equipment manufacturers (OEMs), which take on other company’s products, are usually pan-European, but here, too, you must evaluate each subsidiary individually before granting exclusivity. Easier is almost never better.
**Strong first impressions**

Manufacturers whose devices have sold successfully in markets such as the US or Japan may make the assumption that European distributors will clamor to partner with them. But unless your device is truly innovative in the European market, you will have to make the initial sales pitch and convince distributors to consider supporting you. This requires doing proper research ahead of time, as well as creating a profile of your ideal distributor.

You will need to make initial introductions via mail or email to distributors that may make good partners in EU markets. Introduce your company, outline your business goals and the benefits of your device, and request time to discuss your plans in more detail. If you have not already translated your sales literature into local languages of markets you’re targeting, do so now or outsource the task to a provider specializing in medical translations.

Once you’ve established dialogues with potential distribution partners, it’s important to ask them which types of devices they currently sell, how long they’ve been active in their markets, what percentages of their sales come from your target market, and methods they would use to promote your device in particular. Before you make any final decisions, ask for—and follow up on—client references.

Be prepared for distributors peppering you with questions, as well. Effective European distributors want to make sure they’re dealing with a reputable company producing a quality device and able to deliver a reliable supply in a timely manner.

**Do not overlook cultural differences**

To make an obvious point, Europe is not America. Despite globalization, differences in business practices from country to country in the EU should not be underestimated. North American business environments seem comparatively homogenous—business practices in New York versus San Francisco versus Chicago versus Toronto have a lot in common.

Managing a successful business relationship in France, however, requires approaches that may not work in Germany or Italy, for instance. Having someone on your staff experienced in international business, or relying on an experienced third party to do so, can make a significant difference in terms of time, money and effort.

**Forging an effective distributor relationship**

Now we’ll discuss handling everything that happens after you’ve selected your European distribution partner.

First is contract preparation. Say you’ve selected a medical distributor in France, and are about to make the partnership official with a contract. You have many issues to consider.
One issue that can get many companies into trouble is exclusivity. Yes, your new distributor may be excited about your device and offer vast coverage in France—but you should exercise extreme caution in establishing a relationship with a distributor that will only agree to support your product if you grant them exclusive distribution rights.

Exclusive arrangements aren’t inherently bad, and often mean distributors will put more focus on pushing your product on the market.

But what if that distributor does not or cannot market your product as promised, or if you happen to find another distributor with a more effective operation in France? In general, it’s better to avoid exclusive agreements, as well as pan-European distribution agreements.

It’s also crucial to make sure your contract clearly defines sales and distribution regions for your device. If your new distribution partner in France also operates in, say, southern Germany, your contract with your French distributor should specify that your business relationship only pertains to France if you plan to seek out a different distributor for Germany.

Other issues you should consider in the contract phase of your new relationship include:

- Conditions under which you or your distributor may cancel your contract
- Minimum sales and service levels
- Return policy for your product
- Conditions of sale for your device
- Legal governance

In addition, do not be afraid to explore the "handshake agreement" and try out your new distribution partner for six months or so before signing a formal contract. Sometimes taking this route can get your European business plan up and running faster.

Managing payments with your distributor

Broadly speaking, there are three common payment methods to employ with your distribution partners in Europe: Payment in Advance, Letter of Credit and Terms. Each of these methods exposes increasing amounts of risk to you, the exporter.

Payment in Advance: Your medical distributor pays you up front before your device shipment leaves your loading dock. This method is usually handled through wire transfer, and only at the beginning of your relationship until you develop more trust with your partner.

Letter of Credit (LOC): This method is often used for larger orders, and can protect both you and your distributor simultaneously. Banks issue LOCs to authorize sellers to collect money from buyers’
Bank accounts only once certain conditions are met—proof that products have been shipped, for example.

**Terms or Open Credit:** Providing Terms to a supplier usually happens after your first shipment. You should not underestimate the risk of opting for this payment method, however. There are many stories of buyers placing a few small orders, prepay manufacturers to establish trust, and then place larger orders, but then ask for Terms and pay very slowly—or do not pay at all.

Effective payment management requires vigilance. The Export-Import Bank of the USA (EXIM Bank) offers an excellent export credit insurance program for US medical device and equipment manufacturers.

Finally, if you’re exporting devices to Europe from the US, you should keep track of currency fluctuations and their impact on your market share. If your device is in a price-sensitive category, currency fluctuations could substantially impact your sales. One simple and effective remedy for mitigating currency risk is to open a bank account in Europe.

**Documentation and shipping**

Alas, shipping your device to Europe from another region or continent requires more than just slapping a label on your crate and sending it off. You should make sure that all your documentation is in order before shipping; when in doubt, ask your distributor or freight forwarder for guidance. Customs officials can hold your shipment and cause business delays as a result of inadequate paperwork.

When it comes to shipping considerations, you have many options: CIF, FOB, DDP and Ex Works, for example. You should also be aware that

every product imported into the EU is assigned a Harmonized Tariff Schedule (HTS) code by US Customs. Some medical devices fall under Chapter 90 of the HTS and have duties ranging from one to eight percent. Other devices do not require duties.

Customs officials in the country where your product first enters Europe will determine its classification, which is relevant because that initial classification is then used to determine your device’s rate of duty. HTS codes can be found on the US International Trade Commission’s website.¹

**VAT**

The European Union levies a tax, the Value Added Tax (VAT), that works similarly to sales taxes in the US. You must pay VAT regardless of whether your device will eventually be resold in the EU, however. Your distributor will need to pay VAT (rates usually range from 15 to 25%), but will also collect a refund on the amount paid because your goods are intended for resale.

Keep in mind that governments can take some time processing VAT refunds, meaning your European distributor could face a short-term burden.

**Returns and servicing**
Product returns and servicing are crucial components of your EU distribution plan. Will your distributor handle returns and damaged products? If your product is serviceable or requires regular maintenance, will it need to be shipped somewhere outside the EU, or can it be serviced locally? If not properly managed, shipping costs can exceed the value of your device.

Whether or not your medical device is serviceable should factor into your distributor selection process. If your product costs $900 wholesale, can you afford to have your EU distributor return the device to you for servicing, then ship the product back to Europe and pay associated duties?

Outsourcing returns handling and servicing to your distributor or to a European repair facility may make better financial sense for some foreign manufacturers. Factors to consider in your outsourcing decision should include the value of your device, the level of complexity involved in servicing your product, frequency of maintenance and repairs, customer service requirements and liability issues.

**Performance management**
Who will manage your ongoing EU distribution relationship after the initial “honeymoon” period? Many foreign manufacturers opt to handle this in-house, but such effort requires significant time and resources. Firms often underestimate the time and money needed to nurture their distributor relationships, and end up disappointed in their European sales results. Outsourcing distributor management processes to a company on the ground in the EU can address these challenges.

**To learn more:**
Emergo helps medical device companies with regulatory compliance and market access worldwide. To learn more, visit [http://www.emergogroup.com/services/distribution-overview](http://www.emergogroup.com/services/distribution-overview)

**Export.gov:** provides excellent information on exporting to Europe from the US:  

**European Medical Device Distributors Alliance:** provides excellent information on EU markets and distribution information:  