

# Efficiency increase of the strategic distribution of medical devices in Europe for SMEs

July 2019 - Many medical device companies aim to sell their products on European markets. Their own budget bottlenecks allow only limited market opportunities. What are the reasons and what considerations should SMEs make to increase the efficiency of the strategic distribution of their medical devices?

## Global significance of the medical technology market

The medical technology market is a global market dominated by only a few very large market leaders. Approximately 95% of all medical technology companies are small to medium-sized; they belong to the so-called SMEs.

At the same time, the medical technology market is regarded as one of the most dynamic and innovative.

Well-known market research companies are forecasting average annual global growth of 5.6% (BVMed 2019) for the next few years until 2024.

## Focus on European markets

With sales of 95 billion Euros, the European market for medical devices is one of the largest in the world after the USA. Due to its size and good development prospects, the European market for medical devices is very hotly contested.

The so-called G5 countries, which are Germany, France, Italy, Great Britain and Spain, are the focus of the SMEs willing to enter the market. Since Germany alone accounts for 1/3 of all European sales in the healthcare sector, many medical technology companies want to gain a foothold here. This has the disadvantage that competition is greatest here. However, if the market entry for the SME has been successful, the advantage lies in the ideal benchmark that

Germany offers over other European countries.

## Strategic steps to increase sales efficiency

For an efficient and successful market entry in Europe the following strategic steps have to be considered:

### *1. Marketability Studies or Market Potential Analyses:*

Before entering the European market, the question arises: Does the medical device meet the requirements of the respective target market, where are the barriers, where are the possibilities, etc.? How large is my market potential? ...but also what is my uniqueness or differentiation compared to my competitors?

So-called Marketability Studies, which also include the targeted survey of stakeholders in the respective target segment, can offer valuable insights here. These studies also give hints/recommendations on the market segment that should be tackled first.

Market Potential Analyses in medical technology are mainly based on secondary analyses.

Some G5 countries are disclosing the case numbers of patients treated in hospitals. To that extent, medical device companies have an ideal direct source of valuable data and can use it for further calculations. In Germany, for example, the web-based tool "QB-Analyzer" offers the retrieval of case numbers according to OPS/ICD of all German hospitals.

## 2. CE certification:

To be allowed to sell a medical device in Europe, it must be CE-certified.

The new European "Medical Device Regulation" (MDR) came into force on 25 May 2017. On 26 May 2020 the transition period ends. The MDR will increase the costs for manufacturers of medical devices in particular, as it contains numerous innovations. Out of 59 Notified Bodies in the past, only 2 Notified Bodies have been confirmed according to the new law. It is therefore necessary to bridge corresponding time and bureaucratic bottlenecks.

## 3. Reimbursement by Health Insurances:

If the medical device is covered by health insurance in one or all G5 countries, it is recommended to have appropriate reimbursement analyses carried out "before" the CE application. Necessary expenditure for additional studies required by the health system of the respective country could possibly be combined with the studies for obtaining the CE certificate. Thus, additional costs for further necessary studies can be avoided.

## 4. Distribution/Sales:

As soon as the medical device is CE certified, it may be distributed in all European countries.

This raises the question of direct or indirect sales.

The surveys conducted by our "Marketing Monitor Medical Technology" in recent years have shown that German companies tend to prefer direct sales via their own sales force in their own country and seek strategic sales partnerships abroad. This also applies to all other European manufacturers, such as France, Italy, England and Spain.

The advantages of strategic sales partnerships are obvious: low investment risk, fast market

entry via "experienced" market participants who already have very good contacts to the target group.

Strategic sales partners can be:

- "Pure" distributors, who market the medical devices nationwide with their own investments. The medical specialist trade must be clearly distinguished from this, as it usually operates regionally and is not geared to generating market demand.
- Manufacturers of medical devices who add "complementary" medical devices from other manufacturers to their product range in order to create synergies for the distribution of their own products. The reasons are manifold: more efficient use of the own sales force, no own innovative power etc.

How detailed a medical technology company has to consider these steps depends strongly on the type of medical product and the target orientation of the SME.

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