



Introducing Medical Devices in the German Marketplace

a Practical Guideline

The German Health Care System

In Germany, health care expenditure is an important and rising economic factor. Expenditures amount to 239.357 Mio €, representing 10.7% of the national gross product. There are more than 4.2 million people occupied in the health care sector. There is growing health awareness within the population, which leads to growing expenditures in the German health care system. This in turn has increasingly raised issues on how to finance this sector. Health care expenditures per inhabitant amount to 2.900 € per year and are growing.

90 % of the Population are insured in the Statutory Health Insurance. 10% are privately insured. Benefits from the Statutory Health Insurance are stated in the BEM, a doctor's fee scale which is a uniform value scale. The services of the private insurances are stated in the medical fee schedules for doctors and for dentists (GOÄ/GOZ).

Physicians are established in private offices; hospitals are state and privately owned. Patients usually go to private physician offices for medical services. Hospital services require the referral note from the private office. Private

patients are free to take hospital and professor services any time. The introduction of highly innovative medical devices not listed in the BEM is faced with additional difficulties when they are not paid by the Statutory Health Insurance. Privately insured patients however may have easier access to the reimbursement of those innovative medical devices or services. Alternatively and increasingly, a so-called IGEL structure - Individual Health Care Services - has been established which make innovative medical

Germany is the third largest economy worldwide and the largest economy in Europe with 82.000 million inhabitants and the highest GNP amounting to 2.310 billion € while per capita income (24.800 €) rather ranges in the middle field among the Western European countries.

Germany is a densely populated country with 230 persons per square kilometer.

Germany is a federal country and divided into 16 Federal States: Baden-Württemberg, Bayern, Berlin, Brandenburg, Bremen, Hamburg, Mecklenburg-Vorpommern, Niedersachsen, Nordrhein-Westfalen, Rheinland-Pfalz, Saarland, Sachsen, Sachsen-Anhalt, Schleswig-Holstein, Thüringen.

services available to patients that are willing to pay for them out of their own pocket. However, the company wishing to introduce its innovative medical device in Germany,

which is not listed in the BEM, may not overestimate the willingness of patients especially of those that are insured in the Statutory Health Insurance. to pay for their medical services on their own. Therefore, despite the high population number in Germany, the manufacturer of an innovative medical device may be faced with reduced potential patient numbers and lower sales potential.

The acceptance of a new medical device in the Statutory Health Insurance catalogue must be preceded by comprehensive clinical testing and physicians' approval and may then enter into a long process of evaluation by the Federal Joint Committee of the National Association of Statutory Health Insurance (KBV) and the National Committee for Innovations. They will evaluate the benefit, medical necessity and cost effectiveness of the new medical procedure. This process may take many years; however the KBV has recently established an innovation service to accelerate this procedure with the aim to make innovative medical procedures available to patients earlier than before.





Size for the Medical Markets

Total Hospitals	2.139
University Hospitals	33
Total office-based Physicians	132.895
General practitioners	34.558
Internists	21.644
Orthopedics	5.633
Gynecologists	11.094
Urologists	2.941
Dermatologists	3.569
ENT Specialists	4.219
Ophthalmologists	5.498
Neurologists/Psychiatrists	5.556
Surgeons	5.764
Maxillofacial Surgeons	1.012

Source: KBV SHI Physicians

What are the Prerequisites to Place Medical Devices in the German Market Successfully?

Due to the size of the market, its high quality standard and the central location in Europe, Germany is the ideal entry country for the European markets.

Foreign medical manufacturing companies wishing to introduce their products in the German market are usually faced with a number of obstacles that need to be overcome. Therefore, market entry should be structured and pursued strategically.

Germany is characterized by the strong presence of domestic medical manufacturers. Their sales structures are highly professional and well functioning either with their own direct sales organisations or with a dual structure via distributing companies plus support from their own sales representatives. In addition, there is constant presence with relevant opinion leaders. In general the quality standard is high. There are an innumerable number of bigger or smaller distribution companies, mostly working on a regional level, some on a national level. When choosing a distribution scheme, the large and densely populated German territory must be taken into consideration. Many foreign manufacturers wishing to place their medical products in Germany commit the mistake of granting exclusive distribution

rights to a distributor who is not able to efficiently distribute on a nationwide level. Unfortunately there are no qualifying lists of German distributors available that would make it easy for an outside company to pick the adequate distributor. Thus finding the right distribution partner in Germany may be a tedious enterprise.

Also, the foreign manufacturer wishing to introduce an innovative device should be aware of the fact that it will be required that the newly developed system is on a high quality standard and the testing phase has been completed. There is little tolerance towards low quality or mistakes and inadequately tested systems and the too early market entry from a technical viewpoint may lead to a total loss of the market.

Despite the strong domestic market, the following products have good potential to enter the market successfully:

1. *Highly innovative products with a clear competitive edge*
2. *Highly competitively priced products in the me-too sector*

Price competitiveness in the German market is of rising importance since the income of physicians is falling and there is increasing interest in the supply of individual health services that have to be paid directly by the patient. It must be taken into consideration that the Statutory Health Insurance may automatically impose restrictions to introduce a new product making it available to the approx. 10% of the population only which is privately insured. Foreign manufacturers must also be aware of the fact that the English language will not always be practiced on all levels of business; when dealing with smaller distributing companies or with sales representatives, English will sometimes not be understood sufficiently in order to negotiate a structured market entry.

Marketing literature addressing physicians and patients must be written in the German language; English will not be accepted.

Distribution Channels

Due to the size of the German market and its high quality requirements, it will be indispensable to define the appropriate distribution structure strategically. A strategic approach will lead to more efficient long-term valuable business presence. The

choice of the distribution channel depends on the product, long-term company goals, and investment capacities.

The following distribution channels are available:

- *Wholesalers*
- *Direct sales organizations*
- *Industrial partner with direct national sales structures*
- *Temporary sales force*
- *Legal entity/subsidiary*

Wholesalers

There are an innumerable number of small, medium, and large medical distributors in Germany. Wholesalers distribute on a regional and on a national basis. Due to the high regionalism in Germany, the great majority operates regionally only.

In Germany, it is not always common to give away exclusive distribution rights. Nationally acting companies usually require exclusive distribution rights, whereas the cooperation with regional wholesalers will be restricted to a selected area/state and should be non-exclusive. Unless an efficiently nationwide operating company is chosen for distribution, it will be necessary to find various distribution partners on a non-exclusive basis. Manufacturers giving all their distribution rights to a small distributor who is not able to supply nationwide efficiently, may give away market opportunities without ensuring the entire market coverage thus losing valuable sales potential.

When contracting a distributor, it is necessary to verify the territorial scope of activities and coverage. It must be verified whether the distributor is able to cover the entire German market and has established access to the relevant medical markets.

It is an additional handicap for foreign small and medium sized manufacturers wishing to find a distributor in Germany that often well-established





distributors will not exhibit in the common international trade shows like i.e. Medica or in the relevant national medical congresses. Due to the mostly regionally structured wholesaling organizations, it is not easy to find and to identify the medical disciplines they specialize in. Unfortunately, internet lists on medical distributors or lists from state authorities (i.e. chamber of commerce) usually do not indicate the territory nor the field of activities nor medical discipline so that foreign companies may face great difficulties in finding the right distributor.

Direct Sales Structure

The establishment of a direct sales force in Germany will be the most efficient sales structure, but also of course the most cost intensive one. In this respect, a sales force with employed sales representatives or with independent sales representatives or a mixture of both can be established. It is possible to employ sales representatives without the prior establishment of a legal entity when observing a number of legal/tax aspects. It must be noted however that in the medical field, quality and commitment of independent sales representatives may vary considerably. A structure with independent sales representatives alone, if not well established and accepted with physician offices, may lead to the failure of the market entry. Finding the right independent sales representatives with the respective contacts and acceptance in the market may be long and sometimes sobering process. It must also be taken into consideration that a direct sales force must be trained, supported, and closely managed and a constant communication partner must be available that represents the manufacturing company.

Industrial Partner with Direct National Sales Structures

It is an elegant solution to enter the German market on the basis of a cooperation with an industrial partner that is present in the entire German territory, has a functioning sales representative network, has a vital interest in adopting a new product that will complement

the present product portfolio and, in addition, is dedicated to introduce the new product in the market strategically.

Temporary Sales Force

There is also the option to hire sales representatives on a temporary basis for a determined period of time. This may be a solution to primarily test a product in the market or to introduce a product nationally or in a selected state only.

Legal entity/Subsidiary (GmbH)

There is often the opinion that it will be necessary to establish a legal entity in Germany in order to find access to the market. The establishment and the maintenance of such a unit will cause considerable costs and the legal necessity of hiring a General Manager. Establishing a legal entity in Germany may be the adequate choice for manufacturers that wish to establish a direct sales organization and intend to have direct end customer contact.

It is understood of course that having the legal entity does not sell the product on its own and there will always be the requirement of establishing a functioning sales and marketing structure.

As an alternative, it is possible to establish a functioning sales structure in Germany with an external sales office managing the territory and without having the costs of running a legal entity.

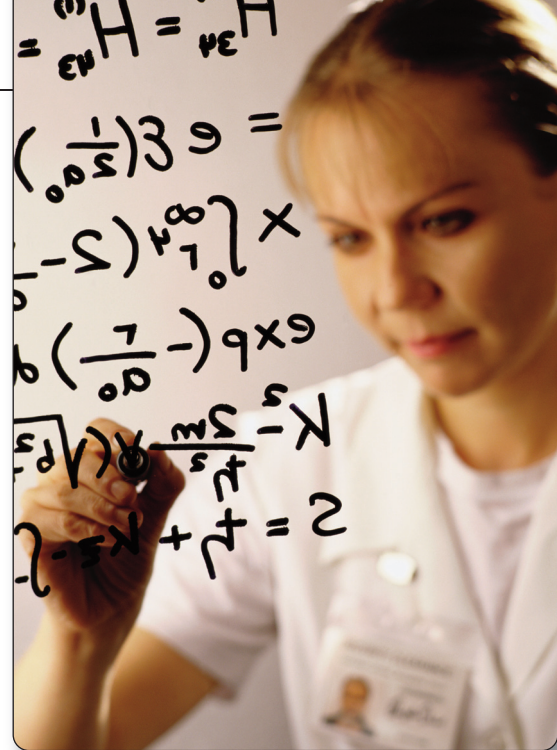
Logistics, importing, shipment and delivery functions, stocking, billing, accounting can also be done by external service companies with a minimum of legal and tax requirements compared to the requirements of a GmbH. It is a matter of defining the goals and objectives in the German market, which will be the basis to decide which distribution structure to choose.

For all schemes, it is highly advisable to manage the structures. German customers are used to have problems solved immediately and to receive all necessary support without delay and without having to contact abroad.

Which Marketing Measures are Necessary to Enter the Market Successfully?

It must be mentioned that the general German mentality is characterized by thoroughness, claim for high quality, reliability and above all the need for safety paralleled by an attitude of scepticism towards new products – especially in the medical field. This indicates that there are a number of tasks and homework to do in order to enter the market on a long-term basis.

It is of course necessary to gain some basic knowledge of the product-related market, define the competitors, position the product against the competitors, position the price, check out whether the product underlies the pay-



ment of the Statutory Health Insurance, and define sales potential. In addition it must be clarified which distribution channel to choose, which marketing support is necessary, which clinical support is necessary and what needs to be invested. It must be understood that all marketing literature must be in German. Only scientific studies are accepted in English.

One word to translations: the importance and the difficulty of correct translations are frequently underestimated. Often leaflets are given to a local translator, often not a specialized medical translator. The outcome can be embarrassing in the target country. 1:1 translations out of a foreign market environment may lead to misunderstandings. It is highly recommended to check translations by a domestic person to exclude translation mistakes. Only medical translators should be chosen for translations and these translations must be revised by a German representative preferably that is familiar with the product, is able to detect translation mistakes and position the product adequately. As a further step, on the basis of further market knowledge, marketing literature can be exactly positioned within the German market frame.

Advertisements

There are of course many means to place advertisements in relevant medical magazines. This commitment will depend on the willingness to invest. It must be pointed out however that an individual advertisement will hardly lead to any sales.

In addition, advertisements will only be of help when a functioning distribution structure has been established that supports the market.





Exhibitions

There are of course a number of national and regional medical congresses with industrial exhibitions. When cooperating with wholesalers or industrial partners, it should be assured that the company is present in the relevant exhibitions. Here too, the direct congress/exhibition commitment is valuable the most when a functioning sales support structure has been established.

Clinical studies

The German medical market is the opinion leading market in Europe. Innovative medical devices must be supported by German opinion leaders and/or University Hospitals and publications. It is advised to enter this process as early as possible since the time frame between study design and publication is between 1 to 3 years. Studies from abroad are only fully accepted when they come from the US and would still need to be supported by German studies. Studies made in Germany can also be used in other European countries, but not vice versa.

Managing the German Market

The above comments show that the scope of activities and investments necessary to enter the German market successfully and on a long-term basis is considerable. At least a minimum of sales and marketing management is advisable, especially small or medium sized companies are not always able to set up a constant communication line due to personnel problems or language or time/time zone barriers. The manufacturer should be in a position to respond to market requirements with the development of effective marketing support measures and its implementation in the market.

The manufacturer should assure that:

1. sales representative are trained on the product
2. a constant communication partner is available
3. meetings on a regular basis can take place
4. end customer service is guaranteed
5. marketing support is given
6. quick and efficient trouble shooting is guaranteed

Summary

The medical device manufacturer wishing to enter the German market professionally should take a strategic approach upon the basis of the desired or possible investment and long-term goals. A business plan should be prepared which takes into consideration the market environment including the reimbursement and Statutory Health Insurance situation, the positioning of the product, distribution channels, marketing support, sales potential, clinical



taken into consideration. It should be assured that there is an established communication line between the German target market and the manufacturer.

Due to the necessary response to the German mentality, which requires trust, quality and support, setting up a functioning business in Germany may be a long, sometimes tenacious process. The manufacturer must be aware of this and tolerate a considerable introduction period. He must be able to overcome obstacles without leaving the long-term goal out of mind. In the end, this will be rewarded with faithful long-term customers and sales. As with any country, the adaptation and response to market needs will lead to long-term success. When observing this rule, Germany may become your most important sales partner in Europe. The strategic input into the German market will be rewarded with a sound and long-term market presence and long-term faith.

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support and necessary investments. A certain advance should be given for the initiation of clinical studies with opinion leaders. The presentation of products, qualities, interests and strategies to German business partners must be professional and target-oriented and should mostly be in German when operating on a regional level. The need for some presence in the market to respond to customers, immediate market needs and changes, to identify risks and opportunities and to give the adequate support should be



SPECIALISTS IN INTRODUCING MEDICAL DEVICES IN THE GERMAN MARKET PLACE

- ◆ Establishment and Management of Distribution Structures
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- ◆ Market Check
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- ◆ Linguistic and Market-related Adaptation of Promotional Literature
- ◆ Press Releases
- ◆ European/German Sales and Liaison Office Services

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