

How to
prioritize
your
expansion
into
foreign
countries

A guide for medical
device companies

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About the author

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How to prioritize your expansion into foreign countries

Whether your company is new to international expansion or not, it is vital to perform local Market Research before launching a new product and before expanding into any international market.

You can begin your research by looking at GNP and population factors such as life expectancy or total fertility figures. However, we have compiled a list of actual total expenditures in key countries. This will allow you to better gauge prioritization of your target markets.

From the table shown below you will notice that the European Union (EU) is the second largest market in the world, after the US. The EU provided a third of the total worldwide expenditures of medical devices in FY 2005. The five largest EU markets, France, Germany, Italy, the UK and Spain, amounted to 78% of the region's total expenditures. The €47.4 billion / year spent equals approximately 26% of WW expenditures.

Japan had a 10% WW market share with a total of €18.8 billion / year in FY 2005. China on the other hands, with a population of 1.3 billion, spent €3.1 billion and represented a WW market share of only 2% in the same year.

Total Expenditures of Medical Devices, Worldwide in FY 2005

	Total Population In Millions	Total Expenditures on Medical Devices (in €Billions)	Worldwide Market Share
USA	296	79.4	42%
European Union	499	61.8	33%
Germany	83	20.0	11%
France	60	10.0	5%
Italy	58	7.0	4%
UK	60	6.7	4%
Spain	43	3.7	2%
Japan	127	18.8	10%
China	1,300	3.1	2%
Brazil	186	2.6	1%
Rest of the World	4,069	21.3	11%
TOTAL	6,477	187.0	100%

Source: Eucomed

Although the above figures speak for themselves in terms of which countries are the most lucrative expansion targets, other factors may influence a company's leadership to change their expansion priorities. These factors may include: 1) Comfort with a particular culture. 2) Business connections within a market. 3) Proximity to the corporate home office. 4) An existing distribution network within a given market.

It is important to note however, that no matter the size of your expansion target, the amount of effort and work to be done from your company will be more or less the same. We therefore recommend that you double check your priorities accordingly.

Why perform market research?

General reports, assumptions and/or anecdotal information should not be a substitute for comprehensive, independent and thorough market research performed in every potential target country. Good market research will allow you to better understand the challenges, opportunities and the hurdles that are specific for that market. It should also map the terrain and identify specific issues for your product.

It would be inconceivable that a company would use market research information from Canada to determine the viability of a product launch here at home in the United States. It would be equally unlikely, that a company would use Brazilian market survey to determine if Argentine healthcare executives would purchase a particular device for domestic use.

What to look for in market research?

Valuable market research will allow you to understand the true potential of your product in a particular market. But remember, the quality of the survey will determine the quality of your results. Try to be as specific as possible when creating your survey. Your efforts up front will minimize your risk and will save you a lot of time, effort and cost when developing your strategy.

We have compiled below a beginning set of questions and insights which we believe will be of great help to you when preparing your market research.

End users

- Market segmentation may be different than in your country

Influencer

- Is it the doctor who prescribes your product / therapy?
- Is it the Physio Therapist (PT) who uses your product / therapy on patients in his clinic?
 - Are PTs allowed to use a product of their choice without the blessing and/or permission of a doctor and/or government body?

- Is your product used by a Lab technician?
 - If so, who decides on using it in the lab, private v/s public hospital, doctor, lab director, etc.?
- Is your product used in surgery?
 - If so, who decides to include it in the surgery kit, the hospital administrator, the surgeon, other?

Alternatives / competitive analysis

- Which therapy?
- Which drugs
- Which products?
- Ex: Balance disorder treatment is different in various countries. Drugs are usually prescribed in Germany v/s physiotherapy in France.

Cost benefit analysis

- Versus existing alternatives
- Versus reimbursement (see Reimbursement point below)

Who pays for healthcare?

- Private insurance
 - Full reimbursement
 - Co-pay
- Public healthcare
 - Full reimbursement
 - Co-pay

Reimbursement

- How can your product qualify for reimbursement?
- How much of your product is / could be reimbursed?
- How much of each competitive product is being reimbursed?

Key Opinion Leaders (KOL)

- Who are they?
- Be careful of the country's political maze, between competing clans
- Can they help you with the Reimbursement process?

Product specifications

- Color coding, if/when applicable (i.e. color coding for Oxygen is Green in the US, Blue in Germany, White in France and Black in Japan)
- Fittings / connectors
 - No two of the following countries have the same gas connectors (US, UK, France, Germany, Spain and Japan)

- Down time – Ex: Hospitals in The Netherlands turn off their MRIs in the evening to save energy which means that the units will not be operative as soon as personnel are back to work the following morning

Regulatory requirements

- FDA, CE, UL, other
 - Which are needed?
 - What do they mean?

Product registration

- In Europe, you need to register your product with the local or with the European authorities before placing it on the market (AMM – Autorisation de mise sur le marche – France / Belgium)
- In France, an insulin syringe company is referred to as a Pharmaceutical company – “Laboratoire Medical”

In order to be successful, you will need to pay special attention to the uniqueness of each market. This means that you will be required to meet local cultural needs and legal/regulatory requirements in each target country. The following list of specifics may have to be modified in each country or region:

- Instruction manual translations
- Product labelling
- Regulatory approvals
- Product registration
- Product specifications
- New drawings
- New part number
- Dedicated manufacturing line
- Inventory parts
- Etc.

Keep in mind, that you remain ultimately responsible for your product, whether it is sold domestically or abroad. Whether you sell your product directly or through an agent or distributor, the onus and burden is on you to understand local requirements. You must modify and adapt your product accordingly. As a manufacturer the responsibility for a product always lies with you.

Also, do not take the easy approach by selling a domestic product in an overseas market. And don't allow an intermediary to adapt your product to a local market. The product may not meet local requirements and may be infringing local laws. This could leave you vulnerable to fines or suits, and ruin your company's reputation.

How to go about performing market research?

Market research needs to be the property of the manufacturer and we recommend that it be done independently from any partner that you may have in the market. This will allow you to receive the information first hand and without bias. Market research can be valuable not only for today's product but also for future marketing needs, and should remain in your possession.

Your own data will also allow you to better gauge the effectiveness of your partners' performance. Is a 15% market share adequate, given your research? Could local results be higher, given a particular demographic mix? Can your success in one country be duplicated in another? Accurate market research will allow you to devise a proper strategy and permit you to concentrate your efforts and investment in places that are most likely to be profitable.

As you may not have a qualified person in every targeted country, we suggest you contact several independent market research consultants/companies to assist you. Keep in mind that a particular consultant may or may not be able to provide you with a true picture of every country within a certain region. Differences can be quite significant.

Contact and interview at least two consultants in each target country. Explore their experience, market knowledge and business relationships within the community. Contact their provided references and try to get recommendations from associates you trust. The value of the information is definitely worth the cost, time and efforts invested.

For any additional information and /or assistance on market research you can send an e-mail to Christian B. Chahine at cchahine@mdtinternational.eu Also, feel free to contact him should you wish to receive a list of first point of contact and market research consultants / companies in your region of interest.