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BRINGING A MEDTECH DEVICE TO THE MARKET IN THE US

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Market Study

BRINGING A MEDTECH DEVICE TO THE US MARKET

A practical guide, based on a fictive product example

Publication date / December 2023

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1. INTRODUCTION

Understanding how to enter the US healthcare market is challenging for many companies. With this market study, we created a step by step approach for a MedTech company to enter the American medtech market based on a number of examples we supported over the years. We took the case of a company bringing a heart monitoring patch (as a fictive example) to the US market.

Imagine a society in which access to healthcare is not restricted to hospital rooms and doctor appointments, and people may easily and proactively monitor their heart health and obtain important insights into their well-being. With the introduction of heart monitoring patches, this vision has become a reality. The market potential for heart monitoring patches is significant in this era of personalized medicine because they provide ease, accuracy, and a new degree of empowerment to people looking to take control of their cardiovascular health.

It is essential for businesses to have a thorough market entrance analysis, looking at the obstacles, regulations, and strategies necessary to successfully introduce a cardiac monitoring patch and create a market presence in the MedTech industry of the United States.

Flanders Investment & Trade (FIT), is the regional investment and trade agency for Flanders (Belgium), with the primary objective of supporting and promoting international business activities involving Flanders-based companies. In this case, it is FIT New York (the Life Sciences department) that wants to support and promote companies interested in the United States. By offering information, guidance, and support to U.S. businesses interested in establishing or growing their presence in the area, FIT seeks to bring foreign direct investment (FDI) to Flanders. In addition to attracting Investment, FIT focuses on promoting Flemish export. They collaborate closely with Flanders-based businesses, offering assistance in identifying export prospects, market intelligence, trade missions, events, and support the participation in international trade shows and exhibitions.

2. MARKET SITUATION

2.1 MACRO ANALYSIS OF THE U.S. MARKET

It is important to know what external factors influence bringing a product to this market. Increasing awareness of these factors will increase strategic thinking, which is crucial for defining the business direction and growth strategy.

2.1.1 Political

Political factors are overall very important in determining whether it is possible and profitable to introduce a new product to the U.S. market. This factor impacts businesses on a local and federal level, so companies should be prepared to handle both local and national political outcomes.

As mentioned before, the United States has a lot of regulations regarding bringing new products into the country. These regulations are established by agencies such as the FDA and depend on the type of product, its intended use, and the level of risk. Getting approval can be a time-consuming process, because of the complex set of procedures and documentation that is needed.

Other political factors that have an impact on a business are trade and taxation policies that apply. These should be considered during the development of the pricing strategy since they affect the profitability of the product. It is crucial for businesses to be aware of any changes made to these policies and to ensure compliance with these, it is advised to consult with tax experts (*Trade Policy*, n.d.).

Furthermore, your product must be protected by patents, trademarks, and copyrights. This should protect your product from the competition, but like the other factors, it can be easily influenced by government policies.

These elements must be properly taken into account by businesses when creating their strategy because they add a risk factor and could lead to failure if ignored. The political environment of the United States is possibly the least stable of all factors that influence the market.

2.1.2 Economic

When bringing a new product to the U.S. market, it is important to evaluate the market demand because if the market is already saturated, it will be almost impossible to compete. The level of demand also affects the success of your product through pricing, sales, and revenue. When the demand for a product is high, companies can expect more sales and charge higher prices and thus generate more revenues.

Although exchange rates are a complex subject, it is evident that anyone involved in export or import must be aware of them and their unpredictability.

The level of the exchange rate between any two currencies is affected by the level of economic activity, the level of market interest rates, the GDP, and the unemployment rate in each of the involved countries. Due to the fact that currency exchanges take place throughout the world every day, often even within a minute, they are always changing. Changes can be minor or rather significant. Businesses are affected by these fluctuations in two ways: one, by changing the price of products imported from other countries and, two, by changing the value of their products to customers abroad (H, 2022).

Another factor that is important to understand is the inflation rate in the U.S., although not all instances of inflation are alarming. According to economists, a healthy developing economy needs a moderate level of price inflation. For this reason, the central bank of the United States utilizes a monetary policy to aim for an annual inflation rate of 2%. This rate is considered to be good for economic growth without significant risk of increased unemployment. Inflation effects can become unpredictable economy and affect consumers' behaviours in both rational and irrational ways if the rate of inflation rises too far above the target. If the rate of inflation falls too far below that target, the country risks an economy that stagnates.

The economy was shut down for several months as a result of the COVID-19 pandemic, which allowed people to save money and spend too little. This imbalance is expected to gradually level itself out, but in the meantime, inflation has already lasted longer than expected. Although the Federal Reserve is raising interest rates to battle inflation, there is certainty that this inflation will remain high for some time. As a result, there will be significant shifts in the economic environment, requiring companies to adapt. Supply and demand principles might also have some unexpected consequences, next to the effects of inflation (Nelson, 2023).

2.1.3 Social

As mentioned before, consumer preferences and taste have a big impact on the demand for imported products. These are social factors that affect consumers' attitudes, interests, and opinions, which in turn impact sales and revenues (Social Factors Affecting Business, 2022).

It is important for businesses to react to changes in the social environment of the United States and to offer products that complement the behavior of U.S. consumers.

Imports may be impacted by social trends and movements as well. For instance, growing ethical and environmental concerns may result in a greater demand for sustainable technology products, which may require importation from other nations. Another example of a factor that makes a big difference in businesses in the U.S. at the moment is social media, not only because of its increased importance but also because of its contribution to the rapid spread of trends.

2.1.4 Technological

How technological advancements will impact employment and the U.S. labor market in the coming years and decades is a recurring subject in research and policy discussions as they appear to change every element of the United States market. These technological innovations have always had an impact, but just as in the past, this process does not currently have a "natural" or predetermined end (Monroe, 2021).

Automation can have both positive and negative effects on the U.S. market. The positive effects are increased efficiency of the production process and the reduction of labor costs. This is the combined effect of AI and robotics replacing human labor and employees getting more skilled in using machines and thus increasing productivity. Another positive effect is that new jobs have been created, some of which pay very well for those who can work well with robotics.

The negative effect is that there are workers who are forced to compete with these automated systems or who are promptly replaced by them.

Furthermore, digital automation has increased inequality in the labor market since the 1980s as more production and administrative workers lost jobs or saw their salaries decrease (Holzer, 2022).

Advances in technology in the U.S. have also led to stronger intellectual property protections. This encourages investment and innovation in new products and may open up new possibilities for companies to import products covered by intellectual property rights.

With transportation technology, both businesses and their products can reach their destinations more efficiently. Faster delivery systems can save businesses money and important time (Daley, n.d.).

In general, technological aspects have a significant impact on the ease and expense it is to import products into the United States. Companies that successfully use these technologies can obtain a competitive edge and expand to the U.S. market.

2.1.5 Legal

The Environmental Protection Agency, the Department of Labor, and the Department of Health and Human Services are just a few examples of federal agencies that enforce federal laws that have been passed by the U.S. Congress. These laws and regulations are essential for businesses to maintain public safety, consumer protection, and regulatory compliance. For corporations to conduct themselves morally and responsibly, rules such as tax codes, employment and labor laws, antitrust controls, and advertising regulations are crucial (*Impacts of Government Regulations on Businesses*, n.d.).

In the United States, each state and local government also has its own set of rules and laws that affect business. They frequently create their laws to supplement federal ones or the absence of them. These states have regulation laws like minimum wage rates, data security, harassment policies, pay equity legislation, and many more. They often have different rules and regulations about each law, so foreign businesses need to be familiar with the laws of each state individually. State and local restrictions are still significant even though federal laws and regulations are essential. Entrepreneurs should be equally informed about their local municipal and state legislatures as they are about the U.S. Congress and White (Uzialko, 2023).

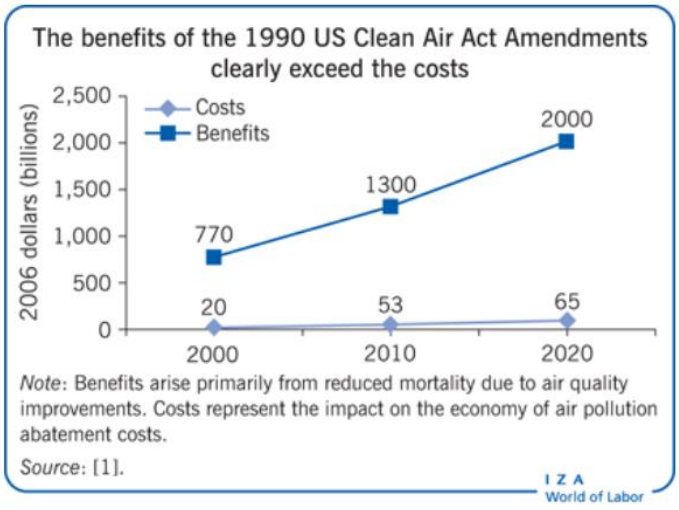
Treaties and other international agreements are written agreements between countries governed by international law. These countries negotiate a treaty, either through an institution created specifically for the purpose or through an existing institution like the United Nations (*International Agreements*, 2018). The United States enters into more than 200 treaties and other international agreements each year. These treaties and agreements have an impact on U.S. laws and regulations, including labor and trade laws (*Treaties and International Agreements - United States Department of State*, 2022).

2.1.6 Environmental

Some of the most important environmental regulations are (*Laws and Executive Orders | US EPA*, 2022):

- Clean Air Act
- Clean Water Act
- Resource Conservation and Recovery Act
- Toxic Substances Control Act
- Comprehensive Environmental Response, Compensation, and Liability Act
- Energy Policy and Conservation Act

Although environmental regulations aim to protect both human health and the environment, they often raise production costs and reduce productivity in companies, causing them to shift investment and production to less regulated regions. Of course, they exist for a reason and have benefits like improving air and water quality, preventing illnesses, and reducing gas emissions. Even though the majority of these benefits come from decreases in fine particulate matter, the costs of some other rules outweigh the benefits. Only environmental regulations whose benefits outweigh their costs (such as decreased mortality) are beneficial to society (Gray, 2015).



(*Overview of the Clean Air Act and Air Pollution | US EPA*, 2022)

2.2 MESO ANALYSIS OF THE MEDTECH INDUSTRY

The American MedTech industry is a true success story. With manufacturing in both major and small communities and international exports of domestic products, the sector is a global leader. American medical technology companies are essential to accurately diagnosing patients, offering them high-quality treatments, improving outcomes, bringing down healthcare costs, and stimulating the economy.

This industry's main strength is innovation. The breakthroughs in medical technology that have already been made during the past generations are just the beginning. The fundamental regulatory and policy decisions made by America set the stage for upcoming advancements.

Some Industry facts are (*Medical Device Industry Facts*, n.d.):

The U.S. accounts for more than 40% of the global MedTech market, making it the biggest medical device market in the world.

The number of patient days spent in hospitals has decreased by 60% since 1980 as a result of medical technology.

2.2.1 Competition in the industry

Many factors influence competition in the U.S. MedTech market. Some of these factors have been mentioned before, because how companies navigate them often determines their competitive advantage. Technological advancements are one of these factors. Because there are so many MedTech companies, they must continuously invest in R&D to keep up with recent developments. This will give them a competitive advancement or help them maintain it.

Healthcare regulations and intellectual property are crucial factors because companies that do not abide by these rules and don't have patents will not be able to conduct business or not have a strong enough competitive edge (Lowden, 2022).

It is important to build trusting relationships with business partners and clients early on to ensure that you have a firm foundation with key stakeholders so when difficulties arise or inconveniences occur from rising prices and/or delays customers will still favor your brand. People anticipate some price increases, but as long as a company provides affordable solutions and has benevolent reimbursement procedures, it can outperform its rivals (Schmitt, 2022).

All this also connects with market share. Companies that have a bigger market share have more leverage to negotiate with suppliers and distributors, build partnerships, and invest in R&D. Businesses will stand out if they have a strong organizational structure, reliable processes, sufficient foresight, and the best teams.

2.2.2 Potential of New Entrants Into an Industry

The U.S. MedTech industry is a dynamic market with significant potential for new entrants. Yet, the industry has high entry barriers, making it difficult for new businesses to establish themselves. Barriers that were already mentioned are the complex regulatory landscape and the amount of competition, but there is also the need to have sufficient capital and the healthcare system that needs to be properly navigated.

- Capital requirements: For U.S. market success, the capitalization needs assessment must be realistic. The majority of foreign businesses lack sufficient funds to enter the market fully, which may be a recipe for disaster. Businesses that desire a share of the American market must invest enough money to properly advertise, do their R&D and clinical trials, and get their regulatory approvals.

  Companies might consider limiting the product lines they offer on the U.S. market unless they are adequately capitalized and ready for all key operational activities. Numerous product lines could be required for revenues in a smaller area, but in the U.S., it might be best to keep things simple until you start to see some growth in the market.

- Complexity of the healthcare system: Most businesses that move here do so from countries with socialized or more decentralized healthcare systems. Thinking that strategies that worked at home will work in the U.S. is a common misconception. Particularly in light of the Patient Protection and Affordable Care Act of 2010 and the current coronavirus outbreak. Flexible tactics and techniques are required in response to a variety of reasons, including changes in product assessment, new purchasing behaviors, and changes in distribution systems and entrance points. Some businesses mistakenly think that reimbursement is the only thing that matters, although health economics, quality, and patient outcomes are equally significant. Hospitals, patients, and other healthcare organizations are the main customers for MedTech products, therefore new entrants must build trusting partnerships with them to be successful. New entrants may find it challenging to overcome the relationships that established businesses in the market may already have (Faries, 2020).

2.2.3 Power of Suppliers and Buyers

The power of suppliers in the U.S. MedTech market is moderate to high and the power of buyers is low to moderate, due to the following reasons (Behnam et al., 2020; Kasi, 2019):

- There aren't as many providers as there are customers, giving them more leverage while negotiating contracts.
- Some of the necessary raw materials and components are expensive and specialized, making it difficult to replace them or obtain them from different vendors.
- Due to the requirement for quality assurance, regulatory compliance, and customization, costs associated with switching are considerable.
- Because of the regulatory environment's complexity and changing nature, both suppliers and buyers are exposed to risk.

As a result, it may be difficult for buyers in the U.S. MedTech sector to be profitable while still obtaining stable supplies from their suppliers. Setting prices and quality requirements for their products and services is, therefore, easier for suppliers.

2.2.4 Threat of Substitutes

Depending on the particular good or service being provided, different replacements pose a different danger to the U.S. medical technology industry. Nonetheless, due to the distinctive and specialized character of many of its goods, the industry generally tends to have a relatively low threat of alternatives (Snyder & Naaz, 2020).

For instance, because they are so sophisticated and highly specialized, some medical devices, such as implantable defibrillators, prosthetic joints, and pacemakers, have few alternatives. Similar to how many drugs are patent-protected, there are fewer alternatives on the market.

However, there can be additional alternatives on the market in other sectors of the economy, such as laboratory testing or medical imaging. For instance, various imaging procedures or techniques may be available for imaging technologies like CT scans or MRIs, and different methods or assays may be available for laboratory testing that can be utilized for diagnostic purposes (Snyder et al., 2021).

Because many of the U.S. MedTech industry's goods and services are extremely complicated and specialized, the threat of alternatives is generally considered to be low. Yet, there can be more alternatives available in some sections of the market, which might affect pricing and competitiveness (Snyder & Naaz, 2020).

3. THE OPPORTUNITY

The U.S. market is one of the most appealing markets for healthcare companies globally. In 2022, the U.S. MedTech market size was valued at a staggering 183,3 billion U.S. dollars. According to data for 2022 from the American Heart Association, about 6 million (1.8%) of the U.S. population experienced heart failure in 2021. The significant rate of heart failure in the country is therefore expected to increase the need for medical devices to improve detection and treatment, which would likely accelerate market growth over the course of the projection period (Medical Devices Market Size, Growth Report, Trends, 2022-2030, 2023).

It is therefore very interesting for Flemish healthcare companies to expand to the U.S. with their MedTech products, specifically with a heart monitoring patch. But wanting to expand and having a great product is not enough to guarantee success in bringing this product to the U.S. market.

Within the healthcare category, there are several subcategories that all have their specific needs, demands, and opportunities. This creates many requirements the company has to meet, different regulations they have to uphold, and a lot of obstacles they need to overcome.

A lot of companies don't know where to start with this complex process. Unfortunately, there is no guideline that explains this process from A to Z. A company has to find the pieces to this puzzle all by itself, which is a long and tiresome process.

Because this is such a tedious task, Flemish companies contact trade agencies, like Flanders Investment & Trade (FIT) to help them with this. Even though FIT has knowledge of this process and has contacts within companies that have successfully brought their MedTech products to the U.S. market, it does not have one guideline and therefore has to spend a lot of time helping these companies.

4. PITFALLS AND MISTAKES OF ENTERING THE U.S. MARKET

First it is important to understand the economic systems and the market structures of the United States. This will give you an advantage when trying to enter the market.

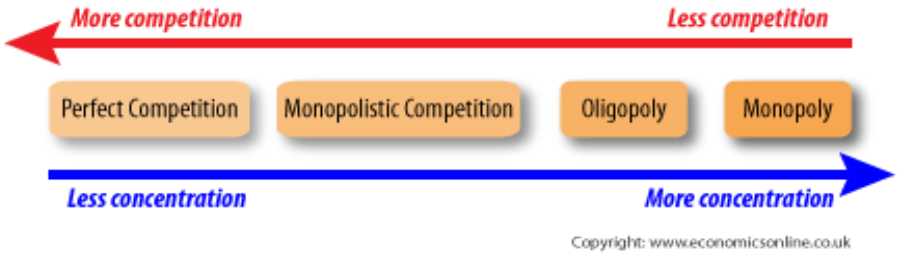
- The four types of economic systems (G, 2021):

Traditional	Common in countries where farming along with other traditional professions predominate and is based on goods, services, and work.
Command	The majority of the economic system is under the jurisdiction of the government (or another centralized, dominant authority).
Market	Free market system based on limited government regulation. People and the power of supply and demand shape economic regulation.
Mixed	Combination of market and command economic model elements.

The U.S. has a mixed economy, because it operates as a free market in terms of consumer products and services, and operates as a command economy in terms of defense. However, it is mostly considered the prime example of a free market (G, 2021).

- The four types of market structures in the U.S. (Indeed Editorial Team, 2023):

Perfect Competition	Monopolistic Competition	Oligopoly	Monopoly
• Many buyers & sellers • Free entry & exit • Homogeneous product • Highest quantity • Lowest price	• Many seller • Relatively free entry & exit • Differentiated product • Substitutes available	• Few sellers • Homogeneous or differentiated product • Difficult entry & exit • Strategic changes of price, quantity, quality, & advertisement to gain advantage	• Single seller • No substitutes • Impossible entry • Small quantity • High price



Competition within industries pushes companies to stay innovative and offer their products for reasonable prices. Based on how much competition there is within an industry, they can be categorized and analyzed via market structures. Understanding this gives you the ability to respond better to the decisions of competitors, which will give you an advantage in the market.

According to the annual ranking from the IMD World Competitiveness Center (IMD business school for management and leadership courses, 2023), the U.S. is one of the 10 most competitive countries in the world. Based on economic performance it is the third most competitive country, with one place above China.

Because it is such a competitive country, entering the market unprepared can mean a very easy and quick downfall for a business. So before describing methods and creating a model that could lead to success, it is important to identify what the pitfalls are for entering the U.S. market and what mistakes companies make far too often.

Pitfalls are defined as "unexpected dangers of difficulties", according to the Cambridge Academic Content Dictionary (Pitfall, 2023). It is because these are unexpected, that far too many companies are unprepared for them.

4.1 REGULATION OF THE U.S. MARKET

Belgium is a complex country because of its division into 3 regions and 3 communities. This division is a lot bigger and a lot more complicated in the United States. Instead of a single market, it consists of 50 markets each with different laws and regulations. It is extremely difficult to navigate this web of federal, state, and local regulations, especially in an industry such as healthcare. Since the government occasionally updates business-related rules and regulations, businesses must continuously update their data and regulations. Corporate data must therefore be regularly audited, controlled, and updated. If a company is unaware of governmental requirements, it could face severe penalties (Impacts of Government Regulations on Businesses, n.d.).

There are lots of consulting companies ready to help foreign businesses navigate these regulations and make sure they are as informed and prepared as possible. Unfortunately, not a lot of businesses know about these or have the resources to hire these services, especially young companies.

4.2 CULTURAL DIFFERENCES

The most essential source of credibility in Europe for international businesses is based on old-fashioned values like having a decent office and formality. In the United States, the benefits of good products and services outweigh age and experience. European companies also overestimate the importance of things that Americans care less for and only affect the price unnecessarily, like design and exceptional engineering. The lack of understanding this often leads to the misinterpretation of demands, buying habits, and business communication (Fabris, 2023).

These cultural differences also include language. Clear and professional communication is very important in the U.S. It could make or break a deal with potential business partners or even customers. Foreign companies that go to the U.S. often don't realize that the English they are using is too colloquial and not appropriate in a business setting. They could be fluent in English during social interactions, but still lack the skills of professional English. This can also be seen in grammatical and formatting errors. The error can be as simple as the month and day being in the wrong place (Finerva, 2022).

Next to these pitfalls that surprise a lot of Flemish companies, they also make mistakes that could be avoided. These mistakes are often wrong decisions made during the preparation for expanding the business to the U.S.

4.3 BAD HIRING DECISIONS

The first instinct of a company is to send a team of their own to the U.S. This team will have the responsibility of finding the first local customers and building the local team, but they often lack enough knowledge of the U.S. market, as well as the experience of opening a new office in a new market. Doing this the wrong way can therefore be an expensive mistake.

To avoid these costs some will even try navigating this process remotely, but managing a U.S. business puts an enormous amount of pressure on employees, and running customer support for U.S. customers is very challenging. Even hiring local employees is challenging, given the intense competition for top talent. Businesses frequently overestimate how simple it will be to find a qualified and trustworthy candidate (Finerva, 2022).

4.4 LACK OF FOCUS

As mentioned before, the U.S. is a very big country that consists of 50 different markets. It has many market segments, demographic areas, and highly competitive industries. When a business has a lot of success in its home market, it tries to grow by expanding its portfolio. This, however, does not work in the U.S. because there is too much competition for companies to focus on multiple markets and target audiences (Fabiano, 2020).

To be successful in the United States requires a business to focus on one or two niche markets. Even then it will be a challenge to enter those markets since it could already be heavily populated with local specialized companies. The challenge of accurately identifying the competition is closely related to this because with 71.153 startups now operational and venture capitalists investing $329.9 billion in them in 2021, the U.S. is the top country for startups (Finerva, 2022).

Another common mistake foreign companies make is underestimating how important it is to fit marketing, design, pricing, and features to the local standards of each demographic area and better suit its potential customers.

4.5 INSUFFICIENT INVESTMENT IN MARKETING

A critical mistake that European companies repeatedly make when planning to penetrate the US market is failing to sufficiently invest in marketing. The U.S. has a profound marketing-oriented business culture, where marketing is designed to leave a big impression on the target group, while in Europe marketing is more personalized to the receiver. Emarketer (Cramer-Flood, 2021) reported that U.S. companies spend 190 billion USD a year on digital advertising. This is 32% of global spending.

One of the reasons this is so different is because European companies have stricter regulatory requirements for marketing and therefore have a more conservative strategy. Moreover, European sales representatives are mostly used to conduct prospecting and find leads, while in the U.S., companies are structured with the expectation that marketing attracts the most leads and generates the most sales.

The U.S. market therefore requires companies to invest greatly in their marketing. Failing to do so will greatly compromise the success of a business.

5. IMPLEMENTATION

5.1 MARKET ENTRY

For successful market entry, a Flemish company needs to efficiently use the above-mentioned independent, mediating, and moderating variables to their best abilities. In this chapter, these variables will be explored in more detail to make sure a Flemish company knows how to implement them when bringing a heart monitoring patch to the MedTech market of the United States.

5.1.1 FDA approval

The process of bringing a medical product to market in the United States necessitates a large investment of time, money, and skill. A crucial stage in this procedure is getting the device approved by the FDA, which guarantees that it is secure and useful for the purpose for which it was designed. The approval procedure can be particularly difficult for a heart monitoring patch because the device must adhere to strict accuracy and reliability standards. Clinical trials, data analysis, and regulatory compliance are a few of the crucial procedures that go into acquiring FDA approval, and they will all be covered in this section.

Although FDA approval is a moderating variable in the contextual model, it is the first thing that a company should get before anything else. The FDA must give its permission or approval before a medical device can be marketed in the U.S. If your heart monitoring patch does not get approved, all other variables will not matter anymore.

First I will explain the difference between FDA approval and FDA compliance. All goods that the FDA has approved are compliant. Your product might, however, be FDA compliant and awaiting official FDA approval. Additionally, you may only refer to a device as "FDA approved" if you have a letter from the FDA stating that it has been approved (Krüger, 2020).

To get FDA approval, you need to follow these 4 steps ("How to Study and Market Your Device," 2022):

- Know the Classification of Your Device

Device classification is based on both the intended application and the usage-indicating characteristics of the device. Your device's class determines, among other things, the kind of premarketing submission or application needed to obtain FDA approval for marketing.

To determine the classification of a device and any potential exemptions, find the regulation number which relates to the classification regulation for the device in question. There are two ways to do this: go directly to the classification database and search for part of the device name; or, if the device panel (medical specialty) the device belongs to is already known, go directly to the listing for that panel and find the device and the applicable regulation ("Classify Your Medical Device," 2020).

The FDA normally classifies heart monitoring patches as Class II medical devices. Class II medical devices are regulated more strictly than Class I devices since they are thought to present a moderate danger to patients. Before being sold in the U.S., they need to meet several performance requirements and receive FDA premarket clearance or approval.

- Choose your premarket submission

If a premarket submission is necessary for classifying your particular product, you should decide on which and prepare it accordingly. The proper submission type is usually noted in the product classification for medical equipment. It should be noted that some device types don't need a premarket submission. Visit this webpage for further details on exemptions. You can move directly to step four if your device doesn't need a premarket submission.

Four of the most commonly used premarket submissions are:

- ❖ 510(k) (Premarket Notification)
- ❖ PMA (Premarket Approval)
- ❖ De Novo Classification Request
- ❖ HDE (Humanitarian Device Exemption)

- Prepare information for premarket submission

After you have created the correct premarket submission for your device, you must submit it to the FDA and communicate with FDA personnel during its assessment. The following should be considered before filing your proposal to the FDA:

- ❖ The submission of some marketing applications is subject to a user fee.

- ❖ Program for Small Business Determination (SBD): The majority of these user fees may be significantly reduced for a company that is recognized and accredited as a "small business".
- ❖ eSTAR: The eSTAR is a PDF form that applicants can use to get help creating a complete medical device submission.

When the FDA has received your submission you could be subject to an administrative review and an interactive review. The administrative review is to determine whether the submission is complete enough to be accepted for substantive review and the interactive review is to improve the effectiveness of the review procedure, so FDA personnel will interact with applicants while a submission is being considered.

- Adhere to Applicable Regulatory Controls

The FDA has the authority to monitor the reasonable effectiveness and safety of medical devices through regulatory controls, which are risk-based regulations.

After this, you wait for FDA approval. If/when your device is approved, you will still need to make sure that your device stays compliant for the rest of its lifespan.

Lastly, it is important to know what CFR 21 is. The Code of Federal Regulations (CFR) contains the comprehensive and permanent rules that the Executive departments and agencies of the Federal Government publish in the Federal Register. The Food and Drug Administration's regulations are included under Title 21 of the CFR ("Code of Federal Regulations - Title 21 - Food and Drugs," 2018). It specifies the requirements for medical device approval by the FDA.

5.1.2 Reimbursement

Introducing a cardiac monitoring patch to the U.S. market and obtaining reimbursement can be a difficult procedure with numerous steps and stakeholders. Companies often neglect to develop a thorough reimbursement strategy in the early stages of product development. Reimbursement may be postponed for another five or six years after the date of FDA approval if the two are not pursued concurrently. Even if these processes are carried out simultaneously and the quickest options are used at every stage of the procedure, it may still take two years or longer after the approval date to obtain only a portion of the insurance coverage (Reimbursement in the U.S. for Device Manufacturers, n.d.).

Understanding the most common payer types and how they differ is the first step. Payers in the United States include private insurance firms, Medicare, and Medicaid. The Flemish

company must determine the product's target market, including the indications and demographics of the intended patient group. They should then identify appropriate payer types that can cover the expenses of reimbursement and guarantee market access for the new device. For instance, Medicare will be a significant payer if the target market consists primarily of older patients (Kuo & Manaker, 2019).

Codes, coverage, and payment make up the three components of reimbursement. The code is a typical alphanumeric sequence that lists medications, medical equipment, as well as treatments, services, and operations. Coding, coverage and payment are inextricably related. Companies must determine which existing coding is appropriate for the new device or acknowledge the requirement for new or updated coding to be created. The lack of the proper code could hinder payment for a product or service because the coding system is primarily responsible for medical device reimbursement (Kuo & Manaker, 2019).

Coverage describes whether or not payers will pay for a certain medical good or service. The FDA's clearance or approval of the product or service is of course a determining factor in coverage decisions (Kuo & Manaker, 2019).

Payment refers to the sum of money given by payers to healthcare providers who make use of the device. Payers pay a fee for the service or operation connected to the medical device rather than for the equipment itself because the payment is based on a fee-for-service model. Numerous elements, including product cost, coding, and agreements between payers and providers, affect the payment amount (Kuo & Manaker, 2019).

5.1.3 Advertisements

In the U.S., laws and regulations make sure that advertisements for medical devices only provide accurate information. Professionals in regulatory affairs are crucial in assisting a company to maintain compliance with various rules and regulations while still achieving marketing and promotional goals.

This means that the FDA is legally able to govern your advertisements and promotions. There are just two clauses in the Federal Food, Drug, and Cosmetic Act (FDCA) that address the advertising of restricted medical devices:

- Any fraudulent or deceptive advertisement for a restricted device falls under the definition of misbranding.
- If the advertising for a restricted product does not include a succinct description of the product's intended use as well as any necessary cautions, warnings, side effects, or contraindications, the product has been misbranded.

Overall, you should be good as long as you accurately market and advertise your medical devices in accordance with the uses that the FDA has approved them for. Ad laws apply to unrestricted devices similarly. There is only one distinction: the FTC has authority (Adfire Health, n.d.).

A restricted device, according to the FDA's (2018) definition is "A device that can only be sold on oral or written authorization by a licensed practitioner or under conditions specified by regulation."

Hospital systems, doctors, patients, distributors, and possibly even the government may be potential customers for your device. You must have everything, from social media posts to attract patients' attention to technical documentation to help a doctor better comprehend your product's capabilities. The only problem with social media promotion is that Facebook does not allow listings to promote the sale of medical devices on Facebook, Instagram, or WhatsApp. Google is less strict in the sense that a company can still promote its device as long as it is government approved, does not have any government or regulatory warnings, and is not an experimental device. Recommendations for advertising a heart monitoring patch:

- Try making your audience smarter by focusing on giving them details of the product.
- Stay consistent. Your audience is connected to 10 devices on average, so changing your advertisement will create confusion.
- Data analytics technologies can be used to track engagement, website traffic, and purchases to determine the effectiveness of your advertising campaigns.

5.1.4 Local sales representatives

Successfully expanding to the United States depends on a skilled, remote sales force that will help a MedTech company break into the U.S. market, engage with clients more effectively, and ultimately produce the most income. Although it might be a challenging process to hire local sales representatives in the U.S. as a Flemish company, with the right planning and preparation, it can be an advantageous investment in your company.

Each nation has its own tax laws in addition to individual employment requirements. A company could hire U.S. workers as independent contractors if they lack the resources to develop and adhere to them. This means that the company will have one less thing on their to-do list because the U.S. employee will be in charge of adhering to the tax codes and regulations that they have experience with.

Finding someone in the United States who is interested in traveling is not difficult. Networking and job postings function similarly for every other profession. Start by exploring job boards and make an effort to increase the company's presence on social media to engage with U.S. citizens (Universal Cargo, 2018).

Another way to find local employees is by working with international recruiting companies. The first advantage they offer foreign companies looking to hire in the United States is that these agencies can save time and money by managing administrative responsibilities.

They also offer another range of services:

- Talent sourcing: When looking for qualified people with the appropriate abilities and expertise, they can use their vast network, databases, and recruitment channels.
- Screening & selection: On behalf of the foreign company, they can conduct preliminary interviews, evaluate qualifications, check references, and run background checks. This way only the best candidates are considered.
- Cultural expertise: The recruiting company may offer insightful advice on cultural factors, assisting the foreign company in navigating cross-cultural difficulties and making sensible hiring selections.
- Legal compliance: Assistance with visa applications, work permits, and other relevant papers. They keep informed of current regulations and aid the foreign company in upholding compliance throughout the employment procedure.
- Market experience: Aids a foreign company in comprehending the local labor market and formulating effective hiring plans.

It's important to remember that international recruiting companies could offer varying services. Depending on the needs of the foreign business, they may adjust the extent of their involvement.

5.1.5 Capital

Last but not least is the mediating variable, capital. It is the mediating variable because it is crucial for a Flanders-based business bringing a heart monitoring patch to the U.S. market to cover the costs associated with the independent variables, as well as the moderating variable. It enables the company to successfully navigate the challenging healthcare industry while gaining a competitive advantage.

Capital can be acquired in many ways such as self-funding, bank loans, venture capital, angel investors, etc. But there are also the options of government funding programs, or accelerator and incubator programs. In Belgium and Flanders, there are numerous government grants and funding programs and several accelerator and incubator programs available for Flanders-based MedTech businesses that are looking to expand to the U.S. Here are a few noteworthy choices:

Government programs	Accelerator/incubator programs
Flanders Investment & Trade (FIT): Provides financial assistance to Flemish businesses for export-related operations, particularly entering the US market.	Start it @ KBC: Offers full support to businesses from a variety of industries. Provides access to mentors, investors, and a community of entrepreneurs.
Wallonia Export-Investment Agency (AWEX): Provides grants and funding programs to Walloon companies looking to expand internationally.	Imec.istart: Business accelerator program in Belgium, run by Imec. They offer coaching, investment, and access to a network of specialists.
Wallonia-Brussels International (WBI): Supports and finances the efforts of Wallonia-Brussels Federation businesses to expand internationally.	Johnson & Johnson Innovation - JLABS: Global life science incubator that gives businesses access to cost-effective lab space and resources including knowledge, community, connections to industry, and entrepreneurial initiatives.
Belgian Foreign Trade Agency (BFTA): Offers support programs for Belgian businesses going global in collaboration with regional organizations.	

Keep in mind that these grants and programs may have varying availability, eligibility requirements, and application procedures. For the most recent information, advice, and assistance in applying for particular grants or programs, it is advised to check the websites of the organizations or to get in touch with them directly.

Additionally, consulting with the local chambers of commerce, business support organizations, and trade associations can offer additional perspective and support in identifying suitable grants and funding programs.

6. CONCLUSION & RECOMMENDATIONS

Throughout this market study, the pitfalls, external and internal factors, competitive landscape, and regulatory factors were examined to gain a comprehensive understanding of the United States MedTech industry. This understanding lead to the development of the conceptual and contextual model, where the variables needed to successfully enter the U.S. were identified.

In this study, it can be concluded that the moderating variable, FDA approval, can be the most challenging to obtain. It is recommended to make this your priority. Without FDA approval the company will be unable to enter the U.S. with their heart monitoring patch, even when all other variables are in place. Since this is such a pivotal first step, it is also recommended to use an FDA consultancy agency because of its regulatory expertise, compliance, quality assurance, and streamlined approval process. Engaging an agency can substantially improve a company's preparation and understanding to successfully navigate the FDA processes, but it does not guarantee approval or exempt companies from their regulatory obligations.

It can also be concluded that the basis of the solution is formed by reimbursement, advertisements, and sales representatives. Reimbursement is an important step to take into account early on in the market entry process. Getting a heart monitoring patch approved for reimbursement can take a long time, so it is recommended to start as early as possible. Reimbursement is what will make the heart monitoring patch more accessible and affordable to a great number of people.

Another conclusion that can be made is that advertising a heart monitoring patch proves challenging due to varying U.S. laws and regulations enforced by the FDA and social media companies. Finding local sales representatives is also not uncomplicated. There are different ways to go about looking for U.S. employees, but it is recommended to use an international recruiting agency for its local market expertise and cost and time efficiency. These two independent variables will make it possible for the healthcare company to sell its product to customers on the market.

Last but not least, capital is as imperative as the mediating variable. There are multiple ways to acquire capital, from self-funding to loans to government grants and programs. It is recommended to explore all options and not pursue only one.

If a Flanders-based healthcare company takes into account the information about the U.S. MedTech market, understands its obstacles, and follows the proposed strategy it can successfully enter the opportunistic U.S. market with its heart monitoring patch in 2024.

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