International Medical Device Marketing

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Abstract

A research of scholarly literature and corporate websites shows some of the challenges involved in the international new product introduction and marketing of medical products. The global medical device market has grown to over $500 billion, with approximately 60% of revenues originating from outside of the United States. The global market represents a large opportunity for healthcare marketers. Critical to the success of an international market includes proper sales channels and service support and careful consideration of cultural issues. Regulatory clearance is a complex area that differs from country to country, creating a significant barrier to entry. Paying for healthcare also creates challenge for device marketers, with complex insurance systems that vary from region to region. While the global market may generate significant revenue, worldwide product launches require extensive research and careful planning.

Keywords: Medical devices, healthcare, insurance, regulatory, medical technology

Introduction

The healthcare and medical device product development, marketing, and sales industry is an international giant and a highly complex marketplace. Numerous large competitors have emerged across the globe, developing products and services critical to the continued embitterment of healthcare services. Regulatory agencies, local customs and the growing complexity of healthcare payments creates challenge and risk for each device maker. With the potential impact on a patient that a product can have, companies must proceed with caution as they grow their market share and dive into new areas of the healthcare business.

This paper will explore the risks that global companies take on in the development of medical devices. It will discuss the current global sales climate, the impact of government regulation as well as exploring the effects of local cultures and treatment beliefs on medical devices. Issues related to insurance reimbursement and payment structure will also be discussed. Many multinationals have created successful strategies for entering international markets, the following aims to illustrate some of the risks and challenges in the growth of medical products.

Market Sizing

The medical device market is a massive one, with a total value of nearly $520 billion in 2018 (Vara, 2019). Of that market, approximately 40% of revenues come from the United States, generated largely by major players such as Medtronic, Stryker, Johnson and Johnson, and Siemens Healthineers among others. The total market size is expected to grow at a rate of between 5 and 6% through 2024 (Financial News Media, 2019).

With approximately 60% of medical revenues coming from outside of the United States currently, and emerging markets growing rapidly, international expansion is ripe with opportunity for device makers. Emerging markets in Africa and the middle east are immature

and represent a large patient population with very little current sales support. European and many Asian markets have mature healthcare systems that marketers can target and grow with. With expected growth of 5-6% over the coming years, it is reasonable to expect more competitors to enter the medical device space and international growth to become an even more important part of a company's strategy.

Sales Channels and Marketing Support

When moving to the international marketplace, medical device makers face a variety of challenges. One large barrier is the distribution network and building a sales channel. In domestic markets, many medical sales organizations utilize a direct sales model with representatives placed all over the country. Having a direct sales force allows companies to have increased control on price, promotion and placement of product. Sales training and marketing collateral is easier to deliver and the quality of both can be controlled. This comes at a great cost. Building a direct network of sales professionals is both time consuming and expensive, preventing some smaller firms from ever making the global leap (Heuberger, Going Global: The Challenges of Selling in Multiple Markets, Part 4, 2000).

A key part to successful medical device product launches is having the support of key opinion leading physicians. These experienced clinicians support through product trainings, contracted consulting and word of mouth advertising. Having an experienced physician supportive of your device means that their department will train incoming practitioners on that product and create customers for your company. Key opinion leaders have a powerful effect on their peers, with the effect of their opinion being up to 100 times larger than that of regular physicians when dealing with introductions of new therapies (Stremersch & Van Dyck, 2009). Companies looking to expand into global markets must identify leading local physicians to

partner with and utilize as key opinion leaders. These physicians will likely be involved in early product development, further improving the device for their particular local market. After product launch, their opinion and promotion can have a large impact on the success of a new product.

Outside of physician word of mouth advertising, some therapies and devices do get marketed direct to consumers. This is common in the pharmaceutical industry with numerous prescription drugs being advertised directly to consumers. The medical device and implant industry are also expanding its use of direct to consumer marketing to educate potential patients on advancing technologies. While patients themselves can't purchase devices, this advertisement can work to inspire patients to solicit their physicians for a particular type of treatment or implant. Direct to consumer marketing must be made with caution. Advertisements need to respect the local culture, be honest about health implications and respect the patient's condition itself. Improper advertising can be offensive to an entire group of people or patient population, directly contradicting the purpose of this style of marketing (Mackert & Harrison, 2009).

Getting Approval to Market: Regulatory

The medical device market and product development is highly regulated. Healthcare providers depend on the reliability and performance of these devices to make an impact on their patients' health. With so much riding on the successful use of a product, standards have been enacted around the globe and proper approval channels must be followed to have the legal right to promote a product for a particular use. Many countries are creating their own sets of rules, creating immense challenge for a manufacturer to meet all the different sets of requirements. The Global Harmonization Task Force, now the International Medical Device Regulators Forum, is

working to simplify this process, but in the meantime, companies employ large regulatory teams that work towards approval clearance using a variety of different standards (Heuberger, 1999).

Europe represents a significant opportunity for medical device makers. Positive economics and a mature healthcare sector make this region of the world a potentially lucrative area to market to. To date, much harmonization has happened across Europe, with the European Union recognizing the Certification Mark (CE Mark) as proof of compliance to European directives. This mark allows manufacturers to market in most European countries. The requirements for compliance are described by the Medical Device Directives, which is divided by device type and risk level. The higher the risk of the device, the more requirements there are. Approvals are granted by certified notified bodies, who perform regular audits of companies and assess technical documentation (De Maria, et al., 2018).

The European regulations are a hot topic in the medical device industry today. The above describes the basics of the current process as regulated by the Medical Device Directive. This process has been shown to need some improvement, so European agencies agreed to a new set of regulations, the European Medical Device Regulation (EU MDR). This regulation is meant to increase the safety of medical devices in Europe and imposes many new requirements that device makers are concerned with. The regulation comes into effect in May of 2020, causing concern for manufacturers in complying with the regulation in time to continue marketing devices in Europe (Mulero, 2019).

Canada is similar to Europe with a rush of changes being enacted in 2019 and 2020. In response to allegations that Health Canada's system was lacking, new regulations around how devices get to market, post market monitoring and transparency to patients are being created. This is in addition to Canada's four device class system that requires devices to be approved by

the agency prior to marketing. Each class of devices represents a different risk level and has a correspondingly increasing amount of information required for approval at each level (Health Canada, 2018).

The United States has it own sets of regulations and process for approvals governed by the Food and Drug Administration (FDA). Much like Europe and Canadian, the American system is risk based and classifies devices based on clinical use and impact to the intended patient population. Also, much like Europe and Canada, this system has come under challenge recently with allegations that the process is in dire need of updating (LaVito, 2018). Many proposals have been made to modernize the Food and Drug Administration's set of rules, as a result medical device marketers must proceed with caution when planning to enter the American market.

Nations outside of Europe, Canada and the United States have their own regulatory agencies and approval process to follow. This level of rigor and variety of agencies to comply with can drastically slow the international spread of medical products. Marketers must carefully plan sales expansion when thinking internationally and include approvals timelines and budget for these activities. A well developed product and local promotional program means nothing without all of the proper approvals in place.

Effects of Culture

Healthcare is no exception from facing cultural barriers across international transactions. Religious belief, language differences, and cultural normatives all play important roles in introducing medical technology to a new region. The healthcare marketer must take great care in understanding the local culture prior to new product launches in a new place.

An important factor for medical technology companies to understand is how different cultures attribute the causes of illness, how they answer the question of "Why is this happening to me?" In the United States, this is rather simple. Americans tend to attribute illness to its empirical causes. Many ethnic groups attribute cause of illness to a deity of some sort. For example, many African patients believe that illnesses are caused by spirits or are the result of a social cause. Latino populations also tend to believe that sickness is a result of God punishing them for bad behavior (Vaughn, Jacquez, & Baker, 2009). In these cases, the marketer must be respectful of these attributions and work with local clinicians to strategize how to present new products. The marketer would be wise to partner their clinical treatment with a homeopathic approach that addresses the belief of the patient.

Technology acceptance rates vary from culture to culture. Westernized cultures that are more economically developed tend to adapt to new technology more rapidly and are more open to technological change, medical or otherwise. Regardless of culture women tend to be more accepting of medical technology change than men. Interestingly, according to a study performed by researchers from Aachen University, people that exercise more frequently are also more accepting of new medical technologies (Alagoz, Ziefle, Wilkowska, & Valdez, 2011). Cultures less accepting of medical change should have slower growth forecasted in sales volumes and a gentler marketing approach. These cultures may be more adept to incremental technology introduction and might appreciate small product upgrades over a longer period of time. Conversely, products aimed at active women, especially those in Westernized cultures, are more likely to adapt quickly and appreciate significant advances in technology.

Religion can have a major impact on the use of certain drugs, implants and other medical materials. Many medical implants, dressings or drugs are derived from animal sources, such as

bovine or porcine sources. Some products are derived from human sources, including stem cells, bone grafts and connective tissue implants. Religion has an impact everywhere, however the least of which is likely the United States and some European nations where Christianity is the predominant faith. Christians, Buddhists and Jews generally accept the use of animal derived products. Where the international marketer must be more aware of religious issues is in regions that are more heavily populated with Hindu, Sikhs or Muslims. Hindus and Sikhs do not accept bovine derived products, whereas Muslims do not accept porcine products (Eriksson, Burcharth, & Rosenberg, 2013). This highly generalized overview barely scratches the surface of religious issues in the use of animal product. In different parts of the world and different, more localized, religious sect's animal use is of varying levels of acceptability. The international marketer must be aware of these differences and use caution to fully disclose the potentially offensive components of their products. A misstep here could destroy the reputation of the device maker in an entire nation, or perhaps an entire religious group of people.

One final cultural barrier to quality healthcare delivery is the language barrier. With much of the marketing materials and device instructions for use being written using technical language, the opportunity for translational errors is high. Patients can be put at risk if products are difficult to understand or instructions for use are not correctly translated to the local language and dialect. Product labeling and instruction for use materials are critical to the correct and successful use of medical devices and pharmaceuticals. The business of medical technology translations is one that is continuously growing, with independent consulting services working to provide proper translation. Companies often perform back translations and parallel translations to verify content of their marketing materials. Third party reviewers are an important part of this

process and can be performed by in-country sales managers, independent consultants or internal reviewers (Fleming, 2018).

Pricing and Reimbursement Issues

Pricing of medical devices is a highly complex matter. To start off, there is far less transparency in healthcare pricing than other industries. A layman can't do simple searches and find prices listed on a manufacturer's website. Hospitals create revenue and pay for costs incurred performing procedures through insurance reimbursement. In the United States, the American Medical Association publishes Current Procedural Terminology (CPT) codes that describe a procedure. These codes are used to bill both private insurance companies and Medicare for reimbursement (Luft & Chang, 1991). This system is not globally accepted. Regions around the world use their own reimbursement coding systems, and reimbursement for the same procedure and set of devices will change from country to country. Even in the European Union, individual member countries have their own unique reimbursement practices and set amounts (European Commission, n.d.).

Some countries have enacted even further pricing pressures, setting caps on profit margins and medical device costs entirely. One of the world's largest markets by population, India, has done this on certain products and is looking to expand price caps to more products (Kalra & Dasgupta, 2018). India represents a multi-billion-dollar marketplace for device makers, many of whom will be challenged to manufacture less expensive devices to fit within these price caps.

The system of reimbursement and pricing creates significant challenge for international medical device marketers. Prices for medical products must be set at a level that is economically viable for both the healthcare provider and the device maker. Lower reimbursement in some

countries will mean that the device company will either sacrifice profit margin, not enter that market or design products specifically for low cost regions. Extensive research must be performed to determine what price points are sensible for different countries.

Conclusion

Medical devices and healthcare are a highly complex market. Medical products present an opportunity to make a significant impact on human life, improving and prolonging the quality of life for patients around the world. With high potential for impact comes high risk and much regulation. Regulatory clearance must be included in marketing planning and in many cases can make an attractive market unviable due to the cost and time involved in getting government approval. Complicated insurance reimbursement creates risk for the both the healthcare provider and the device maker, both in procedural coding and pricing decisions. Additionally, cultural influence and religious belief has a serious impact on how devices and implants are utilized. The sum of all these challenges makes the work of an international healthcare marketer quite difficult, with many areas of expertise required.

The topics discussed in this paper are a small sampling of the hurdles that device companies face in their home countries and around the world. International expansion presents large growth potential but also brings a host of new challenges to explore and overcome. Careful planning and research beyond these areas of focus are required for successful international product launches and commercial success in the United States and international markets.

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