

Executive Summary

Munevo is using technology to improve the quality of life for those with disabilities. **munevo DRIVE** is a smart glass application that provides mobile independence through hands-free wheelchair driving.

Competitive Advantage

Munevo's competitive advantage is twofold: (1) Compared to others such as EyeTech Digital Systems, and LC Technologies Inc, Munevo provides a product that is user friendly and not highly subject to technological interference through virus or unexpected shutdown; and (2) Munevo's product appears more appealing than their competitors: it's lighter weight and far more durable.

Problem Statement

Wheelchair users worldwide are seeking increased efficiency in mobility and a greater quality of life. With strong success in its country of origin and current market, the next step in bringing this product to the global economy will be introducing it to the U.S. market. At minimum, this will require a strategic plan to navigate the complexity of the American healthcare system, Food and Drug Administration (FDA) requirements, and identify best practices for marketing medical technology and distributing the equipment through appropriate channels. Because **munevo DRIVE** is manufactured and distributed in Germany, it will be necessary for company leaders to develop a thorough understanding of the U.S. Customs and Border Protection Agency (CBP) guidelines, FDA, policies for importing products, the U.S. reimbursement process, and the most effective marketing techniques and stakeholders.

Solution

Import Process. All medical devices imported into the United States (U.S.) must meet the regulatory requirements of both the U.S. Bureau of Customs and Border Protection (CBP) and FDA. Products that do not meet FDA regulatory requirements may not be allowed into the country. According to the FDA, the requirements to import a medical device to the United States include: (1) establishing registration and medical device listing; (2) complying with pre-market submission requirements; (3) appropriate labeling; and (4) medical device reporting standards.

Production and Logistics. Munevo's one-year goal is to partner with the largest distributors Numotion and ASL in the United States, leads us to suggest consideration of additional partnerships with Sunrise Medical and Invacare. The three-year and five-year goals involve identifying and using new distribution channels and alternative uses for the product to maintain and create new revenue.

Reimbursement. We propose that Munevo establish strategic partnerships with government agencies, large healthcare systems, and insurance companies who can help them maneuver through the complexity of reimbursement in the U.S. For example, there are a number of large healthcare systems operating throughout the country, and organizations such as the Center for Medicare and Medicaid Services (CMS) that provide insurance and financing options for patients. In addition, The United States Department of Health and Human Services provides grants and funding. Private payer options are also available, but additional research would be necessary in order to better define those options and develop an appropriate strategy.

Through CMS, the reimbursement process includes making a reimbursable claim, ensuring that the claim gets accepted and processed, and understanding that payment will be at an amount deemed reimbursable (which may not be 100% of the price for the product). Patients who qualify for Medicare and Medicaid will have the option to finance the purchase with interest, and most other insurance providers do not afford that option. To receive grants and other funding -- all requirements for having a qualifying device or product would have to be met, and appropriate documentation submitted to, and approved by the agency providing the funding.

Marketing Strategy. The proposed target market in the East Coast and Midwest is roughly 800,000 thousand patients that may benefit from the use of the **munevo DRIVE**. We suggest that Munevo's U.S. sales representatives provide education, Business to Business (B2B) marketing, and events to the medical community to promote understanding of the products' benefits and promote sponsorship and advocacy. To establish appropriate networking channels and relationships in the U.S., Munevo's business development leadership should consider engaging with organizations such as the American Medical Association (AMA) or a Regional Chamber of Commerce and similar entities. Munevo will benefit from word-of-mouth and the use of social media platforms for promotion. We feel that expanding the "test run" component of the marketing strategy -- where providers use donated devices and allow patients to use the product and see its benefits, will be powerful and create loyal advocates for the product.

Conclusion

munevo DRIVE is a product with life-changing results in wheelchair mobility and quality of life. The ease and adaptability to the wheelchair components allows even the most restricted user comfort and a greater sense of personal freedom. Upon approval from the FDA and CMS, Munevo's ability to market the **munevo Drive** in the U.S. will be affirmed. Through the formation of strategic partnerships with providers, suppliers, and various health care payment systems -- the product could either be free of charge to the user or subject to a nominal co-pay. By targeting a geographic region where the potential pool of users is larger, forming the right partnerships, harnessing the power of positive word-of-mouth and use of social media, Munevo's life-changing technology will have a tremendous impact in the U.S..

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