Which Way to Go: CE Mark or FDA Approval?

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One of the biggest criticisms among medical device companies of the FDA is the Agency's inconsistent regulation and lagging device approvals, stifling innovation [1]. Challenges in the regulatory environment are prompting investors to look to other industries or shift investment overseas. A recent report [2] from PricewaterhouseCoopers found that U.S. venture capital funding for the life sciences sector slipped 18 percent in the third quarter of 2011. Additionally, a joint survey of the National Venture Capital Association [3] and Medical Innovation & Competiveness Coalition [4] found that investment in biopharmaceuticals and medical devices has decreased 40 to 41 percent over the past three years, whereas investment in healthcare services, consumer health and healthcare IT has increased 31 to 34 percent during the same period.

Start-ups and large device makers alike have difficulty bringing new products to market without greater predictability and transparency from the FDA. According to an online survey [5] funded by the medical technology industry's Institute for Health Technology Studies, most medical device companies today are seeking regulatory approval and launching their products overseas first. This article will look at whether this is a good business decision for all device manufacturers.

From a timeline perspective, there is generally a one- to three-year delay in launching new medical devices into general clinical practice in the U.S. compared to in the E.U. This is partly because the regulatory process in Europe is less bureaucratic, more efficient, and more predictable than in the U.S. Another reason is that the FDA requires evidence of both safety and efficacy of a device, whereas a European CE Mark only requires proof of safety and that the device performs in a manner consistent with the manufacturer's intended use. Additionally, it's becoming ever more difficult and arduous to conduct clinical trials in the U.S. due to the FDA's clinical data requirements [6]. Thus, the timeline for obtaining a CE Mark is typically much shorter than the timeline for gaining FDA regulatory approval.

For medical device companies with deep pockets, however, launching in the U.S. first or taking a parallel path, in which FDA and overseas approvals are sought in tandem, might be the best approaches. In order to develop a viable business strategy, a medical device company must understand the strengths and weaknesses of the regulatory system, its target market, the amount of internal and external resources required, and the amount of reimbursement available.

Common Regulatory Strategy Options

Seek Approval in the U.S. First

Seeking FDA approval first gives medical device companies with significant financial resources the advantage of being able to launch and market their products to the largest medical device consumer in the world, with about 50 percent of the worldwide market share, sooner versus later. Additionally, medical device

companies can expect more consistent reimbursement, better intellectual property protection, and less foreign competition with this approach.

Seek Approval Overseas First
This might be the best strategy for companies seeking approval of devices for which the FDA requires clinical data. Adding to the E.U.'s appeal is the fact that it is the second largest medical device consumer in the world, with approximately 30 percent market share. Also worthy of consideration is Japan, which has about 10 percent of the worldwide market share of medical devices.

If companies seek approval in Europe first, the FDA can't exclude European clinical data as part of its regulatory review, but generally doesn't like it. Companies that submit European data must make sure that the clinical design protocols in the European country are similar to those in the U.S. by obtaining an approved IDE study first. Also, data obtained from foreign clinical sites can only support U.S. data, not replace it.

Start Approval Process in the U.S. and Overseas in Tandem
This is the ideal strategy in terms of reducing regulatory risks due to costly delays in the launch of a device, but requires the most resources. It's important to note here that most venture capitalists today require medical device companies to develop parallel regulatory strategies before funding. Thus, start-up companies need to determine the various regulatory options and develop business strategies that include both the U.S. and other countries.

Risks and Tradeoffs
For start-up medical device companies, funding is limited. Thus, these companies must determine the tradeoffs of their regulatory strategy in order to minimize their risks. For example, although the CE Mark timeline is faster and the process is more predictable, there is no guarantee that the device will be widely accepted by physicians or reimbursable by the government in each European country. Additional clinical studies might be required in each country to show the efficacy of the device from a marketing perspective. The upside is that once a device is CE Marked, subsequent approvals are much quicker.

In contrast, the FDA regulatory process is currently unpredictable and the approval timeline is longer due to required clinical data showing efficacy. Compounding the problem, the speed of an FDA regulatory review is also highly dependent on the quality of the reviewer, which is declining due to the high turnover rate at the Agency, resulting in loss of institutional memory. However, once a device has received FDA clearance, companies can start marketing their product in the entire U.S. Reimbursement in the U.S., such as Medicare, is also more consistent since there is only a single government.

The most important difference between the regulatory system in the E.U. compared with both the U.S. and Japan is the role of the government. Although both the U.S. and Japan use non-government reviewers for the preliminary assessment of Class I and Class II devices, the government retains final authority over device approval. This is why obtaining a CE Mark is faster than approval in either the U.S. or Japan.

Summary
As this article illustrates, selecting a regulatory strategy is dependent upon several variables. Based purely on timeline, obtaining a CE Mark is always faster than FDA approval. One must remember that a CE Mark doesn't guarantee acceptance and may end up being as costly and as time-consuming as an FDA approval. Furthermore, there are other variables, such as funding and device type, that must be factored into a company's regulatory strategy.

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