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Rethinking Medical Device Market Strategies In Light Of New European Regulations

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IN COLLABORATION WITH Syneos Health

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The European Union Medical Device Regulation (MDR) is set to significantly raise the bar for medtech authorizations in the region. Once the MDR transition period ends in 2020, more medical devices will need to undergo clinical trials before being sold in the EU, forcing companies to rethink established market-entry strategies that use the region as a springboard for global launches.

Throughout the modern history of the medical device industry the EU has offered a truncated path to market to companies. Whereas the US Food and Drug Administration (FDA) demanded extensive data – including results of studies in humans – to approve or clear many devices for sale, authorities in the EU often permitted manufacturers with little more than a quality management system to market technologies.

The presence of a major market that allowed the sale of medical devices on the strength of limited data resulted in the emergence of a well-trodden global commercialization strategy. The countless companies that followed this pathway first sought to secure a CE mark, the clearance needed to sell a device in the EU. CE marks are awarded by notified bodies, independent businesses designated by an EU country to perform premarket conformity assessments of certain products.

After securing a CE mark, a company can begin making commercial sales in the EU while working to bring its product to other markets. The value placed on the CE mark by regulators in markets such as Australia and New Zealand enabled companies to quickly expand globally after receiving clearance to enter the EU. As such, a CE

mark not only gave companies access to a major market, it also served as a springboard for a rolling global commercialization push.

Some device companies never expanded beyond the EU and other easy-to-access markets, figuring that the potential payoffs were too small to justify the risk and investment needed to access other territories. Other companies used sales made in the EU to fund clinical trials designed to unlock markets with more rigorous regulatory requirements, most notably the US.

The US offers an abbreviated route to market to developers of devices that are similar to existing products – a 510(k) premarket submission to the FDA – but even that pathway is long and expensive compared with the EU process. A survey of 204 US medical device manufacturers found it took seven months, on average, to go from first communication to the receipt of a CE mark.[1] In the US, the same process took 31 months. The gap is even wider for novel devices that follow the more rigorous premarket approval pathway.

These divergent timelines, and their effect on the cost of getting a device to market, mean the EU is the first region targeted by many companies. One analysis of novel devices cleared for sale in the EU and US found 63% of products received a CE mark before being made available in North America.[2]

Raising The Barrier To Entry

The laissez-faire system in place in the EU came under attack in the 2000s. Investigative reporters received EU clearance to sell a fictitious hip implant and researchers showed devices that come to market first in the region are more likely to be the subject of post-marketing safety alerts and recalls than products initially authorized in the US.[2,3]

EU authorities sought to improve the situation, including by sanctioning some notified bodies, but a subsequent investigation found a "number of recurring and persistent problems."[4,5] Those problems led the EU to take more drastic action.

In 2017, the EU passed the MDR and began a three-year transition to the new rules.[6] Boston Scientific, one of the medtech sector's largest firms, told investors the regulation "significantly modifies and intensifies the compliance requirements for the industry," in part because it imposes "higher clinical evidence requirements" on device developers.[7]

Those higher clinical evidence requirements will prevent some developers of Class IIa and IIb devices from using an equivalence approach to win a CE mark, thereby forcing them to test their products in humans if they want to access the EU market. The MDR clinical evidence barriers to entry for Class III and implantable devices are higher still.

The scale of the changes associated with MDR means retaining the old go-to-market strategy is not an option. Companies must adapt if they are to thrive. That will mean reconsidering which country or region to target first – or, perhaps more wisely, choosing to pursue multiple markets in parallel – and restructuring clinical and commercial teams around more rigorous data requirements.

The New Go-To-Market Strategy

The EU will no longer be the de facto first choice for initial device launches after MDR. At this stage it is unclear exactly how MDR will affect the time and money it takes to bring devices to market in the EU, but the direction of travel is clear. Gaining a CE mark will become a longer, more costly process.

Securing EU clearances may be particularly troublesome over the next couple of years. MDR requires more devices to undergo thorough review by notified bodies but there are concerns that the system lacks the capacity to cope with the increased workload.[8,9] If, as many fear, notified

body capacity fails to ramp up quickly enough to meet the rising demand, a backlog of submissions could increase the time it takes to bring new devices to market in the EU.

In that environment, more companies will work to enter the EU and US in parallel, or even decide the FDA is more attractive for first-time filings. The agency is encouraging companies to target the US first. By the end of 2020, the FDA hopes to have enacted changes that make it the first market of choice for more than 50% of developers of novel medical devices.[10]

The FDA aims to make it simpler for device companies to access the US, in part by only demanding the minimum amount of information necessary to efficiently address a regulatory issue. Given the US has other benefits over the EU, such as centralized review, a single language and a larger market, even small changes by the FDA could drive companies to rethink their commercialization strategies.

Developers of some devices may find that regions other than the US and EU offer the fastest path to market. Japan, for example, has introduced an expedited, conditional approval system that enables regenerative medicine products – which in other territories could be treated as either drugs or devices – to come to market and receive guaranteed partial reimbursement on the strength of preliminary clinical data.[11] The first product cleared under the new system came to market on the strength of data from a seven-subject clinical trial and secured a price of $122,000 per treatment.[12]

The Value Of Integrated Clinical-Commercial Teams

The changes underway in the EU and the rest of the world will shake up medical device commercial strategies, but there are some constants for companies to cling to. Most importantly, more than

ever, developers of devices will need to show how their products work in humans before bringing them to market.

In this way, MDR will increase the value of integrating clinical and commercial teams. Under the old commercialization strategy, there was little need to consider the influence of commercial factors on clinical development early in the life cycle of a medical device. The low barrier to entering the EU meant companies could ignore clinical development entirely until commercialization was underway in some markets.

That is no longer an option. With regulators around the world refusing to clear many devices for sale without first seeing clinical data, companies need to design their R&D strategies far earlier than in the past.

Companies that design clinical development programs without considering commercial factors run the risk of failing to generate the data they need to market their devices. If, for example, a company wants to market a device as a way to reduce hospitalization, it needs to generate clinical data showing that the product has this effect.

The inherent link between commercial messaging

and clinical data means sales and marketing must inform R&D if companies are to efficiently generate the required results. Integrated teams are best placed to facilitate that exchange of information between commercial and clinical. After MDR raises the cost of getting devices to market, these exchanges and the efficient development programs they facilitate will be essential.

Quickly Adapting To MDR

Many companies have work to do if they are to remain competitive in this new environment. At big companies, having clinical and commercial teams in silos makes it difficult to exchange information. Small companies have a different problem. They frequently lack either the clinical or commercial infrastructure needed to get devices to market under MDR.

Both sets of companies can benefit from working with a service provider that has integrated clinical and commercial teams, such as Syneos Health. This service model offers device companies access to the power of integrated teams without establishing connected internal groups, enabling them to quickly adopt new go-to-market strategies once the MDR transition period ends in 2020.

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