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## Accelerating Market Access: Streamlining Health Tech Regulations



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Launching a health tech or medtech startup in Europe is a complex and resource-intensive process. Entrepreneurs must navigate intricate regulatory requirements that vary significantly across markets, leading to delays, increased costs and uncertainty. Many startups underestimate the time, effort and resources required to bring their solutions to market, which can result in costly setbacks.

Health Tech Hub Copenhagen is stepping in with Health Tech Pathways, a digital platform designed to simplify regulatory compliance and accelerate market access for startups. With the right tools and industry collaboration, Europe has the potential to enhance its competitiveness and innovation in health technology. The initiative aims to bridge the knowledge gap that often hinders startups from successfully entering the market and scaling their operations.

### The Challenges of Regulatory Compliance

Regulatory compliance is one of the biggest hurdles facing European health tech startups. Entrepreneurs must determine whether they need European Union Medical Device Regulation (MDR) certification and, if so, which class applies to their product. Additionally, ISO certification requirements, approval timelines and associated costs pose significant challenges. Many startups struggle to develop a regulatory strategy, leading to delays in product launches or even company failures. Without clear guidance, entrepreneurs risk navigating a fragmented system without fully understanding the steps required for approval.

The process of obtaining certification is often lengthy and expensive, and startups may not always have the necessary expertise to navigate the system effectively. The uncertainty surrounding regulatory approval processes can also make it difficult for startups to secure funding, as investors may be wary of backing companies that face prolonged regulatory hurdles. In some cases, lack of compliance knowledge can result in companies pursuing the wrong certification pathways, causing unnecessary delays and financial losses.

### Health Tech Pathways: A Digital Solution

To address these challenges, Health Tech Hub Copenhagen is developing Health Tech Pathways, a platform funded by a €4.2 million grant from the Novo Nordisk Foundation. This initiative aims to provide startups with tailored regulatory guidance, expert connections and an ecosystem designed to streamline compliance. By centralising resources and fostering collaboration between startups, consultants and regulatory bodies, Health Tech Pathways will help reduce the time and cost required for regulatory approvals. The platform will serve as a self-service hub, promoting transparency and efficiency to support innovation in health technology.

The digital nature of the platform will allow startups to access up-to-date information on regulatory requirements, helping them make informed decisions at each stage of their journey. Additionally, the platform aims to connect startups with specialised consultants and industry peers who can provide valuable insights and guidance. By leveraging these resources, startups can develop robust regulatory strategies, reducing the likelihood of delays and increasing their chances of successful market entry.

Health Tech Pathways is not just a tool for individual startups but also a step towards fostering a more cohesive health tech ecosystem in Europe. By providing a structured and accessible pathway for regulatory compliance, the initiative aims to create a more predictable and efficient process for bringing innovative health technologies to market.

### Opportunities for a Unified European Framework

One of the key barriers to European health tech innovation is the fragmented regulatory landscape, which often drives startups to seek approval in the United States instead. The complexity of navigating different regulatory systems across European countries makes it difficult for startups to

expand beyond their home markets. This challenge is exacerbated by differences in how regulations are interpreted and enforced, leading to inconsistencies in the approval process.

While initiatives like EDiHTA are working to harmonise digital health assessments, a fully unified European regulatory framework remains a distant goal. However, platforms like Health Tech Pathways can significantly enhance startups' ability to navigate these regulations, ensuring they are better prepared for market entry both in Europe and internationally. By leveraging AI and industry collaboration, this initiative has the potential to reshape the regulatory landscape and make Europe a more attractive market for health tech entrepreneurs.

By improving access to regulatory information and creating a more structured approach to compliance, Health Tech Pathways could encourage more startups to focus on the European market rather than looking to the United States for faster approval processes. This shift could, in turn, strengthen Europe's position as a global leader in health technology innovation and create more opportunities for entrepreneurs and investors alike.

Regulatory complexity should not be a roadblock to health tech innovation. Health Tech Pathways represents a crucial step in simplifying compliance, fostering collaboration and accelerating market access for startups. By equipping startups with the right knowledge and resources, the platform will help them avoid common pitfalls and optimise their regulatory strategies.

While achieving full regulatory alignment across Europe remains a challenge, targeted solutions like this platform can provide the necessary tools to empower entrepreneurs and strengthen the continent's position in the global health tech market. With the launch of Health Tech Pathways, startups will have access to a centralised, reliable resource that can guide them through the regulatory landscape more efficiently.

The potential impact of Health Tech Pathways extends beyond individual companies; it has the capacity to improve the overall efficiency of the European health tech sector. By reducing the time and cost associated with regulatory approvals, the initiative will enable startups to bring their innovations to market faster, ultimately benefiting patients, healthcare providers and the broader industry. The platform marks an important milestone in making regulatory processes more efficient and accessible, paving the way for a more competitive and innovative European health tech ecosystem.

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