

# Europe's Attractiveness for Innovation

State of Play and Recommendations

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## State of Play and Recommendations

The European medical technology industry has historically been resilient and continues to mature, thanks to the European region's ongoing attractiveness and for medtech innovation.

Its vibrant research ecosystem and academic institutions, its relatively efficient and accessible healthcare systems, and its growing efforts towards value-based healthcare, all contribute to Europe's continued international competitiveness as a place for the medtech industry to do business.

However, other regions of the world, such as North America and the Asia-Pacific, are becoming more competitive.

The European region has work to do, if it is to retain its historic place as the global "epicenter" of medtech innovation.

European policymakers can and must take key actions to preserve Europe's attractiveness for medtech innovation, specifically by focusing on the region's political, legislative, tax and regulatory climate.

Few industries have greater growth potential than life sciences, but that potential only matters when it is realised and touches the lives of real patients.

We all have a role to play to ensure that Europe's innovation and investment landscape continues to enable the potential of the medtech industry, to save and improve people's lives, while contributing to the sustainability of our environment, our healthcare systems, and our economies.

It is time for health stakeholders and policymakers – at all levels – to engage collaboratively and proactively to unlock the full potential of medical technology innovation.

### **Europe's Innovative Research Ecosystem**

***In summary:** The foundations of Europe's research ecosystem set it up to be an attractive and competitive player. However, risk aversion, heavy administrative burden, and skills shortages present serious challenges.*

#### **Strengths:**

- Europe's incentives, education, and talent make it attractive: it presents a clear opportunity for R&D investments due to European and member-state wide incentives, its well-developed research infrastructure with innovation hubs combining academia, business and local government, and a working environment that attracts and nurtures world-class talent.
- Europe is also undertaking a number of actions to encourage entrepreneurship and widen its pool of talent. For example, to help the medical technologies sector reach its full potential, the path from development to commercialization is being eased by closing the funding gap.
- It is also implementing strategies to create a differentiated medtech talent pool. These factors allow companies, with a good degree of confidence – to de-risk their medtech innovation investments in such relevant areas as sustainability, digital health, and preventive health.

#### **Breaking factors:**

- When it comes to the research and innovation ecosystem, medical technology companies in Europe are challenged by risk aversion, heavy administration, and skills shortages.
- Although Europe's medical technologies innovation landscape outperforms others, there are points of improvement: risk aversion by European investors, burdensome administrative processes, complex and expansive compliance with many misaligned regulations, and medtech-specific skills shortages (such as ICT or digital or sustainability).

### **Europe's political, legislative, and regulatory landscape**

***In summary:** Europe's political, legislative and regulatory landscape has long been its source of strength and differentiation vs. competitors. At the same time, the (recent) risk of over-regulation or non-coherent regulations poses a serious challenge in maintaining Europe's competitive edge and attractiveness for innovation, and ultimately risks negatively impacting patients and healthcare systems.*

#### **Strengths:**

- Predictability, legislative power and access to markets have long been factors that differentiate and strengthen Europe's position compared to other regions. Companies that invest in Europe can enjoy the benefits of unlocking multiple markets via a single regulatory product approval process.
- This dual foundation -- of predictability, stability, and access to the EU market – brings many advantages, among them economic predictability that benefits business. In contrast, the economic and political environment in the US undergoes shifts with each new administration, introducing uncertainty and unpredictability.
- The intentions of the Medical Devices (MDR) and in vitro Medical Devices (IVDR) regulations, such as transparency, predictability, human health, and priority of high safety are also well intentioned. The benefits of playing in the European market are enormous given its size and strategic importance.

#### **Breaking factors:**

- These same regulations that promote stability, trust, and access to the world's 2d largest market have also raised barriers to entry and present serious risks of over-regulation – they have made it

more difficult to support innovation and promote small and medium-sized enterprises and make it increasingly difficult for companies to adapt to the growing volume of legislation.

- Risk- adverse policies can lead to overregulation, or unfitted regulation especially at the EU level. New horizontal EU Regulations – such as those on artificial intelligence or product liability – often overlap and may create duplications and confusion with rules provided by the sectorial EU MDR/IVDR. These worries may cause medical technologies manufacturers to consider prioritising other regions with more innovation-friendly, predictable and stable approaches to regulation.
- The regulations increase administrative complexity and legal uncertainty, especially if implemented in a fragmented way, which can erode predictability of timelines and costs, when compared to other regions around the world.
- Overcoming these barriers is essential for preserving timely patient access to medical technologies in Europe, and the medical technologies industry must work together with policymakers to find solutions that harmonise the current system.

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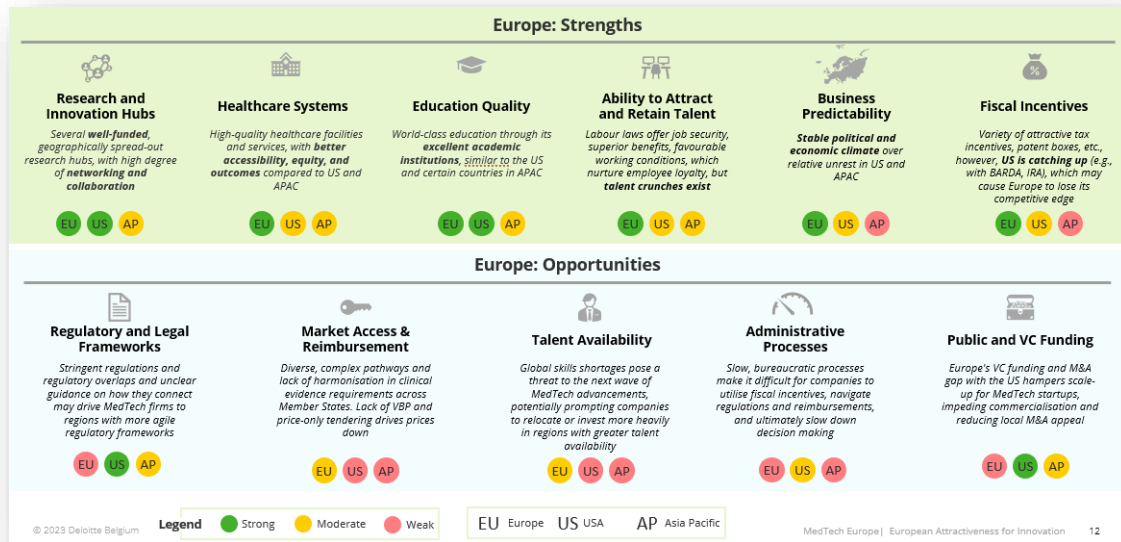
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## Annex 1: Europe Strengths and Weaknesses



### Europe's strengths...

- Research & innovation hubs**  
 Several well-funded, geographically dispersed research hubs, with a high degree of networking and collaboration.
- Healthcare systems**  
 High-quality healthcare facilities and services, with better and more equitable access, and outcomes compared to the US and APAC.
- Education quality**  
 World-class education through excellent academic institutions, similar to the US and certain APAC countries.
- Ability to attract & retain talent**  
 Labour laws offer job security, superior benefits, and favorable working conditions, which nurture employee loyalty, although talent crunches exist.
- Business predictability**  
 A stable political, economic, and regulatory climate compared to relative unrest in the US and APAC.
- Fiscal incentives**  
 A variety of attractive tax incentives, patent boxes, etc. However, the US is catching up (e.g., with BARDA, IRA), which may dull Europe's competitive edge. Incentives are also linked to the higher-quality healthcare facilities and services with better accessibility, equity, and outcomes compared to the US and APAC.

### ...and weaknesses

- [Regulatory & legal frameworks](#)  
Stringent regulations, regulatory overlaps, move to a litigious environment and unclear guidance on how they connect may drive medtech firms to regions with more agile frameworks.
- [Market access & reimbursement](#)  
Diverse national, complex reimbursement pathways and diverse clinical-evidence requirements across EU Member States. Lack of VBP and price-only tendering drive prices down.
- [Talent availability](#)  
Global skills shortages pose a threat to the next wave of medtech advancements, potentially prompting companies to relocate or invest more heavily in regions with more available talent.
- [Administrative processes](#)  
Sluggish administrative processes make it difficult for companies to utilise fiscal incentives and navigate regulation and reimbursement, slowing down decision making.
- [Public and VC funding](#)  
Europe's VC funding and M&A gap with the US hampers scale-up for medtech startups, impeding commercialisation and reducing local M&A appeal.

## About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

[www.medtecheurope.org](http://www.medtecheurope.org).