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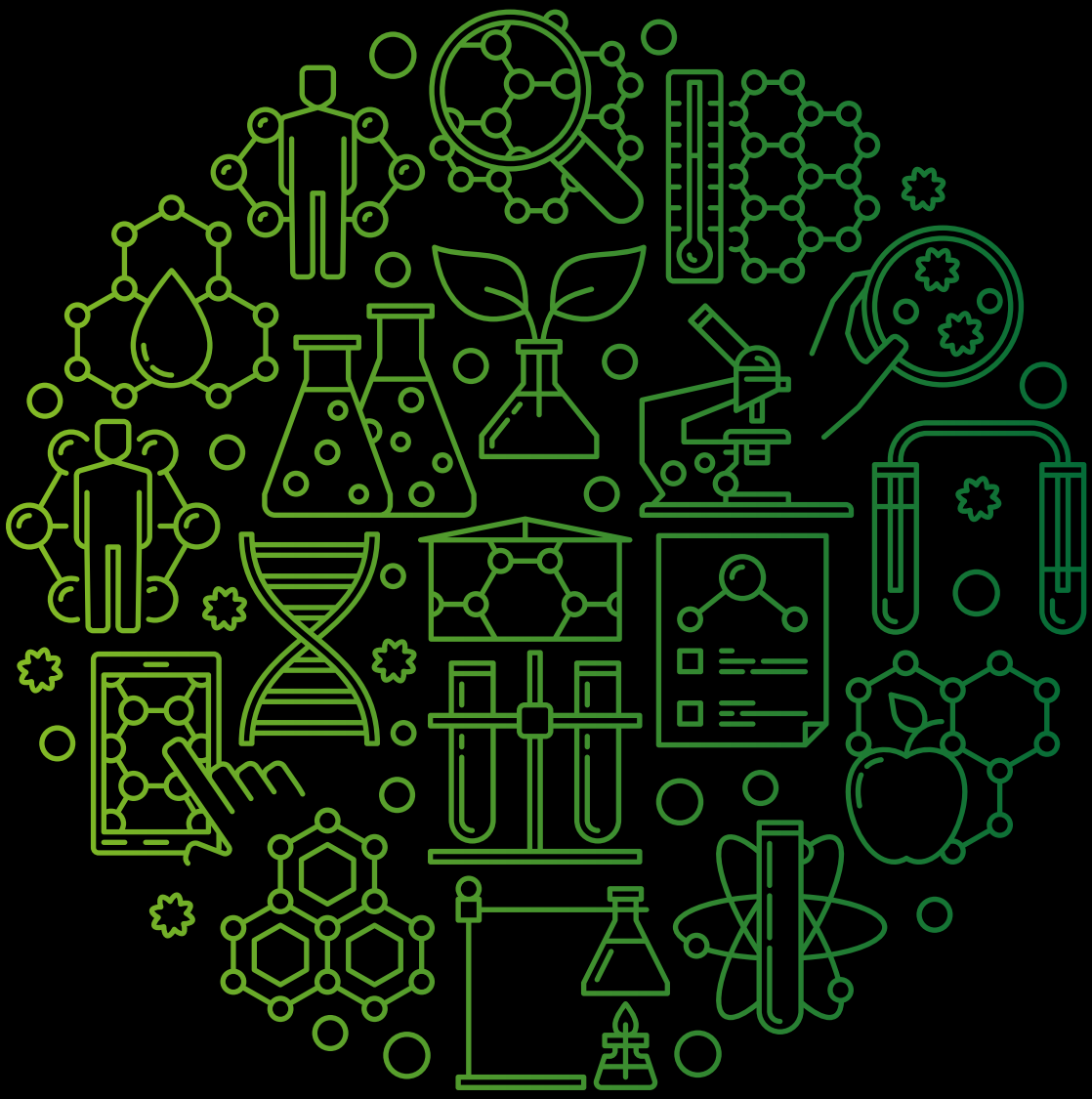


Europe's MedTech Attractiveness

Strong Healthcare Hubs and Talent Pools Paving the Way for Innovation and Patient Solutions

May 2024

MAKING AN IMPACT THAT MATTERS since 1845

Table of Content

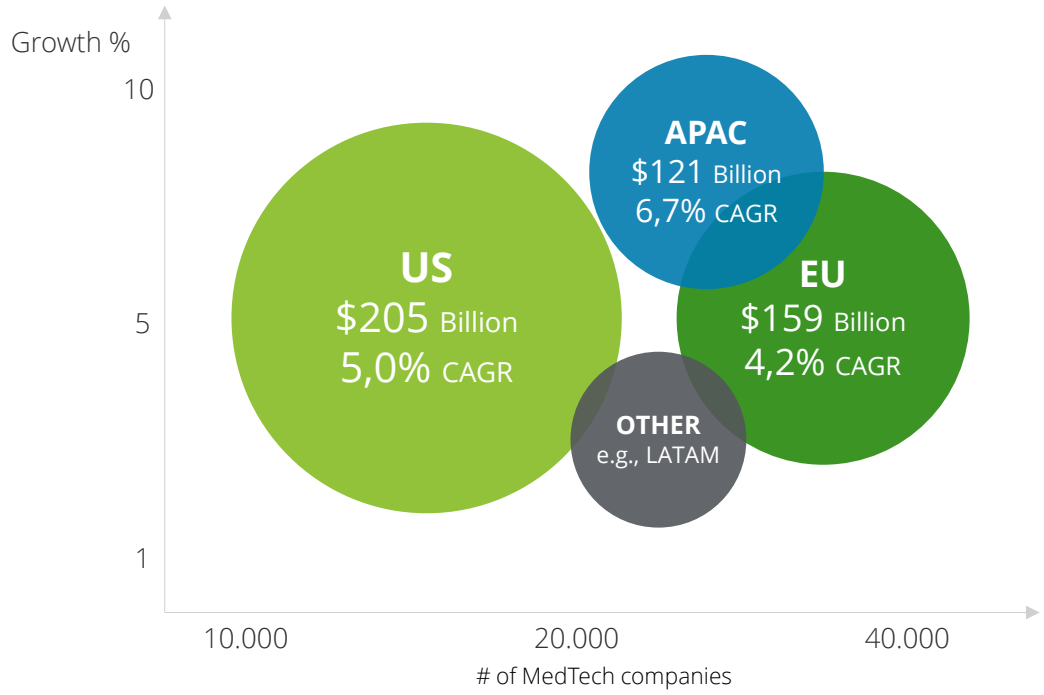
1. Introduction

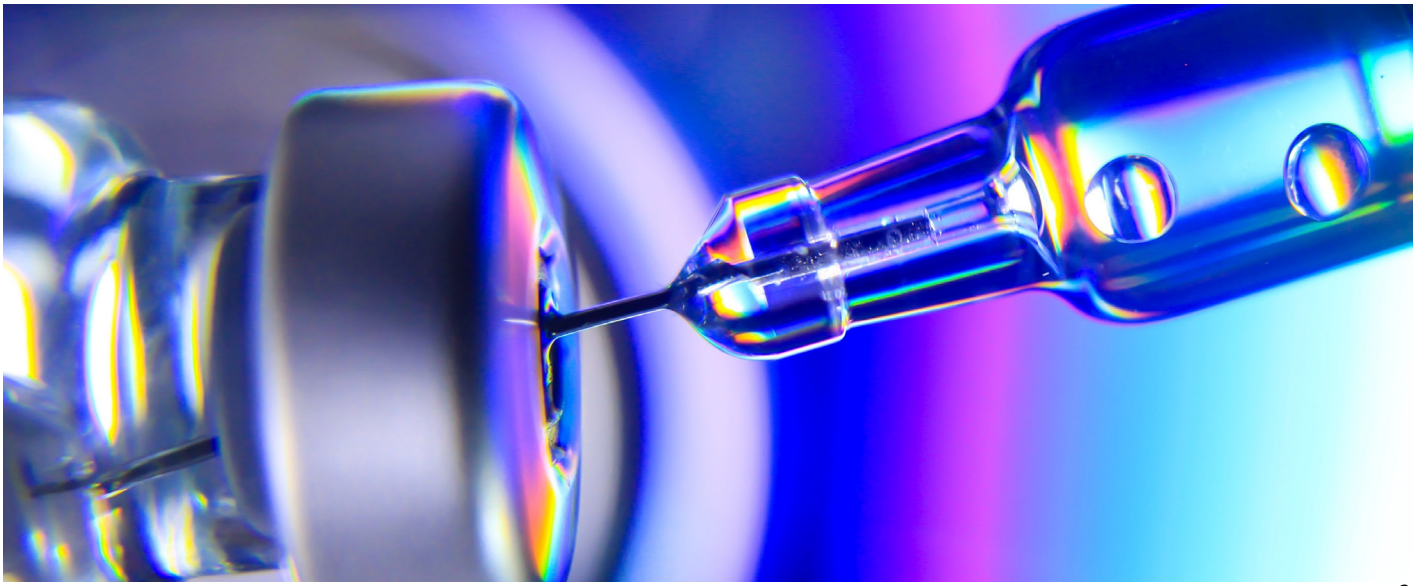
MedTech takes a central position in the transformation of the healthcare sector and global health care landscape

Amidst the current MedTech trends and market dynamics, Europe emerges as the second largest market globally growing almost on par with the US and, slightly behind APAC (**Fig. 1**)

Figure 1: Overview of the Global MedTech Market (MedTech market size (2023) and Market growth (expected CAGR (2024-2028))

Overview of the Global MedTech Market





However, in the evolving landscape of the industry, Europe finds itself at a critical juncture, navigating through multiple transformative shifts and emerging trends that are reshaping the market dynamics. In order to keep its leading position, Europe must proactively embrace and capitalize on these shifts and market trends:

1.1 Transformative shifts within the Healthcare industry :

a. Rising Healthcare costs :

In recent years, healthcare costs in Europe have increased significantly due to factors like advancing medical technology, ageing population, rising prescription drug prices, increased prevalence of chronic diseases or workforce costs.

b. Ageing population :

Older populations (and related chronic diseases) opened a totally new market for devices that give people more and longer health autonomy, improving quality of life and reducing the burden on healthcare systems.

c. Shift towards value based care and prevention :

There is an increasing focus on value based care prioritising quality and outcomes of care delivered to patients over the volume of services provided. By emphasising value, healthcare organisations aim to achieve better patient outcomes, reduce costs, and promote health equity.

Value-based care also encourages healthcare providers to focus on preventive measures, chronic disease management, and population health management, rather than just treating acute illnesses

d. Diagnostics and digital health will play an important role :

The COVID-19 pandemic demonstrated the value of in vitro diagnostics. The role of diagnostics in general will become more important in preventive and personalised healthcare. In addition, there is a shift from sick-care to wellness, rapid growth in virtual care and digital health investment, and regulatory changes for faster approvals and improved access (e.g., Digital Health Applications or DiGA in Germany). Together, these are boosting telemedicine, remote monitoring, and the worldwide market for connected care devices such as wearables.

e. Sustainability:

MedTech innovation is also reorienting towards sustainable medical technologies, prompting a shift in the design strategies and resource use. Exploring new circular business models and reusability strategies , such as device refurbishment, maintenance and repair, recycling, and reprocessing.

1.2 Forces of change in business landscape :

a. Supply chain shocks :

Within the current geopolitical context, short-term supply chain disruptions arise from stricter sustainability mandates, including supplier risk mitigation and substance bans, unpredictable spikes in demand. These factors, compounded by vulnerable production lines and material shortages, may hamper access to crucial MedTech equipment, making it a matter of national security.

b. New competition :

The global MedTech market, dominated by ten key players (owning 40% of the market) sees the US as its largest market, boasting a size of $205 billion in 2023. However, future growth prospects favour the Asia-Pacific region (particularly China, with anticipated growth rates reaching up to 7.5% between 2024 and 2028). This trajectory is attributed to the ageing population, increasing healthcare spending and rising quality of care. Consequently, APAC is poised to expand its market share from 21% to 22%, while Europe is expected to see a small decline from 27% to 26%.

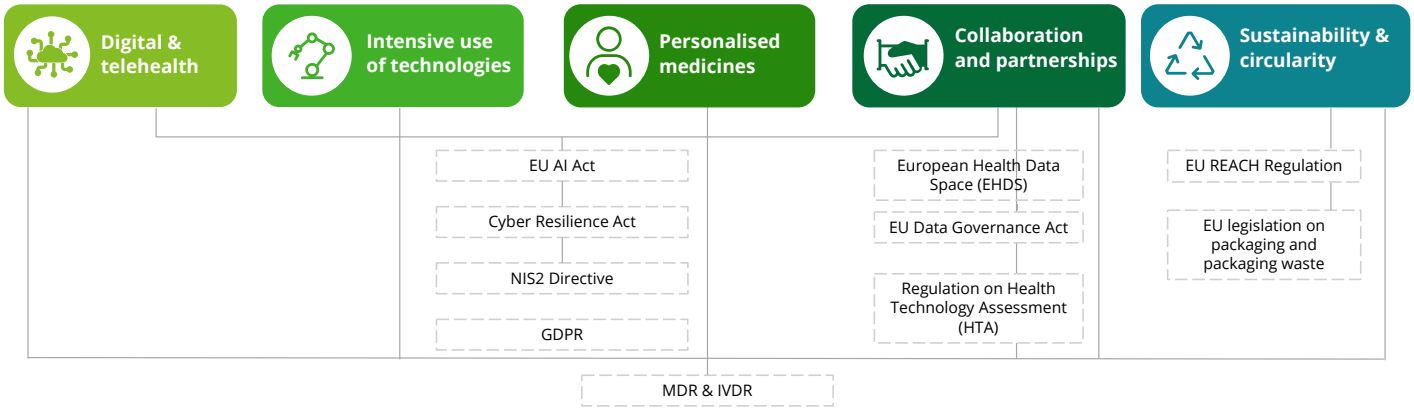
c. Talent shortages :

The global MedTech market faces the challenge of skill shortages (e.g. technology professionals, healthcare professionals and operational workers), especially when it comes to future skills like digital and data, which could hinder the progress of future advancements, compelling companies to consider relocating or intensifying investments in regions with greater talent pools. Consequently, this talent crunch heightens competition among industry players, driving efforts to attract and retain top talent.

d. Increased regulations, from industry specific to industry agnostic :

Europe's MedTech industry is a regulated sector governed by frameworks such as Medical Device Regulations (MDR) and In Vitro Diagnostics Regulation (IVDR) **(Fig. 2)**. Subsequently, MedTech is also a technology driven industry, relying increasingly on data interoperability and AI technology innovations which are also impacted by industry agnostic frameworks like General Data Protection Regulation (GDPR) and the AI act. Lastly, as a manufacturing industry, MedTech companies will also have to work with its supply chain to create more sustainable product and solutions government by specific EU sustainability legislation.

Figure 2: Overview of regulations governing the MedTech industry



2. Objective & Methodology of this study

Comprehensive assessment to gauge Europe's attractiveness across three key dimensions: Product Launch, Research and Development (R&D), and Manufacturing within the MedTech sector

The objective of this report is to evaluate the attractiveness of the European MedTech innovation landscape (compared to other global regions) for R&D, manufacturing, and product launches. To enhance and direct the research, interviews were conducted with experts and industry partners from MedTech Europe.

- About 40 reports were analysed from sources such as the European Commission, US FDA, and other independent bodies (see List of references)
- 3 statistical databases were explored for data analysis (OECD, Eurostat, Statista)
- 29 MedTech industry experts (regulatory and government affairs, R&D, grants and funding, market access, commercialisation, across Europe, US and APAC) were interviewed to validate the research

In order to assess atractiveness, Deloitte's ecosystem framework **(Fig. 3)** was used to identify a set of relevant indicators and sub-indicators. Benchmarking exercises demonstrated strengths and weaknesses, and how they compare with those in other regions

Figure 3: Deloitte ecosystem Strategy Framework

Socio-economic robustness
- Political stability
- Healthcare ecosystem (incl. accessibility, quality, etc.)

Strength of the ecosystem
- Policy and regulatory climate (incl. for clinical trials and medical device approvals)
- Market access and reimbursement
- Peers and industry cluster presence (incl. start-up activity)
- Presence of research institutions

Fiscal and financial competitiveness
- Financial and non-financial government inducements (e.g., R&D incentives)
- Tax incentives or policies
- Funding (access to venture capital, government funding, etc.)

Talent availability
- Quality of education (incl. availability of education and training programs in MedTech relevant fields
- Skilled workforce
- Immigration policies to retain local talent and attract international talent

Ease of doing business
- Legal and IP frameworks (business regulations and IP protection laws)
- Administration complexity (e.g., efficiency of government processes, obtaining licenses, etc.)

Site availability
- Sustainability
- Availability of locations and infrastructure (e.g., incubators, manufacturing facilities, etc.)
- Innovation (incl. digital infrastructure and adoption of emerging technologies such as 5G, AI, telemedicine, etc.)

This report is the executive summary of a Deloitte collaboration with MedTech Europe. For more information, please contact the authors.

3. Why is Europe a good choice

Europe remains an attractive market to develop, manufacture and launch products

a. Continued support for Life sciences & Healthcare as a strategic sector	b. Strong ecosystems & hubs
c. Talent as its greatest natural resource	d. Regulatory innovator
e. Advanced Healthcare system	f. Stability & Predictability

a. Continued support for Life Sciences and Health Care (LSHC) as a strategic sector (locally and at EU level) :

Over the last decade, key MedTech countries such as Belgium, France, Germany, Netherlands, Italy, Ireland and Spain have increased support for the industry through government grants and incentives. After the pandemic highlighted the fragility of national health systems, the EU4Health program was adopted to reinforce crisis preparedness. The €5.3 billion budget allocation sent a clear message that public health is a priority for the EU and that it is laying the groundwork for the European Health Union.

Its objectives were multifold :

1. Promote health and prevent diseases by engaging in global health collaborations
2. Address cross-border health threats, ensuring availability of critical supplies and personnel
3. Enhance accessibility and affordability of essential health products
4. Strengthen Healthcare systems via digital advancements and collaboration among national systems

In addition to that, the European Investment Bank Group and participating EU Member States (currently Germany, France, Spain, Italy, and Belgium) have announced the European Tech Champions Initiative (ETCI): a €3.75 billion fund to support late-stage growth companies in the region.

CASE STUDY

ETCI: Addressing EU's late-stage funding gap

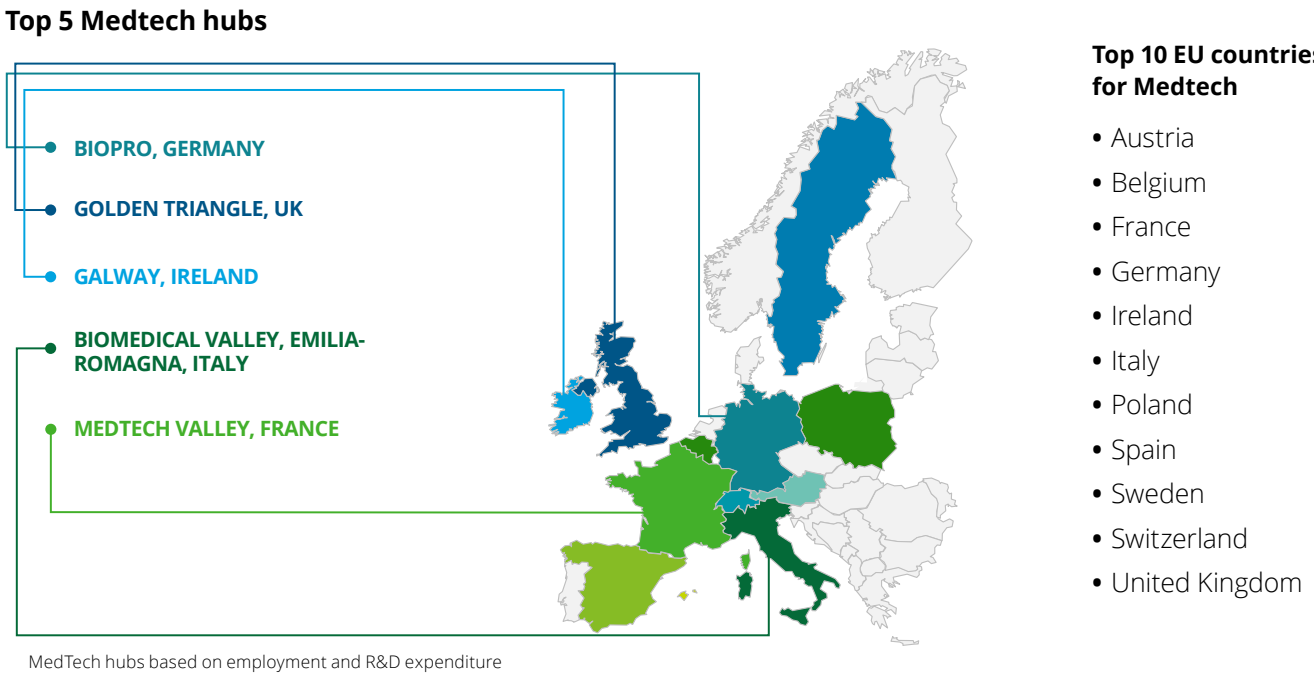
- Feb 2023: **European Tech Champion Initiative** (ETCI) set up to boost equity investments and prevent EU's most promising high-tech companies from being bought out by foreign investors once they become successful
- Seeks to create a **€10 Bn pan-European Scale-Up Initiative** for scale-ups seeking to raise investments above €50 Mn
- ETCI **pools public resources from participating Member States and the European Investment Bank Group** to make significant investments into large-scale Venture Capital (VC) funds, which will in turn provide growth financing to European tech champions
- The initial money pot is worth **€3,75 Bn**, but its **size is expected to increase over time**
- After a three-year-long pilot phase, the **ETCI might be open to private investors**

Next to these different European countries, others like France, with its tax credit for green investments, are also supporting the digital and sustainability transformation of its industry. These initiatives demonstrate EU's continued support for the LSHC sector as a strategic priority and underscore its significance.

b. Strong ecosystems and hubs :

Europe boasts several collaborative innovation networks and hubs **(Fig. 4)**, involving universities, established companies and start-ups (+/- 2000 MedTech start-ups in Europe) generating high levels of patent (e.g. 42% of all patents in the industry are filed at the European Patent Office vs. 35% in US) and publication activity.

Figure 4: Europe has world-class MedTech hubs, which are well funded and supported by local governments[1]



MedTech hubs based on employment and R&D expenditure

c. Talent as greatest natural resource :

European universities consistently rank among the best in the world for life sciences education and research **(Fig. 5)**[2]. Part of this success is linked to a greater percentage of its GDP spent on education than China or Japan with national education systems bolstered by EU-level initiatives **(Fig. 6)**.

Figure 5: Number of Universities in Top 50 for Life Sciences (2023)

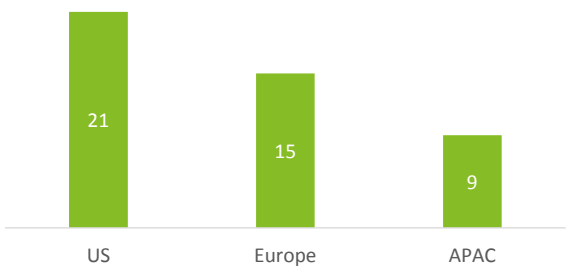


Figure 6: '% of GDP spent on education for selection of countries (2020)

1. Seven most important MedTech clusters, MDDI Online
2. World University rankings, Times Higher Education (2023)

However, it is not enough to develop skilled talent. Talent retention is also critical, which in Europe is made easier through favourable labour laws and EU initiatives like the European Skills Agenda, as well as changes in immigration laws and administration (e.g., single permit) in Member States for highly skilled workers **(Fig. 7).** For example, Finland is implementing a fast-track procedure for highly skilled workers and start-up entrepreneurs and their families while Denmark has implemented selective immigration preferences for highly educated or skilled foreign workers.

Figure 7: Europe offers a greater sense of job security, benefits, social protections, work flexibility, leading to more favorable working conditions that help nurture world-class talent

	Europe	APAC	US
Employee Turnover*	**10,1 years** average time spent with one employer	**3,3 years** average job tenure in Australia	**4,1 years** median years of tenure with current employer and **3,9 years for health workers**
Job security for employees	**High –** robust **employment protections** and presence of **labour unions** offer **increased job security**, e.g., Spain has prohibited employers from terminating employment contracts of striking workers	**Medium –** employment **protections vary across countries** – e.g., short notice period in Japan (14 days), but longer notice periods in China (30 days)	**Low –** most employment is **at-will;** either the employer or the employee can **terminate the relationship at any time** Provides **flexibility for employers** but can also result in job insecurity for workers
Benefits and social protection	**High –** robust **social protections**, including **universal healthcare**, **paid parental leave**, and **retirement benefits**. Provide a safety net for workers who may experience job loss, illness, or other challenges	**Medium –** varying benefits across countries – but most **offer paid parental leave, retirement benefits**	**Low –** employers are generally **not required** to provide benefits such as health insurance, paid parental leave, retirement benefits, but many companies offer these benefits voluntarily
Work Flexibility	**High –** most countries have **legally mandated vacation time** (20-30 days / year) as well as **legal maximum working hours**, e.g., 35 hours in France	**Medium –** labour laws that dictate maximum working hours and compensation for overtime exist in many countries but are **not enforced well** – allowing employees to work longer hours	**Low – no federal requirement** for paid vacation time and no legal maximum on working hours, which makes it easier for businesses to operate longer hours

Note: *Industry-agnostic except where specified

Add to this Europe's auspicious working conditions: greater job security, higher benefits, better social protection and more work flexibility. This explains why European workers spend on average 10.1 years with one employer, compared to just 4.1 in the US and 3.3 in Australia .

d. Regulatory innovator :

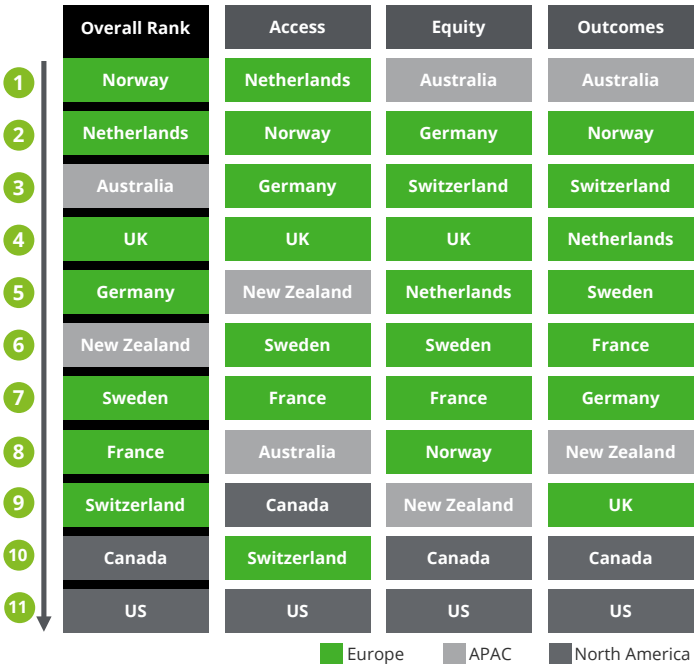
Europe also stands out in another way: it leads the rest of the world in legislative innovation. Europe is the trailblazer in legislating on sustainability, data usage, AI, and other key fields, providing companies with opportunities to innovate in these areas.

Because of the size and importance of the European market, EU regulations set the agenda for global companies. Take the EU's General Data Protection Regulation (GDPR) implemented in 2018. Adhered to by more and more companies, it has influenced countries around the world to consider and implement privacy legislation. The EU's Green Deal (2020) and Artificial Intelligence Act (approved in December 2023) will similarly influence other regions to either sign up or create their own versions.

e. Advanced healthcare systems :

European healthcare systems outperform those in other regions and this is not a question of investments in healthcare systems (**Fig 8**). The US spends far more of its GDP on healthcare than European countries: 16.6% compared to 12.7% in Germany, Europe's highest health spender.

Figure 8: European countries perform well due to universal coverage, investment in primary care and social services



For that, there are four principal pillars supporting Europe's healthcare success. The 1st pillar is universal coverage and lower cost barriers enabling everybody to have access to the care they need, how and when they need it. The 2nd pillar is well-functioning primary care systems. These ensure that high-value services are equitably and locally available in all communities, reducing the risk of discrimination and unequal treatment. A 3rd pillar is low administrative burden on patients and clinicians as time and effort could discourage access to care, especially for marginalised groups. A last pillar is Europe's social services that increase equitable access to nutrition, education, childcare, community safety, housing, transportation, and worker benefits – all leading to a healthier population and fewer avoidable demands on health care.

With universal coverage and reduced cost barriers, MedTech companies have larger market opportunities and increased demand for preventive technologies. In addition, focus on community-based care and health equity can lead to opportunities for collaboration between MedTech companies and healthcare providers to develop solutions tailored to specific community needs

f. Stability & predictability :

Lastly, a voluntary political union made up of 27 diverse countries can only be viable if it is founded on two principles. One is political stability, as seen in a 2021 global political stability index that places 22 European countries in the top 50. The other is a common consensus-driven culture. This dual foundation brings many advantages, among them economic predictability that benefits business combined with the benefits of unlocking multiple markets with a single regulatory process. In contrast, the economic and political environment in the US undergoes shifts with each new administration, introducing uncertainty and unpredictability.

4. Improvement Points

Europe is still an attractive market to invest but there are some challenges which need to be addressed

Over the past years, Europe has seen growth slowing down resulting from a negative perception from MedTech companies towards investing their business in Europe. This negative perception of Europe stems from a series of challenges which need to be addressed :

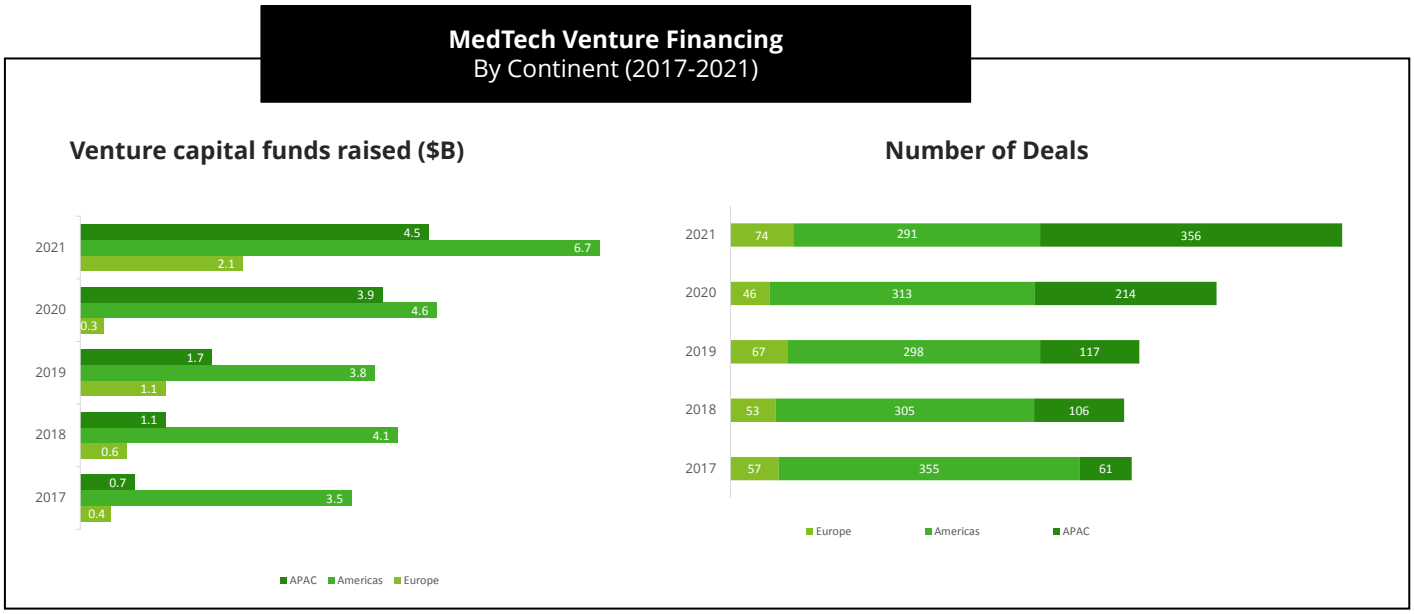
- a. Lack of sizeable funding for innovation
- b. Skills shortage
- c. Complex regulatory frameworks
- d. Low value based procurement adoption
- e. Complex reimbursement pathways

a. Lack of sizeable funding for innovation

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 while increasing potential acquisition interest from foreign organisations.

This is due to the risk-averse nature of European investors. In 2021, $2.1 billion in MedTech venture capital (VC) funds was raised in Europe versus $4.5 billion in APAC and $6.7 billion in the Americas. This discrepancy partly explains the lower numbers of MedTech start-ups in Europe (half in 2022) compared to the US **(Fig 9).**

Figure 9: Venture Capital funding overview and number of M&A deal per region



Regarding public funding, while COVID-era spending clearly helped Europe healthcare systems respond effectively, there are still major hurdles. Starting in 2024, potential cuts in public spending might lead to longer wait times, reduced access to services, and a decline in the quality of care **(Fig 10)**. All of this, diminishing the attractiveness of launching new MedTech products.

Figure 10: Impact of underfunding in healthcare

CASE STUDY: IMPACT OF UNDERFUNDING

FRANCE

- 3.4 doctors per 100.000 inhabitants
- **>6 million people** without a regular General Practitioner(GP) (2022)
- **30%** population have inadequate healthcare access
- **87%** of France is poorly provisioned by HCPs

GERMANY

- **23.000** care sector posts vacant (2022)
- **>30%** of health jobs could be unfilled by 2035

SPAIN

- >**700.000 people** waiting for surgery (2022)
- **5.000** frontline GPs and pediatricians protested years of **underfunding and overwork**

b. Skills shortage :

It is evident that 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 appropriate available talent. As an example, already in 2021, more than 60% of EU businesses faced shortages of digital and ICT skills with similar obstacles being observed in the US, where 65-80% of firms struggle to hire AI talent, and in APAC, where 60-80% of organisations find it difficult or extremely difficult to fill vacancies in many IT roles.

Next to tech professionals, potential shortages in healthcare professionals (4 Mn shortage of health workers by 2030 for Europe) and low-skilled workers could lead to severe bottlenecks in the health value chain. To tackle those challenges, the European Union has already launched several initiatives including industry collaborations **(Fig. 11)**.

Figure 11: European initiatives to address skills shortages

01 | Industrial Skills

- European Skills Agenda includes the Pact for Skills and Blueprint Skills Alliances
- Pact for Skills promotes **upskilling and reskilling for green and digital transitions**, innovation, and competitiveness
- Partners in the Pact include companies, workers, authorities, social partners, Vocational Education and Training providers, and more
- Blueprint for Sectoral Cooperation on Skills fosters cooperation for skills **development in industrial ecosystems – including digital and healthcare sectors**

02 | Health Ecosystem

- Pact for Skills partnership for the health ecosystem aims to **address skills needs and build resilience across the complex network of health systems**
- Launched in December 2022, it covers:
- Skills to support the digital and green transitions in the health sector, for both existing and emerging occupations
- Interdisciplinary skills and skills to enhance the integration of care across patient pathways, and health promotion and disease prevention in health-relevant sectors

03 | Digital Skills

- **Pact for Skills digital skills partnership** aims to:
  - Equip 80% of people with basic digital skills
  - Achieve gender convergence
  - Employ 20 million ICT specialists in the EU by 2030
  - Create an ecosystem-wide upskilling and reskilling framework
- **PANACEA project**: developed a toolkit to reinforce overall cybersecurity for hospitals and the delivery of healthcare
- EC published a Communication on a **Cybersecurity Skills Academy**, which aims to bring together existing European initiatives on cybersecurity skills

04 | Trainings

- Around half of the Member States are developing Individual Learning Accounts (ILA) schemes
- A scheme is already operational in France
- The purpose of ILA is **to provide direct financial support to individuals**, including the unemployed and self-employed, for use in training activities
- The ILA can also be **used by workers in companies**, in coordination with their employer, to respond to specific skills needs

c. Complex regulatory frameworks

Europe's risk-averse policies can lead to too much regulation. Additionally new rules could make it harder to protect trade secrets. These worries may cause MedTechs to seek other regions with more innovation-friendly and agile approaches to regulation.

Stringent protocols, like the Medical Device Regulation (MDR) and In Vitro Diagnostic Device Regulation (IVDR), as well as other horizontal regulations can be perceived by the business community as excessively burdensome (Fig 12), especially for smaller companies that don't always have the expertise in-house. Evolving rule-sets are increasing uncertainty due to a lack of lack of alignment between different regulatory frameworks. The resulting complexity and unpredictability could drive MedTech firms to regions with fewer regulatory constraints on their activities and more clarity about their application.

Figure 12: Overview of regulations governing the MedTech industry

		DESCRIPTION	CHALLENGES
1	MDR	Regulation that governs the **production and distribution of medical devices** in Europe	• Increased **requirements for clinical data,** struggled with **implementation delays** and **introduced uncertainty** in regulatory process • Incentivizes companies to pursue **approvals outside of EU first**
2	IVDR	New regulatory **framework for in vitro diagnostic medical devices**, introducing substantial changes in the sector	• More **stringent regulatory requirements**, **reclassification** of devices, emphasis on **post-marketing surveillance**, leading to heightened complexity and lack of predictability in the system
3	GREEN DEAL	Part of Europe's efforts to become the first climate neutral continent by 2050, includes several directives to **encourage sustainable transition**	• Requires patient-centric implementation of **sustainability requirements** • Increases **reporting requirements** and may **impact supply chains** as well as availability of and access to life-saving and life-sustaining technologies • Initiatives to **restrict use of certain substances**, without clarity on **transition times**
4	AI ACT	Aspires to establish the world's first **comprehensive regulatory scheme for AI**	• Evolving understanding of **how it interacts with sectoral regulations**, e.g., MDR / IVDR • Will **impact already marketed products** and risks requiring changes to the design of existing products
5	EHDS	Aims to enable the seamless transition of health data sharing across the EU for **public health and research purposes**	• May lead to loss of rights' holders' ability to control access/use of their protected data • Lack of clarity on how a health data access body would be able to assess which types of data are protected by **IP/Trade Secrets (TS)**
6	GDPR	Comprehensive **data protection and privacy regulation** designed to strengthen and unify data protection for individuals within EU and EEA	• **Lack of harmonisation across EU Member States** • **Lack of guidance and uncertainty** regarding international data flows. • Lack of alignment between authorities on interpretation of provisions

Compared to the US, Intellectual property (IP) protection in the EU is weaker. That is because European provisions regarding regulatory exclusivity do not extend to medical devices. Thus, the only way for a MedTech company to protect its products in Europe is by relying on the patent system and keeping its know-how confidential. Eastern Europe also suffers from inconsistent implementation of IP protection laws. However, this may improve with the introduction of the unitary patent.

d. Accelerate the shift to value based procurement

Despite pressure from the EU Public Procurement directive, EU-wide adoption of value based procurement (VBP) among providers and procurement bodies is low. This lack of focus on value together with tough pricing pressures prevents companies from demanding higher prices for new or innovative products. Moreover, value means different things to different stakeholders and this lack of a common definition among Member States can negatively impact MedTech products.

As a result, EU-wide adoption by providers and procurers is currently low with a majority of Member States still allowing price-only decisions, and not focusing on the value of the technology.

However, it is important to mention that Europe is ahead of other regions in embracing VBP.
Some countries (the UK, the Netherlands,Ireland, ...) **(Fig.13)** have been eager adopters and began using VBP as a key underlying principle in their MedTech procurement and are reaping substantial benefits from it today.

Figure 13: Examples of value based procurement in Europe

CASE STUDY: EXAMPLES OF value based procurement (VBS) IN EUROPE

Ireland: Published a **new national framework agreement** for procuring medical technology that encourages procurers to put up to 80% of awarding weight on outcomes and benefits to care providers

Netherlands: Advancing value-based contracting as a central concept throughout the Dutch health care supply chain, in tandem with a wider government initiative to shift toward outcome-based health care

UK: NHS Wales systematically applies VBP to large central tenders to an increasing number of products and services from NHS suppliers that are selected based on their ability to reduce costs and improve outcomes that matter to patients

e. Complex reimbursement pathways

With different reimbursement pathways across 27 Member States (as well as regionally) standardised value assessment criteria are missing. For example, only Germany, France, and Belgium have established reimbursement pathways for digital health solutions but even for these countries the path to reimbursement is long, hard and uncertain. Furthermore, reimbursement delays of 5-6 years on average can prevent smaller manufacturers from remaining in business.
Additionally only 8 out of 32 countries offer innovative payment schemes to cover critical new technologies not reimbursed via traditional payer pathways.

On top of that, cumbersome bureaucratic processes make it difficult for companies to utilise fiscal incentives and navigate regulation and reimbursement, ultimately slowing down decision making and pushing MedTech companies to get funding in other regions.

5. Moving forward

Recommendations for industry and policymakers to work collaboratively and proactively to make Europe's innovation and MedTech investment landscape more attractive

Making the European MedTech innovation landscape more attractive will require strategic actions from policymakers and industry :

a. **Create a single, clear and accountable structure building on existing regulatory infrastructure and, empowering existing actors :**

   This new structure should be specific to MedTech to provide oversight and ensure the goals of the present regulatory framework are fully met in line with the specificities of the MedTech business.

   Objective should be to connect existing and future regulations and, to provide clear guidance on compliance requirements.

b. **Establish a unified digital health and single health data market, harmonizing EU countries' approaches to digital health technologies :**

   This includes development of agile regulation for software changes, harmonized access pathways and European-level reimbursement framework for digital health solutions, and harmonized application of GDPR requirements for health data.

c. **Base environmental regulations on industry capabilities and scientific progress, and incentivise compliance, innovation, and environmental responsibility :**

   To promote sustainable practices in the MedTech industry, policymakers should consider a risk-based approach to chemical management and engage in dialogue with the chemicals industry to find suitable alternatives. Future legislation should also align with sector-specific regulations and improve sustainability throughout the life cycle of medical technologies.

d. **Promote and standardise value-based procurement (VBP) through tendering frameworks and value-based pricing :**

   To support the development of a common definition of value and to review tender frameworks to balance quality, patient outcomes and value with pricing considerations. This to limit 'price-only' awarding of public tenders while also encouraging collaboration between the MedTech industry and healthcare providers to develop and implement value-based care models to foster innovation and incentivise companies to bring their innovative products to Europe.

e. **Make MedTech reimbursement systems more harmonized and predictable by sharing best practices / criteria across EU Member States and utilising potential of real-world data :**

   The European Union should support a more unified system for funding and reimbursement standards for medical technologies across its Member States with a European-level reimbursement framework that sets out common standards and clinical evidence requirements for reimbursement while accommodating regional differences.

f. **Attract and retain the right MedTech talent and solve for future talent shortages :**

   To increase the retention of healthcare professionals, it is important to ensure labor market demand and sufficient compensation to motivate qualified individuals to choose these professions. Direct measures in the areas of respect and recognition, training and education, leadership and management, well-being and resilience, and connection and integration are recommended.

g. **EU and Member States can simplify and streamline the administrative procedures associated with availing state incentives :**

   To improve the efficiency of the incentive application process, bureaucratic hurdles and paperwork should be reduced, and user-friendly online/digital platforms should be implemented. Clear and reasonable timelines for approval and disbursement of incentives should be set, and dedicated support teams or units should be established to assist companies throughout the process.

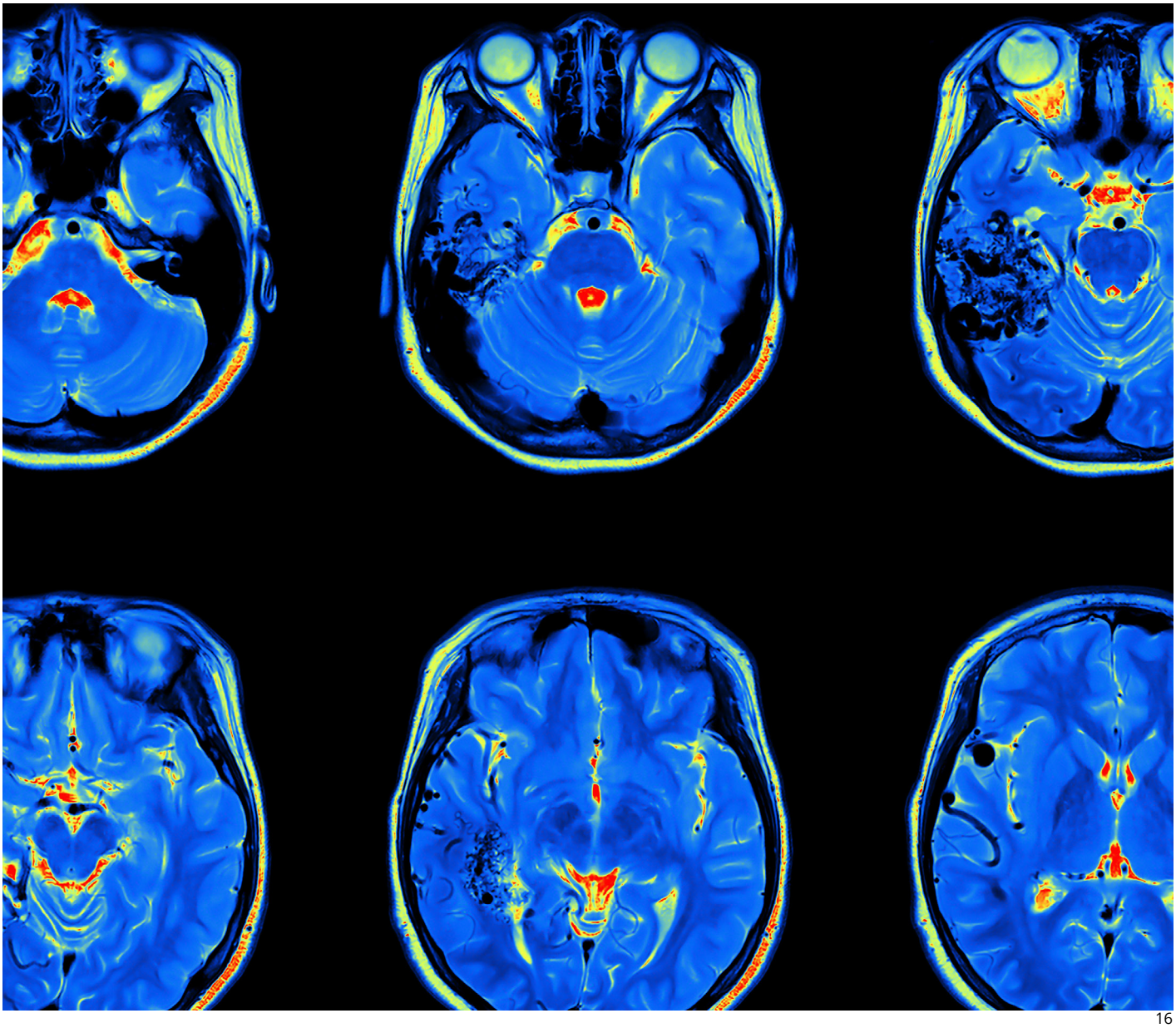
6. Conclusion

Europe’s overall attractiveness

The research done demonstrates that Europe remains an attractive market for MedTech innovation, both for developing, manufacturing and launching products. Driven by high-tech hubs, strong talent pools, local and EU support, in combination with progressive healthcare systems that prove to be attractive markets.

In order to respond to new evolutions that will transform the health care landscape, Europe will need to continue its support for the industry, to invest in even more talent (e.g., digital & data), to align its regulatory and legal frameworks and to invest in a more harmonized market, from a health data, value-based healthcare and market access perspective.

More collaboration between industry and government actors will be needed, along with supporting smaller companies in navigating Europe as a place for innovation.



7. Annexes

Zoom-in 1: Europe's innovative research ecosystem

1.1 What makes Europe attractive?

Incentives, education, talent

Europe presents a clear opportunity for investments in R&D because of favourable R&D incentives in multiple Member States, its well-developed research ecosystem, and a working environment that attracts and nurtures world-class talent.

In general, Europe places a high value on R&D. This takes the form of a wide variety of attractive tax incentives and public funding schemes for R&D. The list includes tax benefits, cash grants, loans and patent boxes. Compared to the US, moreover, Europe imposes fewer post-award monitoring and reporting requirements. And with less competition for grants in Europe than in the US, companies have more success in obtaining them. All of these factors together 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.

It gets better. Europe boasts several collaborative innovation networks and hubs, involving universities, established companies and start-ups. Generating high levels of patent and publication activity, examples of these well-funded MedTech hubs include Medicon Valley, spanning eastern Denmark and southern Sweden; Clust-ER Health in Emilia-Romagna, Italy; and Germany's Mannheim Medical Technology Cluster. This helps explain why 42% of MedTech patents filed with the European Patent Office were by European companies, compared with 37% from US companies, and how Europe's 2,000 MedTech start-ups surpass the number in China. This favourable innovative ecosystem combining academia, business, and local government gives MedTech companies access to research ideas and R&D infrastructure – not to mention world-class talent.

European universities consistently rank among the best in the world for life sciences education and research. It's no mystery. Europe spends a greater percentage of its GDP on education than China or Japan. European countries, among them Spain and the UK, lead the Organisation for Economic Co-operation and Development (OECD) average in tertiary graduation rate. National education systems are bolstered by EU-level initiatives. One such is the European Strategy for Universities, established to strengthen higher education and research, empower universities for green and digital transitions, and reinforce universities for global leadership.

This educational report card should get even better as Europe works through its extensive to-do list. Items include automatic recognition of academic qualifications; improving quality assurance; tracking graduate outcomes; developing curricula for science, technology, engineering & mathematics (STEM) and information & communications technology (ICT); fostering research and innovation through the European Institute of Innovation and Technology (EIT); and enhancing support for green and digital skills.

However, it's not enough to develop skilled talent. Talent retention is also critical which in Europe this is made easier through favourable labour laws and EU initiatives like the European Skills Agenda, as well as changes in immigration laws and administration (e.g., single permit) in Member States for highly skilled workers. Add to this Europe's auspicious working conditions: greater job security, higher benefits, better social protection and more work flexibility. It's therefore no surprise that European workers spend on average 10.1 years with one employer, compared to just 4.1 in the US and 3.3 in Australia.

1.2 What challenges do MedTech companies face in Europe?

Risk aversion, bureaucracy, skills shortages

Although Europe's MedTech innovation landscape outperforms those of other countries in many respects, it does have weaknesses.

The three most serious are a risk-averse culture, a burdensome bureaucracy, and MedTech-specific skills shortages.

A weak point in Europe's MedTech innovation landscape is the lack of high-risk investment funding and support for product commercialisation. This is due to the risk-averse nature of European investors. In 2021, $2.1 billion in MedTech venture capital (VC) funds was raised in Europe versus $4.5 billion in APAC and $6.7 billion in the Americas. This discrepancy partly explains the lower numbers of MedTech start-ups in Europe (half in 2022) than in the US. One innovation expert and entrepreneur describes it this way: "European investors are risk-averse and look for guaranteed returns. While funding is available for research and development, it is a challenge to get public or private funding to bring higher risk products to market."

The resulting VC funding and M&A gap compared to other regions hampers scale-up for MedTech start-ups. This in turn impedes their transition to commercialisation and reduces local M&A appeal, while increasing potential acquisition interest from foreign organisations.

Another roadblock? The cumbersome administrative processes that make it difficult to benefit from state incentives and that hold up decision-making. While some companies persist, others give up, as the R&D head at another company complains, "We spent nearly 18 months trying to get funding for one of our projects. Ultimately, we went to the US for funding. There is a greater willingness to be efficient there."

Although Europe spends a greater percentage of its GDP on education than China and Japan, it lags behind the US. This makes it harder to cope with the global shortage of skills required to support the next wave of MedTech advancement. Already in 2021, more than 60% of EU businesses faced shortages of digital and ICT skills. Similar obstacles are seen in the US, where 65-80% of firms struggle to hire AI talent, and in APAC, where 60-80% of organisations find it difficult or extremely difficult to fill vacancies in many IT roles.

Meanwhile, Europe has a looming retirement problem: in 13 out of 44 European countries, 40% of doctors are aged 55 or older. This is similar to the US, which faces a physician shortage too.

Tackling the talent scarcity could present an opportunity for Europe to differentiate itself from its global competitors.

1.3 How is Europe addressing these challenges?

Encouraging entrepreneurship, widening the talent pool

To help the region's MedTech sector reach its full potential, Europe wants to ease the path from development to commercialisation by trying to close the funding gap. It's also implementing strategies to create a differentiated MedTech talent pool.

To address current VC funding gaps, the European Investment Bank Group and five EU Member States have announced the European Tech Champions Initiative: a €3.75 billion fund to support late-stage growth companies in the region. In addition, the UK has allocated funds to bolster scientific and technological capabilities, while Germany is providing aid to growth-stage tech firms.

The EU is tackling the global skills shortage in three main areas that will impact the MedTech sector. One is up-skilling and re-skilling. A key initiative, the Pact for Skills, helps public and private organisations prepare their talent for the green and digital transitions. It includes a partnership with the health ecosystem to build skills across Europe's complex health network.

To ease internal movement of talent, the European Commission has called on Member States to facilitate social security procedures. Actions include:

- National implementation of the Electronic Exchange of Social Security Information platform
- Establishing a single digital gateway, expected to boost cross-border activity and save companies more than €11 billion per year
- A European Social Security Pass to simplify cross-border social security
- EU Digital Identity wallets for easy verification by social security institutions

And to attract and retain skilled foreign talent, Member States are relaxing immigration rules. For example, Finland is implementing a fast-track procedure for highly skilled workers and start-up entrepreneurs and their families. Denmark has implemented selective immigration preferences for highly educated or skilled foreign workers. And in Spain, international students will be able to work upon graduation.

Zoom-in 2: Europe's political, legislative and regulatory landscape

2.1 What makes Europe attractive?

Predictability, legislative power, access to markets

Despite regulatory processes becoming increasingly complex, companies that continue to invest in Europe can enjoy economic predictability, while reaping the benefits of unlocking multiple markets with a single regulatory process.

A voluntary political union made up of 27 diverse countries can only be viable if it is founded on two principles. One is political stability, as seen in a 2021 global political stability index that places 22 European countries in the top 50. The other is a common consensus-driven culture. This dual foundation 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.

Europe also stands out in another way that impacts business in a positive way: it leads the rest of the world in legislative innovation. Europe is the trailblazer in legislating on sustainability, data usage, AI, and other key fields, providing companies with opportunities to innovate in these areas.

Because of the size and importance of the European market, EU regulations set the agenda for global companies. Take the EU's General Data Protection Regulation (GDPR) implemented in 2018. Adhered to by more and more companies, it has influenced countries around the world to consider and implement privacy legislation. The EU's Green Deal (2020) and Artificial Intelligence Act (approved in December 2023) will similarly influence other regions to either sign up or create their own versions.

In this way, Europe acts like a springboard, opening up multiple markets through a single regulatory process. The CE mark is a good example. It has unlocked approximately 30 markets and facilitated access to 100 more around the world, including emerging markets.

Although the new EU Medical Device Regulation (MDR) and In Vitro Diagnostic Device Regulation (IVDR) have raised barriers to entry, the benefits of playing in the European market are enormous given its size and strategic importance.

2.2 What challenges do MedTech companies face in Europe?

Over-regulation, weakened IP protection

Europe's risk-averse policies can lead to too much regulation. And new rules could make it harder to protect trade secrets. These worries may cause MedTechs to seek other regions with more innovation-friendly and agile approaches to regulation.

Stringent protocols, like the Medical Device Regulation (MDR) and In Vitro Diagnostic Device Regulation (IVDR), as well as other horizontal regulations can be perceived by the business community as excessively burdensome. Add to this overlapping, still evolving rules that could increase confusion due to a lack of harmonisation and connection. The resulting complexity and unpredictability could drive MedTech firms to regions with fewer regulatory constraints on their activities and more clarity about their application.

Compared to the US, IP protection in the EU is weaker. That's because European provisions regarding regulatory exclusivity do not extend to medical devices. Thus, the only way for a medtech company to protect its products in Europe is by relying on the patent system and keeping its know-how confidential. Eastern Europe also suffers from inconsistent implementation of IP protection laws however, this may improve with the introduction of the unitary patent.

2.3 How is Europe addressing these challenges?

Patenting improvements

Registering a single patent separately in each country of operation can be daunting and expensive. Recognising this, in 2023 the EU introduced the Unitary Patent to make the task easier, quicker, and cheaper. This sweeping optimisation measure brings clear benefits. But as the saying goes, the devil is in the details.

The European Patent with unitary effect (also known as the Unitary Patent) is based on the European patent granted by the EPO under the rules of the European Patent Convention (EPC). Thus nothing has changed within the pre-grant phase. But now, after a European patent is granted, the patent owner can request one with unitary effect.

The Unitary Patent allows simultaneous patent registration in 17 participating Member States: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia, and Sweden. It is expected that more will ratify the agreement, eventually establishing unitary patent protection in up to 25 Member States by submitting a single request to the EPO.

Zoom-in 3: Europe's efficient health care systems and push for value-based health care

3.1 What makes Europe attractive?

Universal coverage, world-leading healthcare, innovative payment schemes, value-based procurement

Along with universal coverage, Europe boasts healthcare systems that outperform other regions on quality, affordability, and access. It also offers schemes that speed patient access to innovative medical procedures and technologies. Moreover, Europe leads in value-based procurement. All of this means greater market opportunities for MedTechs.

European healthcare systems outperform those in other regions. And it's not simply a question of money. The US spends far more of its GDP on healthcare than European countries: 14.1% compared to 10.9% in Germany, Europe's highest health spender.

There are four principal pillars supporting Europe's healthcare success. One consists of universal coverage and lower cost barriers. Everyone can get the care they need, how and when they need it. Another pillar is well-functioning primary care systems. These ensure that high-value services are equitably and locally available in all communities to all people, reducing the risk of discrimination and unequal treatment. A third is low administrative burdens on patients and clinicians. These would otherwise cost time and effort that could discourage access to care, especially for marginalised groups. Fourth, Europe's social services increase equitable access to nutrition, education, childcare, community safety, housing, transportation, and worker benefits – all leading to a healthier population and fewer avoidable demands on health care.

Europe's universal coverage and reduced cost barriers offer MedTech companies larger market opportunities and increased demand for preventive technologies. In addition, a focus on community-based care and health equity promotes collaboration between MedTech companies and healthcare providers to develop solutions tailored to specific community needs.

National health systems in Europe tend to be very receptive to new technologies that improve outcomes and lower costs. Many offer initiatives like the innovative payment schemes (IPS) to support critical medical technologies not typically reimbursed through traditional payer pathways. A MedTech Europe study conducted from July to October 2022 identified a large number of such initiatives across Europe. In eight countries (Austria, Belgium, England, France, Germany, the Netherlands, Spain, and Switzerland) the study identified 21 IPS programmes covering procedures, devices, IVDs, and digital health solutions. It also found 33 related initiatives across 17 countries that focused on transforming healthcare systems and/or reimbursement and funding systems.

Accelerating patient access to MedTech

The MedTech Funding Mandate is a commitment by the UK's National Health Service to make innovative medicines, treatments, and procedures available to patients more quickly. All the devices, diagnostics and digital products must be approved by the National Institute for Health and Care Excellence (NICE). Assessments by NICE must show that the products are effective and improve patient outcomes and are cost-saving within three years.

In Germany, the Federal Joint Committee or G-BA (Gemeinsamer Bundesausschuss) is the highest decision-making body of physicians, dentists, hospitals, and health insurance funds. Based on available studies and patient populations, the G-BA assesses new diagnostic and treatment methods, known as NUB (Neue Untersu-chungs- und Behandlungsmethode), according to benefit and need. The NUB process allows hospitals to negotiate individual reimbursements with health insurance companies for novel diagnostic and treatment methods that aren't covered by the standard costing system. In the past, a G-BA assessment took approximately three years. In 2020, the G-BA introduced new legislation that reduced this to two.

Directives within the EU's Public Procurement Framework strongly encourage public authorities to source high-value, high-quality products and services. One result is that Europe is leading other regions in value-based procurement (VBP). This shifts tender discussions away from the upfront purchase price and towards a holistic exploration of value. Greater adoption of VBP is helping companies, providers, and procurers build mutually beneficial partnerships.

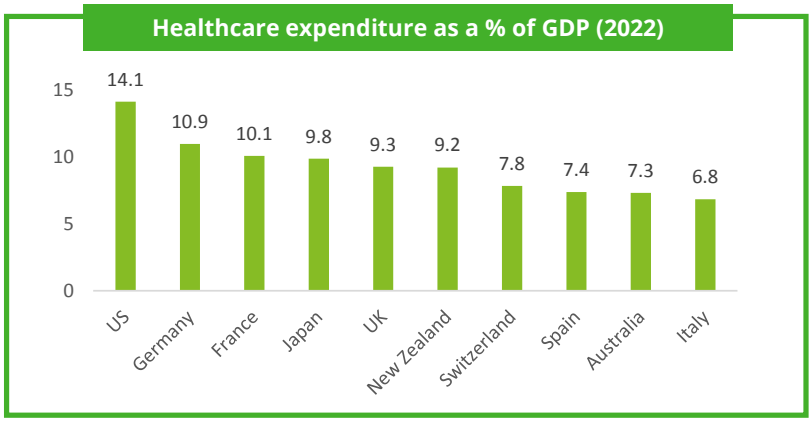
This is confirmed by a MedTech industry leader, who remarks, "While there is room for VBP to expand in Europe, no other market in the world has better VBP than Europe. We are ahead of the pack."

3.2 What challenges do MedTech companies face in Europe?

Underfunding, problematic reimbursement, slow VBP adoption, austerity

It's easy to paint a rosy picture of the European healthcare landscape. Yet this image is threatened by severe underfunding that is already impacting healthcare access and quality. Add to this difficult reimbursement pathways, slow implementation of value-based procurement, pricing pressures, and austerity schemes.

Perhaps surprisingly given Europe's high healthcare scores, its systems are underfunded compared to other regions (especially the US). For example, France in 2022 had fewer doctors than in 2012, along with over six million people without a regular GP, including 600,000 with chronic illnesses. Fully 30% of the population had inadequate healthcare access. And 87% of the country was described as a 'medical desert'. In Germany, 35,000 care-sector posts were vacant in 2021. And more than 30% of health jobs could be unfilled by 2035. In Spain, over 700,000 people waited for surgery in 2022, despite 5,000 frontline GPs and paediatricians protesting for years about underfunding and overwork.



Although COVID-era spending clearly helped Europe healthcare systems respond effectively, this lesson may not have been fully learned. Starting in 2024, potential cuts in public spending might lead to longer wait times, reduced access to services, and a decline in the quality of care. All of this could diminish the attractiveness of launching new MedTech products.

Diving deeper, we see specific weaknesses that hamper innovation in Europe. These include slow, diverse, and complex reimbursement pathways; limited adoption of value-based procurement (VBP); heightened pricing pressures; and Member State austerity schemes.

Reimbursement Challenges

With widely different reimbursement pathways across 27 Member States (as well as regionally) it's no wonder there's a lack of standardised value assessment criteria. For example, only Germany, France, and Belgium have established reimbursement pathways for digital health solutions. Furthermore, reimbursement delays of 5-6 years on average can prevent smaller manufacturers from remaining in business. And only 8 out of 32 countries offer innovative payment schemes to cover critical new technologies not reimbursed via traditional payer pathways.

Low Value Based Procurement (VBP) adoption

Despite pressure from the EU Public Procurement directive, EU-wide adoption of VBP among providers and procurement bodies is low. This lack of focus on value together with tough pricing pressures prevents companies from demanding higher prices for new or innovative products. Moreover, value means different things to different stakeholders: the lack of a common definition can negatively impact MedTech products. Similarly, poorly defined 'green criteria', which vary between Member States, make compliance challenging for MedTechs. Finally, many Member States allow price-only tendering frameworks, driving down prices.

Austerity schemes

Member State initiatives to contain healthcare costs, e.g., payback systems, pose legal, financial, and operational burdens on MedTech companies. This threatens the long-term competitiveness and attractiveness of the European market. Expanding these austerity measures to more Member States could stifle innovation and erode patient access to critical MedTech.

Accelerating reimbursement processes and moving away from a sole emphasis on price-based tendering and restrictive cost-control measures are essential steps to foster innovation and improve return on investment for MedTech companies.

3.3 How is Europe addressing these challenges?

Big funding commitment, harder push for VBP

Responding to the tumult of the COVID-era, the EU has committed a huge investment to make public health a priority. Also, convinced that value-based procurement is the way ahead, Europe will continue pushing for EU-wide adoption.

The pandemic highlighted the fragility of national health systems. In response, the EU4Health programme was adopted to reinforce crisis preparedness. The €5.3 billion budget sends a clear message that public health is a priority for the EU, and lays the groundwork for a European Health Union. Specifically, EU4Health has four objectives, each containing several elements.

The first is to promote health and prevent disease in the EU (with a focus on cancer), together with engaging in global health efforts and collaborations. Next is preventing, preparing for, and responding to cross-border health threats, backed by national reserves of critical crisis-related supplies and a pool of medical and support personnel. The third focuses on essential health products. It will facilitate accessibility, availability, and affordability of medicinal items, medical devices, and crisis-related products. The fourth objective is designed to strengthen EU healthcare systems. It will bolster health data, digital tools, and services to advance the evolution of digital healthcare. It also aims to improve healthcare accessibility; develop and apply evidence-based EU health laws; and support collaboration among national health systems.

A second response to challenges facing the European ecosystem is to double down on promoting value-based procurement. As mentioned previously, some countries have been eager adopters. Following the EU Directive on Public Procurement in 2014, the UK, the Netherlands, Sweden, Denmark, Finland, and Norway began using VBP as a key underlying principle in their MedTech procurement. Today they are reaping substantial benefits.

Despite these good examples, currently EU-wide adoption by providers and procurers is low. A majority of Member States still allow price-only decisions, and don't focus on the value of the technology. But it should be mentioned again that Europe is ahead of other regions in embracing VBP.

In the US, for instance, VBP supporters are grappling with a side effect of the Anti-Kickback Statute and Stark Law. Coming fully into effect in 2022, the federal legislation is designed to ensure that medical services and recommendations remain as free from financial influence as possible, for example by prohibiting physician self-referral. But the rules discourage health systems from pursuing value-based care. Although recent changes introduced safe harbours for value-based arrangements and outcome-based payments, compliance could be a burden for health systems and hospitals.

VBP put into practice

In the UK, National Health Service Wales systematically applies VBP to large central tenders for an increasing number of products and services from NHS suppliers that are selected based on their ability to reduce costs and improve outcomes that matter to patients. And in the Netherlands, in tandem with a wider government initiative to shift toward outcome-based health care, the Dutch health care supply chain is advancing value-based contracting as a central concept throughout its operations. Meanwhile, Ireland is moving in the right direction It has published a new national framework agreement for procuring medical technology that encourages procurers to put up to 80% of awarding weight on outcomes and benefits to care providers.

Zoom-in: Recommendations

The Medtech industry is not standalone and operates in a fast evolving ecosystem with increasing importance of technology, data, sustainability, changing demographics etc. Therefore the industry needs to get organized to adapt to changing environment and support larger and smaller companies in doing so.

Compared to other regions, Europe is and will always be a great environment to develop, manufacture and launch products. This because of the highly skilled talent and R&D hubs, the strong healthcare ecosystem and business predictability and attractive fiscal incentives it can offer.

Off course, there is always room for improvement in other areas such as better alignment between regulations and legal frameworks, simplifying administrative processes, facilitating access to funding and talent. But those improvement areas should not be seen as blocking factors but rather opportunities for EU and industry to work hand in hand to foster and support the innovative environment Europe is.

Making the European MedTech innovation landscape more attractive will require strategic actions from policymakers and industry

For policy markers and industry

1. **Create a single, clear and accountable structure building on existing regulatory infrastructure, empowering existing actors.**

   This new structure should be specific to MedTech to provide oversight and ensure the goals of the present regulatory framework are met in full in line with the specificities of the MedTech business.

   Objective should be to connect existing and future regulations, to provide clear guidance on compliance requirements, and introduce mechanisms for dialogue with Notified. Development of fast-track pathways and funding programs can expedite approval for innovative medical devices, while regulatory sandboxes allow for iterative testing and improvements. In addition, considering reliance on approvals from third countries can speed up market access. A comprehensive approach to litigation, balanced IP approaches, and involving industry representatives in policymaking are also crucial for an innovation-friendly and fair market.

2. **Establish a unified digital health and single health data market, harmonising EU countries' approaches to digital health technologies**

   This includes development of agile regulation for software changes, harmonized access pathways and European-level reimbursement framework for digital health solutions, and harmonized application of GDPR requirements for health data. Recognition of the unique nature and varied uses of personal health data is also important to ensure its utility and cross-border sharing.

3. Base environmental regulations on industry capabilities and scientific progress, and incentivise compliance, innovation, and environmental responsibility

To promote sustainable practices in the MedTech industry, policymakers should consider a risk-based approach to chemical management and engage in dialogue with the chemicals industry to find suitable alternatives. Incentives can be developed for MedTech companies that adopt eco-friendly practices and develop sustainable alternatives. Future legislation should align with sector-specific regulations and improve sustainability throughout the life cycle of medical technologies. In addition, transition periods should be provided when banning certain chemicals to prevent disruptions in the supply chain. Development of harmonized European Green Public Procurement criteria and standardized sustainability criteria can further drive sustainability in the industry.

Role of Industry

- Set up a joint action plan to create EU-MedTech industry funded projects that involve R&D initiatives to find alternative chemicals and materials that are more environmentally friendly and safe for use in the MedTech industry. This may also involve collaborations with academic institutions, or setting up of research hubs
- In addition, conduct assessment on the impact of environmental regulations, including chemical bans, on the MedTech industry - especially in the diagnostics and assays space. Develop business case or comprehensive document to show the impact of these regulations on the MedTech industry, outlining suitable transition periods and how to address instances where suitable alternatives are missing

4. Promote and standardise value-based procurement (VBP) through tendering frameworks and value-based pricing

Support the development of common definition of value and review tender frameworks to balance quality, patient outcomes and value with pricing considerations. This to limit 'price-only' awarding of public tenders. In addition, allowing national evaluation bodies to recognise and use international studies and literature will avoid the replication of medical-economic studies in each EU country. Also encouraging collaboration between the MedTech industry and healthcare providers to develop and implement value-based care models will foster innovation and incentivise companies to bring their innovative products to Europe.

Role of Industry

- Showcase successful implementations of value-based arrangements within your healthcare system to encourage adoption in other regions, including indicators such as, cost-savings and effectiveness gains due to workflow optimisation achieved by the healthcare system, improvements in patient access and outcomes
- Increase adoption of VBP framework by 1) identifying key products / solutions that are most conducive to a VBP approach, and 2) developing value propositions that align with the VBP framework

5. Make MedTech reimbursement systems more harmonised and predictable by sharing best practices / criteria across EU Member States and utilising the potential of real-world data

The European Union should create a unified system for funding and reimbursement standards for medical technologies across its member states. This system should consider the specific nuances of MedTech and provide incentives for innovation across all care settings. A European-level reimbursement framework should be created that sets out common standards and clinical evidence requirements for reimbursement while accommodating regional differences. Member states should align their clinical evidence requirements with these guidelines, and reimbursement decisions should be made in a timely manner. Provisional access for medical technologies should be permitted, generating RWE to support clinical and health economic assessments and accelerate patient access to innovative technologies.

Role of Industry

- Conduct assessment to quantify reimbursement wait times for different product categories (new / innovative and existing category) and build a case for quicker reimbursements

6. Explore alternatives to Member State-level austerity schemes and focus on a balanced value-based healthcare approach that does not hinder innovation

To address Member States' healthcare budget challenges, it is important to work with the MedTech industry to find alternative solutions that do not hinder investment, innovation, and patient access to medical technologies. One solution is to encourage Member States to balance their budget for MedTech innovation with the budget for MedTech commodity products. Additionally, it is important to encourage the creation of predictable and accountable financial systems specific to the MedTech sector, which is largely composed of SMEs or distributors. This will help ensure that the MedTech industry can continue to innovate and provide patients with access to the latest medical technologies, while also supporting the financial stability of Member States.

Role of Industry

- Set up taskforce to assess the impact of payback systems on the industry – e.g., the financial, legal, operational burden associated with the payback schemes, as well as the downstream impact on patient access

7. Attract and retain the right MedTech talent and solve for future talent shortages

To increase the retention of healthcare professionals, it is important to ensure labour market demand and sufficient compensation to motivate qualified individuals to choose these professions. Direct measures in the areas of respect and recognition, training and education, leadership and management, well-being and resilience, and connection and integration are recommended. The EU can encourage Member States to support the MedTech sector with customised technologies, digital solutions, robotisation and automation. A targeted labour migration policy can help alleviate labour shortages in the MedTech sector, and enhancing the match between skills needed and skills available through vocational training for job seekers can mitigate labour and skill shortages.

Role of Industry

- The MedTech industry is best positioned to identify specific areas with skills gaps and create relevant vocational trainings or collaborate with universities to offer targeted educational programs, with a commitment to hire graduates. MedTech companies should also be more open to new MedTech graduates or ex-MedTech graduates wanting to transfer back from other industries, even if it means more initial training, given the niche skill set required by the industry
- At EU level, regulations and policy initiatives have been introduced to create favorable working conditions – including measures to prevent abusive practices in the use of on-demand and similar employment contracts, adequacy of minimum wages and strengthening collective bargaining, so as to ensure fair wages and a decent standard of living for workers. To retain talent in Europe, the MedTech industry needs to recognise the increasing demand for life outside of work and work with 'purpose'. Introducing a faster recruitment process, a hybrid work model, and establishing ecosystems where offices are close to universities, startups, similar companies (Silicon Valley model) can help attract and retain the right talent

8. EU and Member States can simplify and streamline the administrative procedures associated with availing state incentives

To improve the efficiency of the incentive application process, bureaucratic hurdles and paperwork should be reduced, and user-friendly online/digital platforms should be implemented. Clear and reasonable timelines for approval and disbursement of incentives should be set, and dedicated support teams or units should be established to assist companies throughout the process. The incentive landscape should be connected and larger incentives promoted. The EU can also promote investment opportunities and grants to support MedTech R&D and manufacturing related to digitisation, automation, and sustainability

Role of Industry

- Conduct assessments to estimate the time taken to avail State Aid, EU-level incentives, etc. to build a detailed case study for EU to reduce the associated administrative complexities

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