friends of europe

EVENT REPORT

Health check for a competitive medical technology sector in Europe

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Co-funded by the European Union

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Introduction

Against the backdrop of ongoing discussions on Europe's regulatory and innovation landscape, policymakers, industry leaders and healthcare professionals gathered at a recent dinner roundtable, organised by Friends of Europe, to assess the state of the European medical technology sector. The lively debate underscored the need for a streamlined, innovation-friendly approach to this critical sector while keeping patient safety at the core. Issues discussed included reducing bottlenecks at notified bodies, aligning regulations with latest international standards and establishing a fast-track approval mechanism for breakthrough medical technologies.

During the event, several suggestions emerged on the way forward:

- The new European Life Sciences strategy should balance competitiveness ambitions with public health and societal goals.
- Streamline medical devices regulation by reducing complexity, red tape and approval times, while ensuring patient safety.
- Enhance innovation pathways with fast-track approvals for groundbreaking medical devices, particularly in high-need areas like neurology and paediatric cardiology.
- Strengthen stakeholder engagement with regulators at early stages with greater dialogue between clinicians, patients, industry and notified bodies.
- Boost funding and cooperation to support research, innovation and harmonisation across member states, preventing regulatory fragmentation and maintaining global competitiveness.

The Life Sciences Strategy and the Medical Device Regulation

The upcoming EU Life Sciences Strategy is an opportunity to reset the approach to regulation of medical devices. Over the past decade, Europe has lost its position as the premier environment for medical devices to be launched. An overly risk-averse mindset, undefined and long timeframes for approval and chokepoints at national notified bodies have all affected the attractiveness of the EU. The review of the medical device regulation, announced by the incoming Health Commissioner, is an important opportunity to redress this balance and focus on making sure legislation can be implemented effectively.

Industry representatives emphasised concerns about the current Medical Device Regulation (MDR) being overly complex, slow and creating significant delays in device approvals. One participant shared: “We have examples where we get approval in the US [in] 90 days, and [it takes] more than a year or two years in Europe, making the cost five times higher”.

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Furthermore, Europe’s approach to standardisation is lacking. Medical innovation is a fast-moving process with key advances in miniaturisation and digital integration happening quickly. Europe’s standardisation process is slow – often up to a decade behind the leading edge of technology. For device manufacturers, launching a product in other markets with up-to-date standards is more attractive than trying to make things backwardly compatible with EU standards. Participants urged greater cooperation with other standard setting bodies around the world, with mutual recognition allowing manufacturers to produce for Europe and other regions.

Notified bodies and patient involvement in regulation

Although there has been some improvement in the number of notified bodies at national level, participants flagged this as an ongoing challenge. There needs to be significant investment in the capacity and efficiency of notified bodies, with less inconsistency in interpretation.

There is significant variation in regulations across EU member states. Some larger countries, like Germany, have well-established procedures and an established industrial cluster (Germany alone has 40 medical device manufacturers, many of them SMEs), while smaller member states have fewer manufacturers and therefore limited regulatory capacity. The issues at stake are different for these countries, making the process of negotiation and compromise on EU regulation particularly challenging.

Many participants called for better engagement: clinicians and patients want to bring the perspective of the front line of care, researchers and innovators want dialogue with regulators at an early stage of development.

Specific cultural factors can influence the adoption of new technologies, where local attitudes and healthcare practices can determine whether innovative devices gain traction. Patients look for innovations that improve quality of life, such as self-care tools, remote monitoring and diagnostics that support a shift from hospital-based to community care.

Challenges in medical device regulations and innovation

Medical devices cover a vast diversity of products, from small, implanted devices like heart stents and pacemakers to temporary-use devices such as catheters, while also including large equipment used in diagnostics, surgery and treatment, such as MRI and ultrasound machines.

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For this reason, many stakeholders joining the dinner strongly voiced concerns that the current regulatory framework is not fit for purpose, in terms of complexity and bureaucracy, directly impacting patients, with cases of devices being withdrawn from the market, such as critical devices for paediatric heart patients.

All participants agreed that innovation should improve the way healthcare is delivered and create better outcomes for patients while remaining both affordable and accessible. These priorities should shape public policy, rather than being driven solely by competitiveness or commercial considerations. As one expert emphasised, “health systems need to reflect societal objectives, and achieve overarching societal goals. (...) How do the innovations serve the goal of efficiently delivered quality care at an affordable price?”

Despite these challenges, Europe continues to produce groundbreaking medical innovations, particularly within university hospitals. However, many of these innovations fail to be commercialised in the EU, with researchers often relocating to the US, where financing and risk-taking attitudes are more favourable to emerging companies. This represents a significant loss for Europe, as much of the initial medical research is often publicly funded, yet the financial and scientific return of investments end up benefitting other regions. .

Regulatory variability and the need for streamlined processes

The regulatory challenge is easily understood by the fact that there are 80,000 medical devices that need to be recertified every five years. Amid this heavy ongoing workload, a fast-track approval process for genuine breakthrough innovations is urgently needed. This could be similar to current mechanisms already being used for pharmaceuticals (PRIME), with additional specific pathways for ‘orphan devices’, which address rare medical conditions. The EU Health Technology Assessment (HTA) regulation came into force in January 2025 but required many delegated acts by the European Commission, some of which were only adopted at the end of 2024. This has exacerbated implementation challenges at the member state level. A similar risk exists for the revision of the Medical Devices Regulation.

Comparing the European system to the to the US FDA in the US, one participant noted: “The FDA allows companies to consult at an early stage of development, which is a major advantage. In contrast, the notified bodies in Europe are not allowed to provide consultancy or even explain the reasons behind their decisions.”

On patient’s safety, the stakeholders noted that previous regulations have not prevented scandals, such as breast implants and gynaecological mesh, with large numbers of patients being harmed.

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As medical devices increasingly integrate with software and digital products, the stakeholders urged the co-legislators to ensure the coherence across different legislative frameworks, such as: EHDS, GDPR, the Digital Act, REACH, etc. Similarly, participants pleaded for increased financial allocation in the next Multiannual Financial Framework (MFF) to support initiatives like the Innovative Health Initiative and medical research funds.

Looking ahead

Europe has the potential to regain its global leadership role in medical technology, but regulatory inefficiencies and bureaucratic complexities threaten its competitiveness. Addressing these challenges requires urgent reforms, including streamlined approval pathways, enhanced coordination among member states, and increased investment in innovation. By aligning regulations with real-world needs and fostering an environment conducive to breakthrough technologies, Europe can ensure patient safety while supporting a thriving medical technology sector that benefits both society and the economy.

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