

# With health at its heart, Long Live Europe

# MedTech Europe's reaction to the President of the European Commission's State of the Union Address

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Europe's strength, resilience, and competitiveness depend on one thing above all: the health of its people. MedTech Europe welcomes the European Commission's emphasis on competitiveness and simplification outlined in today's State of the Union Address speech, but stresses that Europe must remain a leader in healthcare. Health and competitiveness are not separate goals: they must be advanced together. The medical technology sector calls for a fit-for-purpose regulatory and policy framework that turns Europe's world-class health innovation into timely patient access to drive productivity, resilience and sustainable growth.

Oliver Bisazza, CEO of MedTech Europe, commented: "Health resilience is the foundation of Europe's prosperity. Europe should remain the best place to develop, manufacture, and launch medical technologies. The medical technology industry in Europe welcomes and supports the Commission's push for greater competitiveness and simplification. However, real progress will be measured by whether patients see faster access to life-saving innovations. After all, where there is no health, there is no wealth."

#### 1. No health, no wealth

MedTech Europe regrets that health is not fully recognised as a core enabler of Europe's resilience, competitiveness and social cohesion. Europe must keep health at the forefront of its political agenda and ensure all patients have timely access to medical technologies. Building resilient and sustainable health systems that embrace digitalisation must remain central to the delivery of better outcomes and efficiency.

Structural improvements to the In Vitro Diagnostics and Medical Devices Regulations (IVDR/MDR), coherent alignment across digital and environmental rules, and a Single Market that works for healthcare: these reforms are not ends in themselves. They keep innovation in Europe and get safe, effective technologies to patients faster.

The announced new Global Health Resilience initiative is a welcome step forward, provided it builds on strong stakeholder engagement and collaboration with existing health platforms.

### 2. Simplification and competitiveness

MedTech Europe welcomes the Commission's focus on simplification and urges full use of the omnibus efforts across regulatory, digital and environmental fronts to turn innovation into timely access and stronger competitiveness. Delivering IVDR/MDR fixes that cut administrative burden, aligning Artificial intelligence (AI), Network & Information Security Directive II (NIS2), Data Act and European Health Dataspace (EHDS) coherently, and shaping Green Deal measures to support resilience and access: this is how Europe will ensure a health-centred Single Market that speeds safe adoption and backs small and medium-sized enterprises.



#### 3. A Single Market that works for health

MedTech Europe supports the Commission's strategic objective of strengthening Europe's industrial and healthcare resilience and echoes the President of the Commission: "Our greatest asset is the Single Market – but it remains unfinished."

One step forward will be the inclusion of the fifth freedom for knowledge and innovation in the upcoming Single Market Roadmap. However, given the complexity of medical technologies and their global supply chains, we would caution against pursuing resilience and competitiveness via protectionist policies such as, for instance, 'Buy Europe' criteria in the revision of the public procurement directive. Such policies could backfire and bring unintended adverse consequences for Europe, including its healthcare systems and its patients. For many years, the international rule-based system — based on minimisation of trade barriers, including non-discrimination in public procurement — has served Europe well as a key enabler for patient access to the many benefits of medical technologies. A Single Market that works for health therefore requires modernisation of Europe's approach to public procurement, i.e., by taking further steps towards the rewarding and financing of truly value-based outcomes and reductions in the total cost of care. 'Buy Europe' policies would distract from the need to stay focused on these very important steps, and could therefore serve as obstacles to the very resilience and sustainable investment goals towards which the Commission rightly aspires.

#### 4. Safeguarding access and supply chains

As sanctions and trade agreements progress, the EU needs to safeguard medical technologies to keep care uninterrupted and Europe's health security intact. To protect patient access and resilient value chains, appropriate exemptions for medical technologies and essential inputs should be secured in third-country tariff regimes, starting with the EU-US Trade Deal. Trade actions should avoid disrupting care pathways while supporting Europe's industrial capacity.

#### 5. Sustainability and environment

Holding a course on Europe's sustainability and environmental goals makes sense for the people, the planet, and the industry. A comprehensive enabling framework should unlock the potential of the EU's Clean Industrial Deal for medtech and the broader healthcare ecosystem. Global carbon pricing, next to boosting more renewable energies and energy efficiency, is key to combating climate change. It levels the playing field, rewards innovation and drives emission reductions cost-effectively. Upcoming initiatives, like the Climate Resilience Framework and the Circular Economy Act, should fully consider medtech specificities.

#### 6. Health and competitiveness in the next EU budget

The next EU budget should couple health and competitiveness by prioritising investment in the adoption of high-value medical technologies, interoperable digital and data infrastructure, so innovation translates into earlier diagnosis, better outcomes and efficiency. Delivery should be underpinned by public—private partnerships that bridge research to market, dedicated funding windows for breakthrough technologies, and alignment with the Life Sciences Strategy and Single Market reform to close the launch gap, reduce administrative burden and restore Europe's attractiveness for innovation.

MedTech Europe stands ready to work with the European Commission, Parliament and Member States to translate these priorities into concrete, patient-centred reforms.



# **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 that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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