MedTech Europe
from diagnosis to cure

Towards an EU Single Market Strategy:
Reinforcing the EU Single Market for Innovation, Health Resilience and Competitiveness

31 January 2025

Established in 1993, the EU Single Market is one of the greatest achievements of the European Union. It guarantees that goods, services, people and capital can move freely throughout the territory of the EU. It facilitates everyday life, stimulates growth and boosts innovation. It no less than lays the foundations for European integration, the social and economic welfare of EU citizens and a globally competitive industry.

After 30 years, the EU Single Market[1] represents 18% of the world's GDP. With more than 440 million consumers, it turned into the world's largest trading block and intra-EU free movement of goods grew by more than a factor of 5. With respect to medical technology[2], Europe is the second largest market in the world (26.1%) and had a positive medical technologies trade balance of €11 billion in 2023. The US, China, Japan and Mexico remain major trading partners. There are more than 2.000.000 medical technologies, categorized into more than 7,000 generic devices groups, available in hospitals, community care settings and at home to satisfy the many different patient and healthcare needs.

In Europe, an average of approximately 11% of gross domestic product (GDP) is spent on healthcare. Of this figure, around 7.9% is attributed to medical technologies, i.e. less than 1% of GDP. The spending on medical technology is estimated to vary significantly across European countries, ranging from around 5% to 12% of the total healthcare expenditure. Expenditure on medical technology per capita in Europe is at around €304.

However, Europe's biggest asset has arrived at a critical juncture: An increasingly complex and fragmented regulatory environment has made it a less attractive region for medical technology manufacturers to invest, innovate, manufacture, commercialise and scale up. In addition, Europe faces critical challenges, ranging from new geopolitical realities to climate change, workforce/skills shortages, increasing delays in patients' access to life saving and life sustaining technologies and supply chain complexities and continuous availability of medical technologies. A renewed Strategy for the Single Market represents **an opportunity to reinforce the Single Market for Innovation, Health Resilience and Competitiveness**, and thereby and opportunity to align it with strategic objectives and tap into its potential of being "Much More Than A Market"[3].

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[1] 30th anniversary of the EU single market - Consilium

[2] MedTech Europes-facts-figures-2024.pdf; MedTech Europe Facts & Figures 2023; International Trade Centre, 2025, International Trade Statistics – MedTech Europe calculations; In 2023 intra-EU MD trade turnover (volume of imports and exports) reached 112,6 billion Euros. Where the amount of exports reached 62,9 billion Euros, i.e. 55% of the volume. Between 2021 and 2023 both intra-EU MD trade turnover grew circa 7% on average. This rate is close to the one observed in turnover between EU27+United Kingdom +Switzerland+ Norway and extra-European partners in the same years. Top countries in terms of intra-EU MD trade turnover and exports are Netherlands (turnover - 26 billion EUR, exports – 17 billion EUR), Germany(turnover - 20 billion EUR, exports – 13,3 billion EUR), Belgium(turnover - 12 billion EUR, exports – 7,3 billion EUR), France(turnover – 9,4 billion EUR, exports – 4,6 billion EUR), Italy(turnover - 9 billion EUR, exports – 2,4 billion EUR), Ireland(turnover – 7 billion EUR, exports – 6,2 billion EUR).

[3] Enrico Letta - Much more than a market (April 2024)

MedTech Europe calls for recommitment to and strengthening of the EU Single Market. On the one hand, we observe increasing fragmentation in the internal market with respect to product requirements, divergences in the national transpositions of EU Directives, public procurement, remuneration practices or the capital market. On the other hand, the free movement of healthcare workers across national borders can help manage critical workforce shortages. Most importantly, however, patient access to medical technologies is increasingly under strain following, among other, overly complex regulation, "national blending" and insufficient coordination when implementing the sector's safety and performance, i.e., Regulations (EU) 2017/745 on Medical Devices and (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices. These Regulations are currently under evaluation for potential systems reform, precisely so that their Single Market-related goals can be met in practice. Insufficient synchronisation across policy domains, notably between these sectoral Regulations and other EU legislation (e.g., EU Green Deal legislation, and legislation on Digital Health, Health Data, Product Liability and so on) fuels further market fragmentation and consequently a weakening of the Single Market to the detriment of public health and a competitive medical technology industry alike.

The upcoming Strategy is an opportunity for implementing the EU's commitment to simplification[4], to reinforce collaboration among healthcare system actors, the EU and the private sector to bring the value and multiple benefits of medical technologies to patients and Europe's wider society, ranging from improving diagnosis, treatment, accessibility, and patient well-being, ultimately leading to a healthier and more efficient healthcare system and the wider economy. In short, no health, no wealth.

The strategy should address the following issues, which are critical for leveraging the medical technology sector's prospect in further growth and prosperity to the benefit of Europe, people and planetary health:

- Leveraging the Single Market for Health Resilience
- Supporting a Regulatory System Reform for Efficiency, Innovation and Governance
- Unlocking the Single Market for a successful Green Deal implementation in Healthcare
- Leveraging the potentials of the Single Market for the Digital Transition
- Introducing a 5th freedom for Research and Innovation
- Further strengthening the free movement of healthcare workers
- Further explore on the potentials of the Capital Markets Union to support strategic objectives
- Designing a Single Market that works beyond borders

We further elaborate on our general considerations on the Single Market, current challenges and MedTech Europe's recommendations for the upcoming Single Market Strategy in this paper:

1. General considerations on the Single Market: current challenges and recommendations

The European Single Market - continuing the success story: Integration of European markets and the resulting free movement of goods, services, capital, and people has been one of the foundations of post-war industrial success in the European Union. However, translating research into innovative products, taken up by European healthcare systems, is proving increasingly difficult. Already, Europe is falling behind

[4] EU Competitiveness Compass, 29 January 2025

internationally in some areas, such as Artificial Intelligence, with innovation now reaching European citizens later than in other regions like North America. This also reflects a lack of investment in supporting the development and deployment of medical and digital health technologies. Combined with barriers arising from the complexity and lack of capacity in the regulatory system as well as a fragmented market, this puts the competitiveness of European companies at significant risk.

Broad challenges in the single market include the following:

- **Divergences in the transposition of Directives** are common, as seen e.g. in the implementation of the WEEE or the NIS Directive. Where Regulations are adopted, they often still leave space for differing national interpretations or guidance that may create market access barriers – examples are the GDPR or Medical Devices Regulation.
- **Coherence between different pieces of legislation impacting one sector or product category** is lacking, ranging from merely duplicating to potentially conflicting requirements. An example is the need for a coherent implementation between the Artificial Intelligence Act and the Medical Devices Regulation or the increasing number of reporting requirements between different pieces of cybersecurity legislation.
- **Timelines for implementation** often do not correspond to the capacity of EU and national regulators to create the necessary infrastructure. That includes the designation of Notified Bodies (e.g. under the MDR), development of guidance documents (e.g. on due diligence under the Batteries Regulation) or harmonization and reference of technical standards.
- Once legislation is in place, **enforcement by national authorities is fragmented and often lacks resources**, especially in areas where it is needed to maintain a level playing field between European companies and global competition.
- **Implementation of the New Legislative Framework for products**, and especially the Blue Guide, are not aligned with latest technological advances, including the transition to a circular economy and conformity assessment of stand-alone software.
- COVID has shown the **fragility of the single market** in a crisis when member states for example introduced barriers to the free movement of people that impacted the ability of field services engineers to travel and deliver much-needed maintenance and repair services for medical equipment.

Examples of related single market challenges:

- **Free flow of data-enabled innovation:** Fragmented implementation of the General Data Protection Regulation, diverging national and local rules, create privacy and data protection challenges that reduce the European industry's competitiveness and innovation potential in data analytics and Artificial Intelligence, endangering the digital transition in the health sector. Member states do not hold a single position on the legal concept of personal data and non-personal data, and no adequate and recognized standards exist on the anonymization of personal (health) data. Conditions on data processing for scientific research purposes are fragmented. Some member states retain cross-border data transfer restrictions (often as part of the criteria for public procurement and use of cloud services or within local healthcare regulations).
- **Public procurement of innovative technology**: Public procurement should be a powerful tool to drive innovation and the competitiveness of European industry as well as support the European Union's strategic priorities including the digital and green transitions. However, transposition and implementation of the Public Procurement Directive is fragmented between

member states, increasing administrative burden for companies and making it more difficult not only to procure cross border but also to scale innovation across the entire EU. In addition, price only procurement continues to occur and overall continues to dominate purchasing decisions for health technology.

- **Harmonized standards in support of the single market**: Harmonised European standards represent a consensus by stakeholders on how to meet market needs, while at the same time facilitating compliance with EU legislation and supporting the circulation of goods in the Single Market. However, over the last years, some administrative processes around the harmonisation of standards on the EU level severely slowed down the final publication of European standards in the Official Journal of the EU. The result is a situation where standards are not available to the users, and manufacturers have to resort to alternative and often costly ways to demonstrate compliance with EU law. This prevents using the potential benefits of Single Market governance, as it unnecessarily complicates EU market access.
- **Transition to a Circular Economy**: Various studies and reports highlight the importance of embedding circular economy principles in the European Single Market for the EU's transition to net-zero and future competitiveness of a resource-scarce continent. They also clearly point out the existing barriers, often the result of EU and national legislation developed many years ago based on a linear model of production and use. These include restrictions on the purchase of refurbished medical equipment in national procurement regulations, a fragmented application of reprocessing rules under the Medical Devices Regulation, or limits in chemicals legislation to the use of recovered spare parts for repair, upgrades and in the manufacturing of new medical devices.
- **Effective environmental regulations**: A successful green transition requires effective regulation. However, environmental regulation often remains incoherent and fragmented. For example, in the implementation of the WEEE Directive, definitions and reporting requirements, including exemptions and evidence, as well as fee calculations differ between member states. For packaging, a Regulation has successfully been adopted but, in the meantime, national labelling schemes persist. Coherence is also lacking between newly-adopted legislations, e.g. thresholds for applicability in CBAM and the Deforestation Regulation or definitions of concepts between the EU taxonomy and other environmental legislations, such as the Sustainable Products Regulation.

Recommendations for the future of the Single Market:

- A political commitment is needed for the preferred adoption of Regulations over Directives, starting with the revision of the Public Procurement Directive.
- Any impact assessment for new legislation should include a sector-by-sector assessment of how newly proposed requirements may interact with existing legislative frameworks.
- Any action plan or strategy to be developed in this mandate should include single market objectives in its scope (e.g., effective harmonization of the NIS2 Directive under the Action Plan for cybersecurity of hospitals or removal of single market access for innovation under the Life Science strategy).
- Simplification of reporting requirements should not remain limited to few areas but be comprehensively addressed to streamline requirements and reduce administrative burden in all relevant areas, as the EU Competitiveness Compass[5] suggests.

[5] EU Competitiveness Compass, 29 January 2025

- The TRIS Directive (EU)2015/1535[6] should be properly enforced and its notification process strengthened.

2. Leveraging the Single Market for Health Resilience

Enrico Letta's report, *"Much More Than a Market"*[7], emphasizes the necessity of integrating a European dimension into the health sector to ensure access and sustainability for EU citizens, especially in light of demographic changes and potential future crises.

The report advocates for leveraging the Single Market to strengthen health resilience, proposing the development of a more unified European health policy. This includes fostering collaboration among member states, enhancing the efficiency of healthcare systems, ensuring equitable access to medical services and innovations across the EU and addressing the global context. Promoting a more integrated and resilient health sector would allow the EU to better prepare for future health challenges, including those stemming from climate change or supply chain risks, and improve the overall well-being of its citizens.

Today, the EU only has a supporting competence in health policy, as primary responsibility for healthcare provision lies with the Member States. However, the COVID-19 pandemic has once more highlighted the need for the EU to have a rapid response capacity to enable it to react to major health threats in a coordinated manner. This has not gone unnoticed among the European population, with the April 2021 Eurobarometer revealing that 38% of European citizens consider healthcare to be the number one task of European institutions, ahead of topics such as economic recovery or fighting climate change. It would thus be of the utmost importance to prioritise health and acknowledge the strategic relevance of the medical technology sector in the Single Market Strategy, to enhance transparency, cooperate more closely and intensify dialogue.

In particular, an EPRS study[8] finds added value in terms of increased budgetary efficiency in consolidating healthcare expenditure at EU level in the areas of prevention and procurement. This budget-neutral shift from spending at Member State level to EU level would generate yearly added value of €17 billion for procurement and €3.5 billion for prevention, the study concludes.

Recommendations:

- Make health a priority in the upcoming Single Market Strategy and acknowledge the strategic relevance of the medical technology sector
- Articulate a new vision for the Single Market, as the motor of the twin transitions and the foundation of European citizenship and public health
- Enhance cooperation, transparency and dialogue among Member States and healthcare system actors to reinforce the EU's health and crisis preparedness and resilience of its healthcare systems, which are under increasing systemic strain, in particular due to climate change risks[9]

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[6] Commission Report on the Operation of the Single Market Transparency Directive from 2016 to 2020 (COM(2022) 481 final) stresses the untapped potential of Directive (EU) 2015/1535 with respect to addressing persisting bottlenecks in relation to the Single Market and the Green Transition.

[7] Enrico Letta - Much more than a market (April 2024)

[8] EPRS_STU(2023)734690_EN.pdf

[9] European Climate Risk Assessment | European Environment Agency's, February 2024

- Setting bold goals to leverage technology and healthcare innovation accelerating the digitalisation of health systems to improve efficiency and effectiveness in healthcare delivery
- Prioritising investment and deployment of advanced health technologies, innovation procurement through public tendering and an overall consistent, innovation friendly regulatory environment that facilitates the roll-out of new health technologies
- Advance policies that enable integrated, scalable, and value-driven care models
- Support a Regulatory System Reform for Efficiency and Innovation

Further links:

- MedTech Europe position "Attractiveness of Europe for MedTech Innovation", June 2024
- Deloitte Report, 2023 Europe's MedTech Attractiveness

3. Supporting a Regulatory System Reform for Efficiency, Innovation and better Governance

In May 2017, two regulations (EU) 2017/745 on Medical Devices (MDR) and (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDR) replaced three previous medical devices directives, thereby providing for further strengthening of the single market given their direct legal effect across all EU Member States.

Only a few areas within these regulations (e.g. language requirements, penalties for non-compliance) are open to national implementation legislation. Nonetheless, many areas of national interpretation and implementation practice exist, which hamper the single market for medical devices and *in vitro* diagnostic medical devices (IVDs). The below entries are examples only of some notable areas and should not be considered as exhaustive:

- A European database for medical devices ("EUDAMED") is a central feature of the MDR and IVDR and is intended *inter alia* to provide centralization of information and facilitate coordination between Member States around registration and traceability of devices, clinical investigations & performance studies, vigilance, certification and market surveillance. In practice, the development of EUDAMED has seen delays, resulting in a multitude of national processes and requirements being put into place in these areas. A great deal of EUDAMED is expected to become mandatory for use by early-2026 and this will gradually replace national practice. However, areas of national practice remain:
    - Due to delays in this section of the database, all clinical investigations and performance studies need to be registered nationally (in different infrastructures, which can be challenging for multi-country studies). There is no mandatory coordinated assessment of applications for authorization between Member States until 2033. This means manufacturers of devices face administratively burdensome and confusing practices. The European Commission is running a COMBINE program to address issues where possible.
    - IVDR and MDR specifically allow Member States to develop their own registration databases for distributors; these are not foreseen to be included in EUDAMED at all even if this database includes all other economic operators: manufacturers, importers and authorized representatives. National distributor databases provide for considerable duplication of information which already exists in EUDAMED. Lack of linkage between EUDAMED and national distributor databases also does not support traceability of devices. Requiring device data at national level other than a list of distributed unique device identifiers can be regarded as a measure having equivalent effect.

- MDR and IVDR each have a legal basis for providing derogation from conformity assessment, to allow products onto the EU market in the interest of public health or patient safety or health[10]. This derogation must first be made by one Member State before it can be translated into an EU-level derogation. In practice, this derogation has been used by individual Member States to support their public health needs but has barely been used at EU level – no such derogations were used during the COVID pandemic and they have been used only once since even though there are reported shortages of medical devices and IVDs.[11]
- National authorities govern the auditing bodies ('Notified Bodies') under IVDR and MDR. Notified Bodies, which assess devices on the EU market throughout their lifetime, can take different approaches depending on the interpretation of their national authority. This can be greatly – but not always – mitigated by best practice documents produced by the Medical Devices Coordination Group. For example, notable fragmentation is seen in the Notified Body depth of review for recertification of devices as just one example.

Today, European companies face mounting compliance costs, reporting requirements, and increasing fragmentation in the Single Market.[12] The medical technology sector is no exception. Costs have gone up sharply due to the IVDR and MDR as compared to the previous directives:

- For the IVD sector: Costs have gone up by 100 % conformity assessment and 50% for performance evaluation since IVD Directive.
- For the MD sector, the inverse is true: costs have gone up by 50% for product certification and by 100% or more for clinical evaluation since the medical devices directives.[13]

The impact of heightened costs coupled with other barriers including complexity, lack of predictability and efficiency in the regulatory system is being felt in discontinuations of many products currently on the market and moves by significant percentages of manufacturers to launch future products first outside of Europe.[14]

The unpredictability, complexity, and burden of the regulations means that many devices on the market today as well as new, innovative medical technologies are not reaching patients in Europe as they should. The competitiveness of the wider industry and even the viability of many small businesses (SMEs) is at risk[15].

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[10] IVDR Art 54 and MDR Art 59

[11] 1 out of 2 clinicians has experienced issues with the availability of medical devices since the introduction of the MD Regulation. 2 in 3 said that the replacement device was less effective than its original. See survey report by Biomedical Alliance in Europe '*Clinicians concerned about limited availability of medical devices',* January 2023.

[12] Single Market - Compendium of obstacles - 12 Feb 2024, containing a list of 100+ existing obstacles across all economic sectors

[13] MedTech Europe 2024 Regulatory Survey: key findings and insights

[14] See survey report by MedTech Europe '*Transition to the IVD Regulation - MedTech Europe Survey Results for October 2022*', October 2022. This point refers to the transition from the Directives to the Regulations.
See survey report by MedTech Europe 'Analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation', April 2022. Also see MedTech Europe 2024 Regulatory Survey: key findings and insights.

[15] For example, signs that start ups smaller & medium-sized business are closing can be found under these surveys: Key takeaways under Dutch IGJ 2023 survey report, Manufacturers, please take timely action to meet IVDR requirements; Also see survey report by the German Chamber of Commerce and Industry (DIHK), the Medical Mountains cluster initiative, and the German industry association SPECTARIS '*Current assessment of the German medical device manufacturers on the effects of the EU MDR*', December 2023: while the report did not address business closure specifically, the percentages of planned and reported discontinuations of devices are severe enough especially for smaller companies, to indicate that their business viability is at risk.

- In the European Commission's targeted evaluation of the IVDR and MDR, the Commission should **develop a package of legislative reforms each for the IVD Regulation and MD Regulation** to ensure that these regulations deliver on their original objectives of *a robust, transparent, predictable and sustainable regulatory framework which serves a high level of safety & health whilst supporting innovation, the smooth functioning of the EU internal market, and the great many SMEs that are active in this sector*.[16]
- An **improved, single accountable governance of IVDR and MDR** – is vital for ensuring a smooth, efficient and innovation-friendly single market for medical technologies
- As urgently as possible – the European Commission should **adopt several 'bridging measures'** to support devices availability and the viability of the medical technology industry. These include measures to provide more predictable assessment procedures, more efficient change control, and to put in place a pathway for breakthrough innovation and adapt recertification to follow the product lifetime.

Further links:

- MedTech Europe position, The Future of Europe's Medical Technology Regulations
- MedTech Europe's open letter to Commissioner Kyriakides on the urgent need for action on the medical technology regulations
- MedTech Europe position "Smooth transition to the mandatory use of EUDAMED"
- EU Competitiveness Compass that acknowledges the urgent simplification needs of today's regulatory system and the need to close the innovation gap in life sciences across sectors

4. Unlocking the Single Market for a successful Green Deal implementation in Healthcare

MedTech Europe envisions a reinforced fully functioning EU internal market as the EU's strongest asset and catalyst of both, a high level of environmental protection and a competitive medical technology industry in the EU. Sustainable products circulate freely from one Member State to the other and thereby access to medical technologies for patients and health practitioners is improved. Supply inputs, such as raw materials, for the manufacturing of medical technologies can be sourced across national borders thereby reducing costs. A fully functional internal market is a powerful crisis management tool supporting security of supply, as the COVID-19 pandemic has also evidenced.

MedTech Europe observes an increasing trend of fragmentation, especially regarding Green Deal product related requirements due to an increasing number of often conflicting national measures in parallel to EU regulation. The sector's regulatory system also sees "gold-plating", i.e. the addition of specific local requirements at national level, which further increase barriers to a fully functional internal market serving patients needs.

[16] Paraphrased, preambles 1 and 2 of IVDR and MDR

Europe is the fastest-warming continent in the world. Besides impacts on health at the individual level, the European Environment Agency's (EEA) first-ever climate risk assessment report[17] confirms that climate change causes increasing systemic risks to our health systems. While climate mitigation measures remain without alternative, the report clearly demonstrates that building resilient, sustainable healthcare systems is key for withstanding further negative climate change impacts on people's health and wellbeing.

Not only does the EEA acknowledge that health system capacity is key to protecting the most vulnerable. Health infrastructure can also be directly affected by climate change, e.g. by large-scale flooding or high temperatures, and climate change impacts on the overall health system can cascade into many economic sectors. Besides, climate change also comes with increased strains on the availability of and access to medical technologies considering ever more complex global supply chain challenges, fragmented policy frameworks, overall system inefficiencies, workforce shortages, financial constraints, and geopolitical complexities, all of which will only increase the risks to the safety and health of patients. A reinforced Single Market can support managing climate impacts on both, citizen's health and healthcare system resilience and doing so in a more cost-efficient and timely manner.
The Single Market is also a vital lever for the transformational synergies of the Green and Digital agendas: As the Annual Single Market Report 2025[18] confirms, the health industrial ecosystem stood out with respect to reducing its impact on the environment. It saw the sharpest drop (of around 60%) in material extraction across all sectors over the period 2017-2022, mainly due to the shift towards digitalisation and to technological advancements in pharmaceuticals and medical devices

Recommendations:

- Set up a strategic dialogue with the medical technology sector and other healthcare system actors that share the vision of advancing the resilience and sustainability of our healthcare systems holistically to prevent adverse impacts on patient care
- Complete the EU internal energy market: accelerate the roll out of renewable energies and smart clean energy infrastructures
- Further leverage the transformational synergies of the Green and Digital agendas to increase overall system efficiencies and sustainability performance
- Strengthen monitoring, implementation and enforcement of Single Market principles to put an end to market barriers resulting from divergent national measures.; effective enforcement must be guaranteed, and infringements sanctioned.
- Act as a guardian of the EU Treaty when national action runs counter the functioning of the EU internal market
- Boost an EU internal market for waste in support of the circular economy
- Provide timely guidance on how to understand and implement various EU legislations, such as on CS3D, Batteries Regulation or Packaging Regulation
- Promote industry-driven consensus standards in support of the green transition
- Support the creation of European standards and guidelines in full alignment with global standards and using synergies stemming from CSRD, CS3D and other legislative instruments
- Have a holistic approach in defining environmental requirements for products, parts and packaging

[17] European Climate Risk Assessment | European Environment Agency, Feb. 2024; Climate Risk Assessment confirms urgency of addressing systemic risks to health systems - MedTech Europe, Feb. 2024

[18] The 2025 Annual Single Market and Competitiveness Report - European Commission, 29 January 2025

- Patient safety must not be compromised when implementing the new Sustainable Products Regulation (ESPR); include MedTech Europe as a member of the new Ecodesign Consultation Forum
- Developing a life cycle assessment methodology linked to product category rules is a powerful tool to address healthcare products. Although there is a strong push for the application of PEF (product environmental footprints) in Europe, these have the limitation of not being suitable to address complex products, such as healthcare products. Standards able to address LCA and PCR should be supported and the development of sector specific standards for healthcare should be encouraged
- Promote value-based procurement in a public sector that leads by example
- Ensure capacity building for purchasers of medical equipment, including training to support the application of Green Public Procurement criteria
- Support the development of circularity indicators[19]
- Earmark funding and unlock financing for the green transition of the medical technology sector under the announced Competitiveness Fund as well as new initiatives on decarbonisation and clean technology, such as the envisaged proposal for an Industrial Decarbonisation Accelerator Act or the new EU Life Sciences Strategy
- Introduce a European scheme to boost and integrate national tax incentives for investment in sustainable innovation
- Invest in hospitals and other healthcare delivery organisations – for example, via the Cohesion or European Regional Development Funds
- Leverage digital solutions to reduce carbon footprint, including generation of evidence for their benefits in reducing healthcare's environmental footprint. In particular, governments should promote the development of standards to harmonise ways to quantify, e.g. avoided emissions accomplished from digital solutions so as to be able to compare outcomes from non-digital solutions
- The TRIS Directive (EU)2015/1535[20] should be properly enforced and its notification process strengthened (see also Commission Report on the Operation of the Single Market Transparency Directive from 2016 to 2020 (COM(2022) 481 final).

Further links:

- MedTech Europe Position Paper "Implementing the Green Deal in Healthcare" of November 2024
- Clean Industrial Deal: MedTech Europe recommendations, December 2024
- Medtech_Europe recommendations for the Circular Economy Act_final.pdf, Jan 2025,
- MedTech Europe recommendations for Chemicals Industry Package_final.pdf, Dec 2024

5. Leveraging the potentials of the Single Market for the Digital Transition

MedTech Europe emphasizes the **transformative potential of digital health in revolutionizing healthcare** by addressing critical challenges, such as workforce shortages, aging populations, and the rising burden of chronic diseases. Digital health technologies promise to improve access to care, enhance the quality of patient outcomes, and boost the efficiency of healthcare systems. To realize this potential, fostering trust in

[19] Material Circularity Indicator | Ellen Macarthur Foundation

[20] Commission Report on the Operation of the Single Market Transparency Directive from 2016 to 2020 (COM(2022) 481 final) stresses the untapped potential of Directive (EU) 2015/1535 with respect to addressing persisting bottlenecks in relation to the Single Market and the Green Transition.

these technologies is essential, alongside ensuring collaboration among policymakers, healthcare professionals, patient groups, and industry stakeholders.

Artificial intelligence (AI) plays a pivotal role in advancing digital health. By enhancing diagnostics, personalizing care, and streamlining administrative processes, AI supports healthcare professionals in delivering better outcomes while reducing their workload. AI-driven technologies enable innovations such as improved radiology workflows, robot-assisted surgeries, and automated patient monitoring, leading to significant health and economic benefits.

A MedTech Europe study highlights that AI could save 400,000 lives annually, create €200 billion in healthcare savings, and free up 1.8 billion working hours. However, trust in AI technologies is crucial, necessitating clear, balanced regulatory frameworks like the EU AI Act and the MDR/IVDR to ensure safety, transparency, and innovation while maintaining Europe's global competitiveness in medical technology.

Health data is another cornerstone of digital health transformation, with its effective use and governance being key to unlocking the full potential of these technologies. Although the healthcare industry generates a vast amount of data, only a fraction is utilized. Unlocking this data could drive innovation, enhance patient outcomes, and support groundbreaking research. The European Health Data Space (EHDS) initiative aims to establish a framework for secure and interoperable health data sharing across the EU, enabling more effective primary and secondary use of health data. MedTech Europe supports this initiative, recognizing its potential to overcome barriers to cross-border data sharing, foster patient empowerment, and accelerate the adoption of digital health solutions.

Cybersecurity is critical to ensuring trust and reliability in digital health technologies. With the rise of cyber threats targeting healthcare providers and systems, robust cybersecurity measures are vital to protecting sensitive patient data and maintaining the integrity of healthcare operations. The increasing digitalization of healthcare has made medical technologies vulnerable to malicious attacks, such as ransomware, that disrupt services and compromise patient safety. The medical technology industry invests significantly in state-of-the-art security measures to protect devices, data, and systems while complying with stringent regulatory requirements. MedTech Europe advocates for strengthened collaboration between public and private stakeholders, investments in cybersecurity literacy, and legislative initiatives such as the revised Network and Information Security Directive (NIS2) to bolster resilience across the healthcare sector.

MedTech Europe underscores that digital health transformation depends on building trust, fostering innovation, and implementing frameworks that enable the secure and effective integration of technologies. By prioritizing AI, data governance, and cybersecurity, stakeholders can collaboratively create a healthcare ecosystem that addresses current challenges and delivers sustainable, high-quality care for all. The EU Single Market is an important competitiveness lever in these areas.

Recommendations:

Data Act

- Recognise the complexity of the healthcare sector
- Provide precise definitions and a clear scope
- Take existing legislation into account, especially the rules outlined under Medical Devices Regulation (MDR), In Vitro Diagnostic Regulation (IVDR), and General Data Protection Regulation (GDPR)
- Avoid the erosion of the protection granted by IP rights and trade secrets

European Health Data Space

- Maintain a reasoned and logical scope to achieve its intended objectives
- Have clear and consistent requirements and provisions
- Enable and encourage access to good quality data for secondary use while ensuring compliance with the General Data Protection Regulation (GDPR)
- Ensure consistency with the existing EU regulatory environment, in particular with sectoral legislation

Artificial Intelligence

- Increases the quality of patients' outcomes and supports healthcare professionals
- Ensures efficiency and sustainability in healthcare systems
- Supports timely access to safe, effective, and innovative medical technologies
- Promotes research & development and innovation using AI technologies in Europe
- Ensures the competitiveness of European medical technology companies

Cybersecurity

- Sets harmonised baseline cybersecurity requirements for digital products and services
- Recognises the capabilities of existing sectoral legislation, specifically the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), including the associated guidance of the Medical Devices Coordination Group (MDCG)
- Enshrines a sectoral approach to medical technology cybersecurity and a consistent regulatory interplay with existing and future EU law
- Contributes to the security of digital product users and patients, while equally promoting innovation and the provision of state-of-the-art technologies

Further links:

- Vision for Strengthening Cybersecurity in Europe's Future Healthcare Systems
- Charting the path forward: Joint stakeholder statement on the implementation of the EHDS
- Medical technology industry perspective on the final AI Act
- Stakeholder coalition calls for legislative refinement of the EHDS

6. Promoting the respect of fundamental Single Market Principles in Public Healthcare Spending

Digital health technologies hold great promise to transform healthcare. In particular, there is a rapid evolution in the development of technologies referred to as digital medical devices (DMDs), which can cover a multitude of solutions that enable diagnosis, monitoring, treatment and follow-up of patients.

Digital health has proven benefits in reducing the cost of healthcare services, hospitalisation rates and length of hospital stays (ex. telemedicine is projected to save the global healthcare industry more than €20bn in costs by 2025, rising from almost €11bn in 2021). To enable the wider adoption and uptake of digital health services, MedTech Europe strives to showcase the value of DHTs and to support the development and implementation of mechanisms to enhance their timely access – while enabling the digitalisation of healthcare in Europe for the establishment of the right environment for their deployment.

Despite the promise of DMDs to transform healthcare, their adoption in clinical practice is very limited, their regulatory environment is still developing, and coverage decisions are lacking or incomplete. In addition,

there are no standardised evaluation methods or common language at the moment to help address the uncertainty around investing in digital health technologies.

Recommendations:

- While funding/ reimbursement decisions for health technologies are a national competency in Europe, the development of common methodologies could incentivise member states and regions to consider the value of DMDs more systematically and to learn/ share good practises for DMDs adoption.
- Carry forward the SME Relief Package

Further links:

- MedTech Europe reflection paper_Harmonised_Assessment_for_DMDS, January 2025

7. Introducing a 5th freedom for Research and Innovation

While the global technology race accelerates, the EU significantly lags behind in terms of investments in RD&I compared to its global competitors. This is in particular true for private investments. This shortfall hampers the EU's ability to fully capitalise on its scientific and technological potential. **For the sake of its long-term competitiveness, the EU needs to do more to attract and retain private RD&I investments in Europe**.

In this regard, the EU Framework Programme plays an important role. Public RD&I investments enabled through the EU Framework Programme are crucial to alleviate market failures and to stimulate private RD&I investments by lowering the risks that such investments represent for the industry. **By pooling resources and expertise through the EU Framework Programme, Member States and the EEA countries, industry, RTOs and academia aim to tackle complex challenges collectively, accelerating the pace of technology maturation and innovation and supporting the EU positioning in today's technology race which is currently under duress** (See EU Innovation Score Board 2023).

The impact of such collective and coordinated EU RD&I investments has been recently demonstrated by the Ex-post evaluation of Horizon 2020 which found that the highest degree of financial leverage per each euro invested was achieved in European partnerships. In the institutionalised partnerships, private partners' contributions with resources (in cash or in-kind) more than doubled or even tripled the volume of EU investments.

The collective EU RD&I investments need to be reinforced in the next EU budget (MFF). **National RD&I investments should in parallel be ensured and at minimum meet the target of 3% of GDP, aiming at leveraging private RD&I investments**. Committing to EU technological leadership should ensure that proper and timely investments are made.

To further support EU Competitiveness, FP10 must focus on excellent cross-border collaborative RD&I, with a strong industrial participation. To do so, the focus on competitiveness must be reinforced in Pillar II, and should similarly be a key driver for activities in Pillar I and Pillar III. Pillar II is the only truly collaborative part of the FP today, breaking silos to promote the flow of knowledge between and within the private and public sectors as well as between basic and applied research. A significant part of FP10's total budget should not only be allocated to Pillar II, with an enhanced focus on European Industrial Competitiveness but the activities in Pillar II must also be driven by strategic EU priorities and clearly defined industrial needs.

Pillar II is crucial to:

Build long-term trust-based public-private partnerships (PPPs) amongst a wide variety of European RD&I actors, which is an indispensable element in strengthening Europe's RD&I ecosystems. This ensures the industry's uptake of novel technologies and scale-up into new solutions, products and services, improving people's well-being and quality of life, and increasing European long-term competitiveness. The FP's current Pillar II, containing the key EU industrial partnerships, especially the co-programmed and institutionalised partnerships, supports this ambition. Therefore, Pillar II with its industrial partnerships will need to be further strengthened with an adequate budget.

Reduce risk and uncertainty and stimulate private investment in Europe by demonstrating the EU's support for technology-intensive sectors, while preserving technology neutrality for a level playing field on the internal market. This would give the right incentives for industry to invest in RD&I in Europe, rather than in third countries and to support the delivery of the EU green and digital transitions.

Europe has much better potential in the global innovation race than what it is currently performing. To remain a model of economic and social prosperity, Europe needs to strongly invest in pan-European collaborative RD&I fostering collaboration, driving technology maturation and innovation, and leveraging the expertise of RD&I public and private actors to strengthen its competitiveness and assert its leadership in key technological domains, as well as pave the way for a prosperous and sustainable future.

Recommendations:

- MedTech Europe supports the introduction of a 'fifth freedom' suggested by the Letta Report, dedicated to the free movement of research, innovation, knowledge, and education, ensuring that Europe remains competitive in a rapidly changing global economy.
- MedTech Europe calls for stronger European competitive excellence in Research and Innovation (R&I), simplification, and its recognition of the need to bolster the EU's capacity to innovate and lead in the area of health. We also welcome the acknowledgement of the importance of the Life Sciences sector within Europe's R&I ecosystem as an area ripe for investment and synergies. The emphasis on fostering an attractive and inclusive R&I ecosystem resonates with our commitment to work cooperatively with public and private partners to strengthen Europe's competitiveness.
- European leadership in health relies on a strong R&I ecosystem, supported by programmes like Horizon and the future FP10: Health R&I requires governments, industry, academia, and civil society to work together. Strengthening these collaborations – including public-private partnerships – is crucial. We bring this deep expertise and knowledge to our active role in the Innovative Health Initiative, which sits within the current framework programme of Horizon Europe and aims to translate health research and innovation into tangible benefits for patients and society.
- FP10 is an opportunity to boost European health innovation and competitiveness for the benefit of patients, healthcare professionals, health systems, and society. The medical technologies industry has ideas for further strengthening R&I and boosting competitiveness in FP10. These include reducing the administrative burden for businesses, especially SMEs and start-ups, and creating better funding strategies that fit the innovation timeline.

Further links:

- Joint Statement for an Ambitious FP10: Investing in Europe's Future Competitiveness through Collaborative Research, Development, and Innovation
- Medtech Europe contribution to Heitors Expert Group on FP10.pdf

8. Further strengthening the free movement of healthcare workers

The shortage of healthcare workers poses a significant challenge to global and European health systems, which was exacerbated by the COVID-19 pandemic. The World Health Organization projects a shortage of around 10 million healthcare workers by 2030.[21]
At the same time, demand for care will continue to grow due to an ageing population[22] and a rise in chronic disease, such as cardiovascular diseases.

Recommendations:

- Tap into the potentials of digitalisation to relief workforce challenges
- Further pursue the European Skills Agenda for Sustainable Competitiveness, Social Fairness and Resilience

9. Further explore on the potentials of the Capital Markets Union to support strategic objectives

Stronger local capital markets are a pre-condition for having a more EU-wide capital market that helps delivering on the EU's strategic objectives. For the CM initiative to develop further, action is needed both, from Member States and from the EU institutions. While progress has been made since the CMU initiative was launched in 2015, EU capital markets remain fragmented.

As a consequence, health among other ecosystems faces a single market relevant challenges, such as:

- A Lack of or insufficient information
- Overlapping/diverging (EU/national) product requirements, rules, procedures or taxes
- Insufficient cooperation or communication between national administrations
- Insufficient digitalisation of information or of procedures
- Lack of mutual recognition
- Insufficient enforcement of legislation by Member State or Commission
- Issues around authorisations/licences/permit requirements, or other document requirement

The Letta and Draghi Reports have highlighted the need for better functioning capital markets and a possible materialisation of a CMU as a tool for the EU in financing the green transition and in strengthening European

[21] World Health Organisation, Health and Care Workforce: Time to Act, September 2022. https://www.who.int/europe/publications/i/item/9789289058339
[22] By 2050, almost 130 million EU citizens will be 65 years or older. Eurostat, Ageing Europe - statistics on population developments. Ageing Europe - statistics on population developments - Statistics Explained (europa.eu)

competitiveness. This is all the more relevant with respect to financing in the climate transition as Europe lags behind the US in tapping the potentials of a Capital Market Union.

Recommendations:

Carrying forward the CM initiative could help SMEs to grow, companies and people to invest, citizens to cater to their financial needs, and investments to be carried out where they are needed the most. To advance the capital markets initiative, the EU and Member States could investigate to:

- Better harmonise regulations, including tax rules (e.g., energy taxation)
- Ensure that all EU Member States take measures to advance the CMU, by i) establishing a monitoring mechanism to counter fragmentation and monitor progress, ii) agreeing upon updated CMU KPIs to measure our competitiveness, and iii) forming a high-level expert group to update the Commission on market developments and try to find solutions on controversial matters.

10. Designing A Single Market that works beyond borders

In the face of an increasingly complex and unpredictable global landscape, the Letta Report outlines that the European Union is compelled to extend its focus beyond internal concerns, placing significant emphasis on the external dimension of the Single Market. Today, it is no longer possible to make a clear distinction between these two dimensions, but about taking them in consideration together.

With the green and digital twin transformations, which are based on the deployment of critical technologies that have a global footprint and that are based on global standards, the ability to shape these standards is essential for Europe's competitiveness. Economic security emerges as a condition for economic stability and resilience, especially in light of recent challenges such as the pandemic, the resurgence of conflict, and the energy crisis. These events have highlighted the vulnerabilities inherent in Europe's current development model, which relies heavily on global trade interdependence. The Letta Report stresses that adapting to the new global context requires seeking an harmonious balance between the integration into the global market and ensuring security, with the aim of enhancing our competitiveness and resilience.

Besides the call for a strategic and cohesive approach to extend the Single Market's influence beyond EU borders, the Letta Report recommends balancing openness with security, establishing an Economic Security Council, defining Critical Technologies, coordinating Export Controls, advancing trade agreements and recognising both the challenges and opportunities of EU enlargement.

Recommendations:

- Implement the Letta Report recommendation into the Single Market Strategy, notably to seek an harmonious balance between the integration into the global market and ensuring security, with the aim of enhancing competitiveness and resilience
- Reinforce the Single Market and the global harmonisation of standards, such as for waste, circularity or secondary raw materials, with respect of the quality and safety for patients and healthcare practitioners

- Align Commission decision of 3 October 2023 on the list of Critical Technologies for Economic Security with the Critical Entities Resilience Directive under which health has been identified as critical infrastructure

Conclusions

Strengthening the EU Single Market is crucial for enhancing sustainable growth and competitiveness of the medical technology industry and advancing public health. A well-integrated market eliminates regulatory fragmentation, enabling medical technology companies to streamline operations and reduce costs. By harmonising standards and removing trade barriers, businesses can scale faster and bring innovative products to market more efficiently, boosting their global competitiveness.

For small and medium-sized enterprises (SMEs), which constitute a significant portion of the medical technology sector, a unified regulatory framework reduces the complexities and expenses associated with navigating diverse national regulations. This enables them to allocate more resources to research and development (R&D), fostering innovation. A robust Single Market also facilitates cross-border collaboration, allowing companies to leverage diverse expertise and access a larger talent pool, further enhancing their ability to develop cutting-edge technologies.

From a public health perspective, reinforcing the Single Market improves access to life-saving medical technologies across EU member states. Harmonised regulations and well coordinated implementation ensure that high-quality products are consistently available, reducing disparities in healthcare provision. Patients benefit from faster access to diagnostics, treatments, and medical devices, while healthcare systems gain efficiencies through economies of scale and better procurement practices.

Moreover, the Single Market supports resilience in healthcare supply chains by enabling smoother cross-border trade and reducing dependency on external suppliers. This became particularly evident during crises like the COVID-19 pandemic, where a unified approach was critical to ensuring the availability of medical supplies.

In conclusion, reinforcing the EU Single Market in the face of new challenges aligns with the goals of promoting innovation, health resilience and competitiveness. By fostering innovation, reducing costs, and ensuring equitable access to medical technologies, a strengthened Single Market positions the EU as a leader in healthcare innovation while safeguarding the well-being of its citizens.

MedTech Europe stands ready to further contribute to the development of the EU Single Market Strategy.

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.

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