



REALISING EUROPE'S FUTURE POTENTIAL IN HEALTH

the time to act is NOW!

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A successful, vibrant future European Union depends on having a healthy, active workforce and a range of innovative industries. However, Europe's ageing population means that it stands to lose almost 10 percent of its workforce to retirement or disease by 2050 with no overall change in total population¹. This shift in demographics will see chronic diseases increase dramatically and place even more demands on Europe's already-stretched healthcare systems.

Without reform and restructure, the EU will need to devote an increasing share of resources to funding healthcare while observing a rapidly-shrinking workforce. This will quickly become unsustainable; already average healthcare spend in the EU is approaching 10 percent of GDP, a rise of almost 25 percent since 2000². Ultimately, this will undermine its ability to maintain global competitiveness and to meet the expectations of its citizens.

If Europe is to realise its future potential, it must support its citizens and keep its future workforce healthy – but it needs to act now. Healthcare delivery needs to be radically reconfigured to make it financially sustainable and keep healthcare accessible to all EU citizens. The key is to focus on those outcomes that are effective and that matter to citizens and patients; i.e. a value-based approach.

A truly value-based approach will leverage and realise the potential of medical and digital technology. To date, healthcare professionals, patients and payers have only just begun to enjoy these advantages and efficiencies; adopting a value-based approach will see these benefits increase dramatically.

COCIR members are devoted to delivering these highly innovative technologies; however political support for ensuring broader EU wide uptake remains vital.

MEDICAL IMAGING TECHNOLOGIES are essential for accurate diagnosis and for monitoring treatment effectiveness. Coupled with Artificial Intelligence (AI), imaging technologies can help identify where and when to intervene.

RADIOTHERAPY TECHNOLOGIES have evolved to become essential for preventing premature deaths in and treating a number of cancers more effectively, both as a standalone therapy and in conjunction with chemotherapy and surgery.

DIGITAL HEALTH TECHNOLOGIES permit e.g. large-scale data analyses and AI applications that e.g. can predict, prioritise and screen at-risk populations, identifying priorities and supporting clinical staff at the point of decision or point of care.

With healthcare systems currently straining to meet demand, **THE TIME TO ACT IS NOW.**

COCIR offers six core policy recommendations to incoming European policymakers and key healthcare stakeholders to make this a reality. Three of these recommendations address how to improve the efficiency of healthcare systems; the others to ensure that innovative industries can continue to drive Europe's future economy.

¹ Source: The Schuman Report on Europe, State of the Union 2017 <https://www.robert-schuman.eu/en/bookshop/0214-the-schuman-report-on-europe-state-of-the-union-2017>

² Source: World Bank <https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?locations=EU>

COCIR'S CORE RECOMMENDATIONS FOR

Better healthcare systems

1. Boosting Healthcare Systems Efficiency with technology-led, value-based approaches.
2. Developing New Care Models to support an integrated care approach.
3. Unlocking the vast potential of wider using and sharing of healthcare data.

COCIR'S CORE RECOMMENDATIONS FOR

A vibrant medical & digital technology sectors in Europe

1. Supporting the EU economy and workforce by investing in healthcare research and innovation.
2. Implementing better regulation that makes the European Single Market frictionless and seamless.
3. Encouraging international trade to ensure European health technology industry remain globally competitive.

COCIR'S CORE RECOMMENDATIONS FOR *Better healthcare systems:*

1. BOOSTING HEALTHCARE SYSTEMS EFFICIENCY

Demographic change in Member States is making better management of chronic diseases essential; however, restrictions on healthcare budgets make this a challenge. A major element in resolving this dilemma is creating more efficient healthcare systems that prioritise the most valuable interventions. This necessity is already been recognised on some levels; innovative therapies, procedures and devices are now assessed for cost-effectiveness before being reimbursed.

Yet this approach can only work if the assessment framework is fit for purpose; yet for many medical and digital technologies, it is not the case. Current approaches, such as Health Technology Assessments, fail to take account of their numerous specificities. As a result, rather than improving efficiency, these approaches increase the burden on manufacturers and slow patient access unnecessarily.

It is vital that teaching hospitals have clear guidance and goals on approaching innovation procurement and Key Performance Indicators (KPIs) for introducing and evaluating new treatment protocols and techniques.

TO ADDRESS THIS, COCIR CALLS UPON THE EU TO:

- > Establish robust, effective indicators and appropriate methodologies for assessing multifunctional medical and digital technologies.
- > Ensure dynamic market access and innovative procurement processes that encourage the rapid uptake of innovative medical and digital technologies.

2. DEVELOPING NEW CARE MODELS

Health systems have traditionally prioritised - and therefore resourced - acute care services. Acute care absorbs up to 80 percent healthcare expenditure, with only 3 percent allocated to prevention. Yet the sustained increases in chronic diseases and non-communicable diseases make it clear that this no longer reflects reality. Resources urgently need to be reallocated to match demand.

An integrated care approach offers a solution, maximising the benefits of diagnostic and therapeutic systems at all healthcare provider leveraging health IT. The technology already exists to e.g. interconnect and share data between hospitals, homes and community. It will need investment in IT infrastructure based on Healthcare IT standards to make it work, but the efficiencies gained should rapidly repay the investment.

Maximising the benefits of a shift to managed care requires leadership. The European Commission must encourage Member States and Regions to cooperate to ensure national and regional approaches are compatible, allowing joint processing of operational, financial and clinical data.

TO ADDRESS THIS, COCIR CALLS UPON THE EU TO:

- > Aid and encourage Member States in developing national and regional roadmaps for adopting integrated care.
- > Invest more in scaling up successful integrated care projects.

3. UNLOCKING THE VAST POTENTIAL OFFERED BY HEALTHCARE DATA

Many sectors already enjoy the benefits of large-scale data analysis; healthcare should also embrace these. Collecting, collating and analysing health data, both population-based and individual, will inform and improve decision-making of every aspect of health and healthcare delivery. AI applications can bring further benefits. Yet the lack of a shared data model for social and health care complicates developing holistic tools and is slowing their dissemination.

In addition, society currently lacks sufficient trust or enthusiasm for data sharing. We need to find tools to accelerate the social contract between individuals and those using human and other data to improve health and well-being for all. Giving individuals a deeper understanding of the value of their data will help them draw pride from their contribution to improving human health.

Our sector seeks to be a leader in developing these tools. We want to work with public authorities, civil society, patient groups and other technology and health actors to help develop the tools to make this a reality. Data protection rules are important protecting everyone's privacy but should not create obstacles to innovation or the prospects for the digital health economy.

TO ADDRESS THIS, COCIR CALLS UPON THE EU TO:

- > Enhance the current standards for Digital Healthcare by defining, implementing and deploying a shared data model, with interoperability standards and models as required.
- > Boost stakeholder understanding, confidence and enthusiasm in the value of data sharing and the benefits of data-related technologies.
- > Harmonise the Data Protection Framework implementation for healthcare.
- > not Hamper innovation and technology with imbalances in regulatory approaches.

COCIR'S CORE RECOMMENDATIONS FOR *A vibrant medical and digital technology sector in Europe:*

1. SUPPORTING THE EU ECONOMY AND WORKFORCE

The sustained, continuous advances in diagnostics, imaging, radiotherapy and medical IT have revolutionised approaches to care. These technologies are now essential in effective care delivery. These will play pivotal roles in transitioning to integrated care and in tackling the burden of chronic conditions and non-communicable diseases.

The EU should support the healthcare sector, particularly medical and digital technologies. There needs to be wider recognition of the added value (concept) of these technologies and greater commitment to funding the large-scale deployment of complex digital health solutions. The EU also needs to encourage Member States to maximise their role by committing to the necessary investment.

TO ADDRESS THIS, COCIR CALLS UPON THE EU TO:

- > Increase funding for, and investment in, medical and digital technologies during the next Multiannual Financial Framework.
- > Invest in the entire innovation cycle, from research and innovation, through commercialisation to standardisation and deployment.
- > Make healthcare innovation integral to the Horizon Europe and Digital Europe programmes as well as part of Cohesion Policy.

2. IMPLEMENTING BETTER REGULATION

The medical device industry is currently undergoing substantial regulatory reform. Many of the newer regulations are 'siloed', thus undermining the basis of the European Single Market and stalling potentially harmonised standards that support smarter, better regulation. EU regulations that assess patient safety EU-wide, rather than country-by-country, provide a level playing field for the market.

The Medical Devices and General Data Protection Regulations, as well as various environmental regulations, are also drastically increasing the regulatory burden on manufacturers. Regulations like the Medical Devices Regulation, the General Data Protection Regulation, as well as various environmental regulations, have significantly raised the bar on protecting the life, health and wellbeing, and the privacy of EU citizens and the environment. Unfortunately the impact on administrative burden of some provisions has not been properly assessed and risk to undermine the efficiency and effectivity of these regulations. Time-to-market is increasing and SMEs face growing, sometimes overwhelming, administrative demands.

Europe should support the sector, one of the EU's most dynamic, through better regulation. This will help ensure it remains an attractive location for manufacturers to invest. Otherwise, healthcare providers and patients may lose out on timely access to innovative therapies.

TO ADDRESS THIS, COCIR CALLS UPON THE EU TO:

- > Champion the effective and timely implementation of regulations and their enforcement in Member States.
- > Implement these in a way that they support a level playing field for manufacturers.
- > Ensure that the system for harmonising European standards functions effectively.
- > Measure whether regulations deliver the desired impact when implemented.

3. STRENGTHENING INTERNATIONAL TRADE

European medical device companies develop their devices and services for a global market; the European economy will only see its full potential in a stable, rules-based global trading system and environment. However, increasing national protectionism is hindering international trade, stalling progress on new trade agreements, while existing agreements are not being fully implemented and enforced. At the same time, public mistrust of globalisation and of international institutions is growing.

If European companies are to remain successful and contribute as part of a thriving European economy, the EU must maintain its commitment to a global multilateral trading system and encourage its partners. Eliminating tariffs and technical barriers to trade will benefit companies of all sizes, from multinationals to SMEs alike will benefit.

COCIR CALLS ON THE EU TO:

- > Work on converging regulatory frameworks and processes globally
- > Promote the use of international standards in trade agreements
- > Increase efforts to negotiate trade and mutual recognition agreements for medical devices globally.

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COCIR COMPANY MEMBERS:



NATIONAL TRADE ASSOCIATIONS MEMBERS:



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