COCIR Position

The EU's Multiannual Financial Framework

COCIR's recommendations for funding healthcare innovation in the 21st century

Table of Contents

1. Introduction

COVID-19 laid bare the consequences of prolonged underinvestment in healthcare and health resources. The pandemic affected virtually every aspect of healthcare provision, directly and indirectly, with delays in diagnosis and treatment causing an additional death toll beyond COVID-19. The long-term consequences of COVID-19 are visible in the low work satisfaction of healthcare professionals brought to breaking point and the resulting current staff shortages across Europe. Russia's war against Ukraine is putting additional pressure on healthcare systems. EU countries at Ukraine's borders have received historic numbers of refugees. Hospitals and other healthcare organisations across the European Union suffer from higher energy costs. Medical device manufacturers struggle with limited supply of key components such as semiconductors.

At the same time, the crises of the past few years highlighted how much today's healthcare systems can already rely on innovative technology. The burden on nursing and medical professions would be disproportionately greater without the day-to-day relief provided by excellent diagnostics, effective therapy solutions, and efficient digital processes. During the Covid pandemic, for example, radiation therapy was able to replace many inpatient surgical procedures thanks to outpatient settings and enabling of remote access. These factors will become even more important - both in an increasingly uncertain world and in times of aging, potentially multimorbid, populations.

In addition, healthcare systems also face the longer-term trials of climate change and the digital transformation of the economy and society. Europe has been at the forefront of health research and innovation that can provide substantial solutions to these challenges. However, translating research into innovative products, with uptake by European healthcare systems, has proven slow. This reflects a lack of investment in supporting the development and deployment of medical and digital health technologies. Already, Europe is falling behind internationally in some research areas, such as Artificial Intelligence. Combined with barriers arising from the complexity and lack of capacity in the regulatory system for medical devices, this puts the competitiveness of the sector in Europe at significant risk.

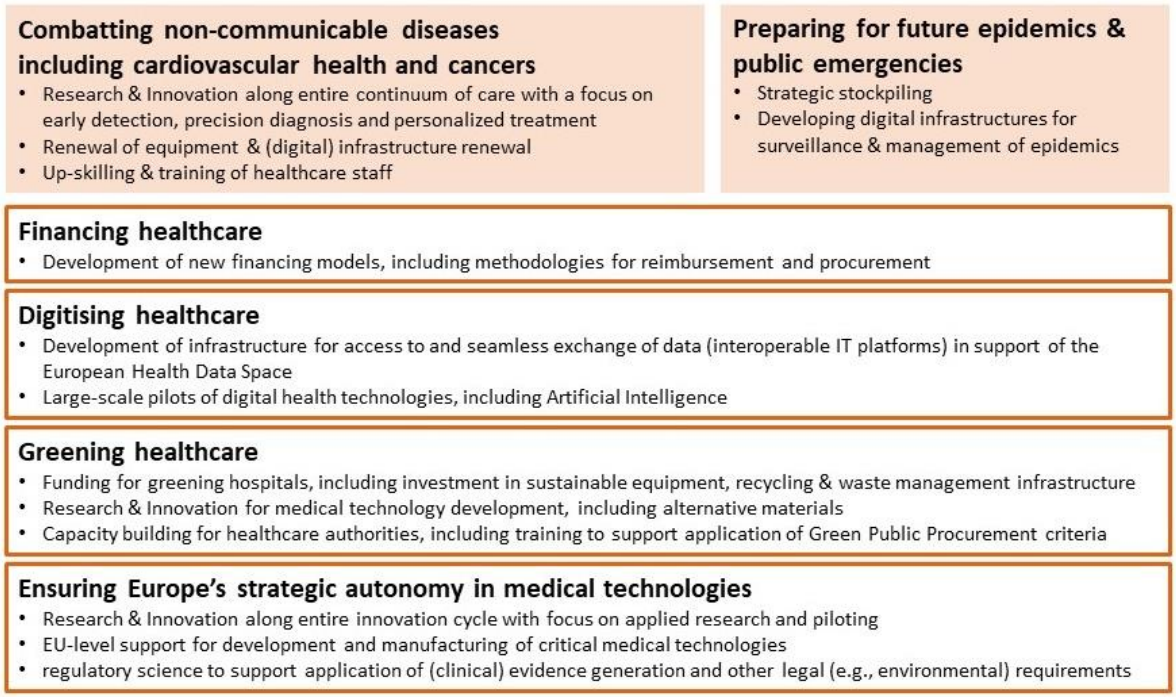
Reforming and transforming healthcare systems to meet future needs represents a historic opportunity to ensure that the European Union is better prepared to meet future pandemics and other crisis situations. EU-level investment in healthcare and medical technologies, from research to the market and to the user, lies at the heart of creating a more resilient European economy.

The upcoming review and revision of the Multiannual Financial Framework is the right moment to reflect how to use EU funding to achieve the best outcomes for European patients and citizens. Europe is at a crossroads. Depending on the decisions taken today, we either face a future where patients have access to the right diagnosis and treatment at the right time, provided by satisfied healthcare professionals and enabled by a competitive medical technology and digital health industry in Europe. Or we go down the road of decline, where European citizens do not get access to the best healthcare possible and pressures on healthcare systems increasing even further.

In the current document COCIR –the European Trade Association representing the leading industries in the medical imaging, radiotherapy, electromedical & health ICT sectors – provides insight and recommendations to achieve the ambitious goals addressed by the Multiannual Financial Framework.

2. Summary of key recommendations

To address the healthcare challenges of the 21st century we must both tackle non-communicable diseases and increase preparedness for potential future pandemics. Achieving these goals requires targeted activities, but also an overarching, systemic approach to address healthcare financing, digitization and greening and to implement incentives and a regulatory framework necessary to ensure Europe's strategic autonomy. COCIR's recommendations for these areas are outlined below.



3. The value of medical and digital health technologies

Medical and digital health technologies enable better outcomes and quality healthcare provision across the continuum of care, from screening, early detection and precision diagnosis, through personalised treatment, to outpatient care, monitoring, and rehabilitation.

COCIR members' technologies contribute to all of these areas:

Medical imaging technologies (including both hardware and software) support improved detection and diagnostic accuracy with imaging-based precision diagnosis which increases the chances of survival and post-treatment (or after-care) quality of life. These technologies also improve treatment effectiveness through image-guided therapy, resulting in lower side effects and ultimately lower mortality rates. For example, radiotherapy has reached an unprecedented level of sophistication: On-treatment imaging allows for the therapy delivery to be adapted to the patient's changing anatomy, taking into account any movement of the tumor, thus increasing the treatment's effectiveness in terms of outcome, clinical workflow, and patient quality of life.

Artificial Intelligence-enabled software can further personalise and adapt treatments to improve patient outcomes, while improving efficiency of workflows by having information readily and quickly available, increasing the throughput and reducing lead times.

Telemedicine and mobile apps increasingly enable patient self-management. They can, for example, reduce mortality in chronic diseases through monitoring and rehabilitation, and sustain lifestyle changes.

4. Experiences in the 2021-2027 Multiannual Financial Framework

4.1 Horizon Europe

Horizon Europe is an important vehicle for establishing a competitive European industry by funding outstanding research and supporting R&I activities at a broad range of Technology Readiness Levels, and COCIR welcomed the emphasis put on Pillar II clusters and missions to improve citizens daily lives by tackling global societal challenges.

COCIR provided detailed feedback on the past and future of Horizon Europe during its interim evaluation, suggesting:

- Horizon Europe should further strengthen the complementarities between different clusters and missions, as the challenges for society cannot be addressed in silos. To reflect the increasing digital transformation of the European economy and society, the initiatives supporting digitization in Health should be increased, for example by introducing key performance indicators or quotas for digital aspects in calls within the health cluster.
- Horizon Europe should further improve industry participation by strengthening the dialogue between the European Commission and industry stakeholders at all levels and facilitating industry involvement in decision-making and implementation.
- Horizon Europe should further balance open science and IP obligations with commercial interests to ensure a clear path from innovation to clinical implementation.

In addition, to ensure access to cutting edge R&D and innovation, Horizon Europe should also ensure that legal entities outside of the EU can fairly participate in EU funded research programmes.

4.2 Digital Europe

COCIR supported the creation of the Digital Europe Programme, which filled a gap in the EU funding landscape. Funding the large-scale deployment of complex digital health solutions is vital for supporting and scaling up the digital transformation of health and for improving access to digital health technologies.

The early implementation of the programme has been focused on setting up infrastructures (e.g., testbeds for Artificial Intelligence). These are valuable projects, especially for SMEs that currently lack access to testing and validation infrastructure. We are also very supportive of the use of EU funds to create the infrastructure for access to and seamless exchange/sharing of health data, as demonstrated by, for example, the Cancer Imaging Initiative. We recommend:

- Latest scientific and technological developments should be leveraged and deployed to support a successful creation and implementation of a European Health Data Space with the broader aim of fully achieving the Digital Single Market in health. Following the example of the Cancer Imaging initiative, the roadmap for implementation of the EHDS should identify further data gaps and allocate funding for the set-up of federated data infrastructures.
- The programme should provide more focus on funding large-scale pilots and deploying of digital health technologies and services at scale, through long-term partnerships and collaborations across EU regions and countries.
- Creation of networks between large companies and SMEs in value chains should be better supported to address market failures.
- To ensure access to cutting edge R&D and innovation, Digital Europe should also ensure that legal entities outside of the EU can fairly participate in EU funded innovation programmes.

4.3 Recovery & Resilience Facility

The Recovery and Resilience Funds are an essential part of Europe's recovery from COVID-19. COCIR has provided detailed feedback to the implementation of the Facility in EU member states, recommending:

- More efficient collaboration and coordination around common goals that are based on concrete measurable and widely accepted indicators, such as the COCIR Golden Rules.
- Consideration of economic (inflationary) pressures when setting budgets for procurement and contracting processes.
- Adoption of EU guidance to allow for the case-by-case extension of deadlines for procurement and activation of EU funds at national and regional level.
- More extensive consultation of the health and clinical community when developing tenders for digital solutions in a healthcare setting.
- More effective enforcement of EU Public Procurement rules, to ensure a compliant and timely execution of the national recovery plans. National entities should be held accountable towards creating fair and transparent public tender procedures. This will ensure an efficient use of EU money and improve access to high quality medical equipment. The European Commission should monitor that a sufficient number of private entities can compete in procurements by ensuring objective technical specifications based on international recommendation.
- Complementarities with other funding instruments, including Interreg and Cohesion Funds.

In the context of the discussions on RePowerEU and the Net-Zero Industry Act, the European Commission has published guidance to support the re-allocation of Recovery and Resilience Funds. While we support the objectives of the Green Deal and understand the urgencies of the current energy crisis, this should not be used as an opportunity to re-allocate funds from healthcare spending. **We urge the European Commission and member states to maintain the current funds allocated to healthcare in the national recovery plans.**

4.4 EU4Health Programme

COCIR has always been in favour of a dedicated health programme within the EU's Multiannual Financial Framework, especially as an instrument to support reform efforts and implementation of EU health policy. However, due to both the limited funding available and the fragmented implementation approach, the programme currently does not fulfill its potential.

In the future, a coordinated and ambitious Health Programme should provide continuous support to healthcare systems in becoming and remaining (financially and environmentally) sustainable as well as resilient towards crisis. It should support member states in reforming their organizational and financial models, and in updating infrastructure and modernizing equipment. Following the example set by the Recovery & Resilience Facility, targets and milestones should be set in alignment with the European semester, including built-in mechanisms for exchanging best practices between member states. This will also ensure complementarities with other programmes supporting health innovation and the development of innovative medical technologies.

4.5 Cohesion & European Regional Development Funds

The ERDF and the Cohesion Funds constitute the EU's most powerful investment tools to address inequalities in access to care between member states and support Member States in providing the best care and health infrastructure to their citizens. COCIR strongly supports the link between access to funds under these programmes and the European Semester process.

However, how individual EU Member States incorporate health investments in their Operational Programmes remains heterogeneous. In addition, we see little alignment between the EU's healthcare priorities and funding allocated at national level. For example, Europe's Beating Cancer Plan now has its national equivalent in many of the Member States. However, there is almost no correspondence between the targets set in these national plans and the 2021-2027 Cohesion Operational Programmes. We therefore propose that in future national plans and targets should align to Operational Programmes when planning outcomes, reforms and developments in healthcare systems.

5. COCIR vision for healthcare innovation in the European Union

Past years have shown the need to invest in European healthcare and health innovation, including more coordination at European level. Future iterations of the EU's Multiannual Financial Framework need to move from *ad hoc* crisis response towards a more sustainable approach to EU funding in healthcare.

In the current Multiannual Financial Framework, funding is scattered across several programmes, sometimes with overlapping objectives. The goal should be a coherent vision, aligned around the outcomes that the European Union wants to achieve. **We ask for an integrated roadmap for funding healthcare and health innovation in the EU's Multiannual Financial Framework, with complementary actions identified in various programmes.**

Based on the experiences outlined above such a roadmap should incorporate:

5.1 Preparing for future epidemics and public emergencies

COVID-19 has brought into sharp focus the need to better prepare for future epidemics and pandemics, as well as crisis situations impacting healthcare systems such as wars, wild-fires or floods. Future EU funding should support:

- Creation of digital infrastructure to enable early detection, appropriate surveillance and management of outbreaks of infectious diseases
- Strategic stockpiling of medical equipment that can be quickly activated to respond to health emergencies and other crisis situations
- Innovative development and procurement of medical technologies, following a BARDA-like model
- Connecting national healthcare systems

5.2 Combatting non-communicable diseases, including cardiovascular health & cancers

The burden of noncommunicable diseases remains a major public health challenge, also as an indirect consequence of the recent pandemic. According to WHO projections, in the absence of change the total annual number of deaths from non-communicable diseases will increase to 55 million by 2030. Cardiovascular Diseases account for 36% of all deaths and around 20% of all premature deaths (before the age of 65) in the EU. According to recent estimates, more than one person in three will be diagnosed with cancer at some point in their life. EU funding in this area should focus on:

- Research & Innovation across the entire continuum of care, including disease risk stratification by combining perinatal, epidemiological, imaging, and genetic data, enabling the development of minimally invasive and personalised therapy
- Support for member states to invest in effective screening programmes
- Investment in IT infrastructure to allow remote care
- Renewal of equipment and ageing technologies, as well as creation of innovative healthcare infrastructures such as rapid diagnostics clinics

5.3 Financing healthcare

Reform of national reimbursement and procurement systems is essential to consider new business models and serves as a basis for future investments. Due to financial pressures and staff shortages, healthcare delivery

organisations are also increasingly focusing on productivity and workflow management. EU funds should support payers in piloting innovative payment models and methodologies, and support healthcare institutions in piloting and establishing new clinical management solutions to improve workflow efficiencies.

5.4 Digitising healthcare

Digitisation and increased connectivity are driving exponential growth of data, creating new opportunities to generate health insights and lifestyle recommendations with the help of data analytics and artificial intelligence. These new solutions require meaningful use of the data that consider the needs of citizens and care providers. For instance, the provision and collection of data from patient monitors, imaging devices, and electronic health records augmented with AI turn clinical data into actionable insights for patients, providers, and consumers. In addition to providing clinical insights, the same system, informatics, and services also provide better operational forecasting to improve productivity and efficiency not only within health institutions but across entire health systems.

In clinics and hospitals, medical technologies can equip healthcare providers to innovate and transform the way care is delivered. By listening closely to their needs, medical technology providers co-create solutions that help improve outcomes, patient and staff experience and productivity. By embedding AI and data science in medical devices and technologies they leverage the value of data in clinical and operational domains, support clinical decision making and improve the quality and efficiency of healthcare services and systems.

To support these processes, EU investments should consider:

- robust capital investment in the digitalization of hospital infrastructure. This does not only include investment in medical devices and technology, but also into strategic change to digitize hospital and patient management.
- EU funding should encourage greater adoption of digital health products and services. Investments into imaging, monitoring, health IT platforms or telemedicine, e.g., teleradiology, could help identify where human resources can be shared across geographic regions to evade healthcare staff shortages.

5.5 Greening healthcare

Innovation is a key enabler to promote sustainability in healthcare. Members of COCIR are continuously engaging in finding more sustainable solutions while simultaneously improving clinical performance and effectiveness. For several years, COCIR has been working on the Good Refurbishment Practice for Medical Electrical Equipment with set requirements for quality, safety, and effectiveness. In addition, COCIR members are committed to minimizing the environmental footprint of its products along the whole lifecycle, starting from the design and manufacturing until the end of life of equipment. Furthermore, COCIR members communicate along the whole value chain, within and outside of the EU, on how to responsibly manage the products.

EU funding can accelerate these efforts and support the green transition for medical technologies and the broader healthcare sector. This can be achieved through support for research and innovation, and through funding to healthcare delivery organisations to green their infrastructure and operations:

- Greening hospitals, including life cycle assessment methodology development, investment in sustainable equipment, recycling, and waste management infrastructure.
- Research & Innovation for medical technology development, such as the development and use alternative materials.
- Funding for capacity building for purchasers of medical equipment, including training to support the application of Green Public Procurement criteria.
- Support for road-mapping and the implementation of environmental policies and regulations at the level of member states.

5.6 Ensuring Europe's strategic autonomy in medical technologies

A flourishing and competitive medical technology sector is key to ensuring continued access to essential medical and digital health products. An industrial strategy for medical devices is key to maintaining Europe's competitiveness and attractiveness. Such a strategy should include funding along the entire innovation cycle of technologies as well as manufacturing capacity. Existing instruments, such as the Important Projects of Common European Interest should be reviewed to remove unnecessary administrative rules and processes. Creating autonomy should not preclude collaboration with organisations outside the European Union, for example in health research & innovation, as long as reciprocity is maintained.

Funding is only one instrument, and any industrial strategy should encompass a review of existing legal and regulatory rules, including state-aid, product compliance regulation and trade policy (such as reciprocal access to procurement markets).

6. Conclusions

Innovation in healthcare only takes place when all stakeholders can contribute – patients, healthcare professionals, payers, academia and industry. That should be reflected in the design of programmes, from setting the targets and outcome to implementation of individual actions. That also means that EU funding programmes must remain attractive to companies of all sizes. Funding and reporting rules should be lean, with the least necessary administrative burden. We are concerned by increasing obligations related to Intellectual Property rights and access to research data. The legal framework should focus on enabling concrete impact of funding, including exploitation of research results and direct positive outcomes for European citizens. Operational efficiency can also be achieved by funding larger programmes and projects with higher budgets.

Funding also cannot be effective if it is not linked to systemic changes and reforms. These changes include modernizing reimbursement, procurement, regulatory, and other legislative frameworks. The Recovery and Resilience Facility has been a first attempt but remains a time-limited crisis instrument. For the next Commission mandate and funding period, the European Union should take an ambitious step forward and develop an integrated plan for healthcare.

7. Further reading

COCIR Paper on Enhancing Value in Cancer Prevention and Care: Industry Perspectives and Recommendations, July 2020

Joint industry contribution on the Multiannual Financial Framework

COCIR's Mission Proposal for FP9, March 2018

COCIR Publication on Medical Imaging Equipment Age Profile & Density 2021 Edition

COCIR calls for greater support for Medical & Digital Health Industry, 07.06.2018

Multiannual Financial Framework: A modern budget for a healthy Europe? (cocir.org), 04.05.2018

COCIR Contribution to MFF 2021-2027, 27.7.2018

COCIR Initiative on Good Refurbishment Practices

COCIR Feedback to the evaluation of the Recovery & Resilience Facility, 6.12.2022

COCIR feedback to the public consultation on the present and future of the Horizon Europe Framework Programme, 2.2.2023