



## **COCIR Position Paper Towards an innovation-driven healthcare model**

Across Europe although national healthcare organisations differ, and underlying reimbursement and investment principles vary widely between Member States, all EU and National policy makers share the same goal: to increase the access, quality and efficiency of healthcare for the benefit of European citizens.

Healthcare is perhaps the most challenging of all our societal issues, and overcoming the anticipated demographic and disease-related burdens will not only require the cooperation and collective resolve of all stakeholders, but will also require a shift toward a more innovation-driven, patient-centric healthcare model.

COCIR, a non-profit trade organisation, represents the medical technology, devices and health IT industries. For over 50 years, its member companies have developed and commercialised innovative technologies to advance healthcare delivery. COCIR believes that the innovative solutions developed by its members have a key role in addressing the increasing and unsustainable productivity, accessibility and affordability gaps.

**This position paper provides an industry perspective on opportunities and challenges of innovation-driven healthcare and sets out a list of expectations for a future innovation-friendly environment in Europe:**

- 1. Establish a mechanism to ensure a robust evaluation of innovations during the product-development cycle**
- 2. Enable rapid access to market for innovative products and services with added value**
- 3. Adopt a clear strategy on EU level to support innovations**
- 4. Access to further financing Research and Development investments**

### **Why invest in Innovative Technologies?**

Today healthcare services face fundamental changes fuelled by financial constraints, demographics, extraordinary advances in medical knowledge and technology and better informed patients battling chronic conditions and co-morbidities. They provide a huge breadth of medical offerings and service a mobile, larger and ageing population. And they do this with shortages of specialist staff. But, many are now viewing innovative technologies as the key to meeting these challenges.

Innovative medical technologies and health IT have always been a major driving force in the quest to increase healthcare quality, today however these technologies can provide so much more. IT enabled medical technologies are driving integrated patient-centric care pathways that can improve the efficiency and productivity of healthcare. They can also enable healthcare professionals to do things differently, for example, by allowing procedures that used to only be conducted in hospitals to be done in a General Practitioner's office.

Whether you are addressing the need to improve medical consistency, patient safety, productivity or connectivity; or looking to maximise the use of human and financial capital, it is clear that investing in innovative products and solutions will enable this transformation.

Healthcare organisations now have the opportunity to set up environments in which physicians can instantly share imaging and test results with colleagues in the same building or across the country or continent. Some patients have immediate access to their own records and are able to transmit or carry these from one healthcare provider to another.



### **Challenges in the innovation process**

Innovation has become a key enabler of all healthcare organisations. In addition, pioneering technologies are set to become game changers; new digital information, nanotechnology and genetic engineering have the potential to redefine healthcare, making old assumptions invalid and creating unanticipated opportunities for improving existing services. However, the process of invention and creating innovative technologies requires various components, which have to work in a systematic manner. Firstly, it requires highly skilled and trained people, especially in the field of engineering, technology and Information Systems. Those areas are essential for developing Medical Technologies and eHealth systems. Member States maintain training facilities and world-class universities, but common efforts must be taken to ensure the necessary workforce will be educated and that measures are taken to attract and integrate highly skilled individuals globally.

Secondly, a supportive Regulatory framework is a key pillar for innovation, it is therefore important for Regulators and Notified Bodies to be more aware of scientific progress to enhance early scientific advice. The current European framework for medical devices has been broadly recognized as a sound and effective one, both inside the EU and beyond. The New Approach concept, with its reliance on harmonized standards ensures that devices placed on the market represents "state of the art" products. However, the system could be improved and simplified. COCIR supports any move that would enhance predictability, such as early dialogue between manufacturers, scientific experts, Notified Bodies and competent authorities regarding 'innovative products' that could lead to early guidance for manufacturers. For medical devices, several horizontal regulations have to be applied in addition to the Medical Device Directives. This can create a complex framework which in some cases may cause conflicting situations, uncertainties and delay the innovation process.

Thirdly, the development of innovations is a costly process with uncertain results. Risks should be shared through private and public investment. The EU provides various funding programmes, however those mechanisms are not leveraged to their maximum effect and fail to support innovation. In research, funding is primarily focused on fundamental research and tends to neglect applied, marketable innovations. In addition, in the area of eHealth, funding of many programmes stops even after a successful pilot period due to a lack of funds for ongoing deployment.

In respect of EU support for improving healthcare infrastructure in eligible Member States, the uptake and use of structural funds for healthcare is progressing slower than expected due to a number of administrative, technical and political issues hindering the access and utilisation of these funds. In general, the funding landscape at European level has become too complex for eligible beneficiaries. Actions are needed to remove those bureaucratic barriers to ease the access to funding but also ensure compliance with the funding regulations.

### **Challenges for the implementation of innovations**

Europe needs to ensure that healthcare systems keep pace with the changing healthcare challenges. The management of chronic diseases and in particular, the increasingly common incidence of patients with co-morbidities, will require transformations within healthcare that enable a more patient-centric integrated approach linking services outside the hospital in the community and home, and delivering better public health to address aspects of prevention.

While innovative medical technologies that can drive this paradigm shift are available today, many Member States often view innovative medical and information technology as a cost, rather than an opportunity to improve quality, efficacy and the productivity of healthcare.



Currently many purchase decisions are price-driven with little, if any, attempt to consider the 'value' provided by a technology or method. "Cost vs Value" is the most basic of economic questions, and given that efficient use of the monetary resources is a top priority for decision makers, it would be better to assess the full potential value of a product or process solution over its entire lifecycle. Current procedures do not necessarily take into account the downstream advantages of innovations in process improvements and efficiency gains in daily operations. Instead they tend to focus on the initial higher investment costs without considering later productivity gains and improved patient outcomes.

Encouraging a proactive technology-pull by users, rather than just a technology-push by suppliers/providers is required for innovative technologies to have maximum transformational effect. To help secure this it is essential that Member States employ mechanisms that can be applied in the early stages of a new product's lifecycle to ensure that products with clinical and economic value receive adequate reimbursement. Based on the fact that reimbursement policies are defined nationally, within the European Community 27 different reimbursement decisions are taken, which differ and are based on different criteria. Therefore it is necessary to ensure transparency about criteria describing essential factors and introduce a common baseline to predict the future reimbursement probability.

### **The importance of the Medical Technology and IT Industry for Europe's health**

The last century has produced innovations in the healthcare industry which have enhanced life expectancy, quality of life, diagnostic and treatment options, as well as driving efficiency and cost effectiveness of the healthcare system. These include, but are not limited to, innovations in the process of care delivery, administration and surgical interventions. In a study by Fuchs and Sox<sup>1</sup>, diagnostic modalities (e.g., magnetic resonance imaging, computerized tomography scanning, mammography), and procedures (e.g., balloon angioplasty, coronary artery bypass graft, cataract extraction) are a major part of a list of top 10 medical innovations.

The European Medical Technology Industry is contributing in enhancing efficiency and quality of medical care and enables healthcare providers to face future healthcare challenges. It provides technological innovations to prevent, diagnose and treat various diseases as well as support and enable process innovations by Information Technology. Those developments are driven by the need based on clinical utility as well as cost and process efficiency.

Given the right tools, appropriate incentives and investment, hospitals in Western Europe will transform. And although the drivers of change will be universal – increase efficiencies, increase access, and increase in quality of clinical outcomes – the adaptations will not, and should not, be a one-size-fits-all change, as the demographic and regional health issues will be different across our borders.

The situation we face in Eastern Europe is no less a challenge but clearly here the infrastructure funds will be a huge force for good. Investment in the IT infrastructure and innovative technologies will be crucial if those structural investments are to fulfil the same requirements that are clearly understood to be necessary in the Western European countries.

#### Other references:

- COCIR White Paper "[Towards a sustainable healthcare model](#)" issued on 19 Nov. 2008
- COCIR "[10 Recommendations on eHealth](#)" issued on 8 Oct. 2007
- COCIR Position paper "[Measuring the value of Medical Technology, Devices and Healthcare IT – The role of Health Technology Assessment \(HTA\)](#)" issued on 6 Oct. 2010
- COCIR Position Paper "[Towards an optimised use of Structural Funds in health](#)" issued on 23 Nov. 2010

<sup>1</sup> Fuchs, V.R. and H.C. Sox, J.R. 2001, *Physicians' Views of the Relative Importance of Thirty Medical Innovations*, *Health Affairs (Millwood)* vol. 20: 30-42