



## ***Overcoming barriers to eHealth***

## What is eHealth?

Information and Communication Technology (ICT) has changed the way people carry out a broad variety of activities, including how they manage their health and receive healthcare services. “eHealth” is a framework for harnessing the capabilities of ICT to enable patients to obtain better care and health outcomes, and to help healthcare systems achieve higher quality and productivity. eHealth has the potential to provide invaluable benefits to patients, who should not be viewed merely as “part of a system” but rather as its central point of focus. It empowers patients and enables them to take greater control over the management of their health and healthcare.

Thus, eHealth can be defined as an umbrella covering all forms of innovation in the healthcare model using Information and Communication Technology (ICT). Therefore, eHealth solutions constitute medical devices such as infusion pumps and pacemakers, as well as services that can improve prevention, diagnosis, treatment, monitoring and management which use ICT.

eHealth includes, but is not limited to:

- information and data sharing between patients and health service providers, hospitals, health professionals and health information networks;
- electronic health records;
- telemedicine services;
- portable patient-monitoring devices;
- operating room scheduling software;
- robotised surgery.

Innovations powered by eHealth also have the potential to drive higher quality, more productive healthcare systems that can in turn provide equitable access to safe, user-friendly services for tens of millions of European citizens. These objectives are critical due to the increasing incidence of chronic diseases and ageing populations in Europe which will drive ever-greater demand for high quality, efficient healthcare.

Finally, eHealth drives economic growth in Europe. According to the 2010 study Business models for eHealth that was commissioned by the European Commission, “the European eHealth market was estimated at €14.269 million in 2008 and is projected to reach €15.619 million by 2012, with a compounded annual growth rate of 2.9%”.

Consequently, eHealth has become the third largest industry in the health sector behind pharmaceuticals and medical devices, with an attractive growth potential.

## What is the EU perspective?

The European Union has a responsibility to oversee the development and implementation of eHealth policies and actions. With the ever-greater migration of patients within the European single market, European institutions are stepping up to ensure that patients’ rights in cross-border healthcare are appropriately safeguarded. However, much stronger action by the EU is essential to ensure that the benefits of eHealth overcome the potential obstacles and in particular that patients receive safe, equitable and innovative healthcare.

## What is the industry perspective?

For Eucomed, eHealth is a critical tool to facilitate the provision of healthcare through ICT with a view to:

1. enable European patients to be more engaged in managing their own health, with proper training and under the supervision of professionals;
2. improve healthcare quality and productivity in Europe;
3. enable efficient and secure access to data by clinicians, payers, care providers and patients;
4. facilitate the sharing of knowledge and best practices across Europe, and open the door to new treatments;
5. contribute to more equitable access to healthcare for European citizens across the EU Member States;
6. increase the adaptability and sustainability of healthcare systems that are presently facing challenging financial and demographic burdens.

## Overcoming barriers to eHealth

Eucomed and its members are committed to playing their part in enabling the transformation of healthcare systems across Europe through eHealth and will support policies, legislation and pilot programs if they are in line with (most of) the following criteria:

1. Ensure that the needs of patients, providers and healthcare systems remain at the centre of eHealth policies. If patients perceive that eHealth revolves around their well-being they will identify with the system and make optimal use of its resources. Patients should be properly informed of eHealth capabilities, in addition to its limitations, while also being properly trained on how to use the relevant products and equipment.
2. Ensure a framework for technical and semantic interoperability in the health sector that enables standardisation and harmonisation of currently disjointed national and local eHealth systems. For example, the work already undertaken by the European Patients Smart Open Services project (epSOS) and the CALLIOPE Thematic Network and should be done collaboratively, leveraging the expertise of healthcare workers and the medical technology industry. Collaboration is also key to creating mandates for standardisation of eHealth products and health ICT systems, building on the work of eHealth Standardisation Mandate 403 and ensuring that all current and future projects meet specific requirements that place a priority on patient safety, with appropriate benchmarks, timeframes and eventual impact evaluations.
3. Ensure an appropriate value-based reimbursement and funding framework which properly compensates healthcare professionals, including doctors, nurses and caretakers for the use of eHealth technologies and remote services. This will create incentives for healthcare workers to fully accept eHealth and adopt new technologies and processes, thereby further spurring

innovation. Reimbursement and funding systems must provide financial incentives for fostering innovation in eHealth services.

4. Ensure the legal certainty of eHealth products and services across Member States. Such a framework should include regulations on the security, protection and processing of electronic medical records and patient health data in general; the transparency of eHealth systems and the determinations of liability. These reforms will help drive interoperability standards, public trust in eHealth applications and uptake of best practices.
5. Establish a leading European voice in presenting the value of eHealth for the future of EU healthcare systems. This should involve raising awareness of the vital role of eHealth for the future of a sustainable and healthy Europe.
6. Emphasise the appropriate uptake of new technologies to ensure that healthcare is provided in the most effective and efficient way.
7. Allocate increasing funds to the health sector with particular priority given to eHealth technologies and projects. This should be based on a recognition that eHealth is an investment with long-term implications for resolving many increasing strains on current European health systems, including ageing populations; a greater proportion of chronic, elderly and immobile patients; increasing health disparities; and growing demand for patient access and empowerment.

## eHealth and software as a medical device

eHealth is closely connected to medical devices and as such, a number of standalone software packages which are used in healthcare delivery should be considered medical devices.

The revised Medical Device Directive explicitly states that standalone software which meets the definition of a medical device as stated in the directive should be qualified as medical devices. Consequently, this software package should be CE-marked in accordance with the directive.

Such software which is categorised as a medical device constitutes an intricate part of the complex environment we call eHealth...

## About Eucomed

---

Eucomed represents the medical technology industry in Europe. Our mission is to make modern, innovative and reliable medical technology available to more people.

Eucomed members include both national and pan-European trade and product associations as well as medical technology manufacturers. We represent designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.

The industry we represent employs more than 500,000 highly skilled workers, turns over €95 billion per year, invests some €7.5 billion in R&D and encompasses of approximately 500,000 different medical technologies from sticking plasters and wheel chairs through to pacemakers and replacement joints.

Eucomed promotes a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of society.

For more information visit [www.eucomed.org](http://www.eucomed.org)