

Brussels, 31 January 2007

Response to Consultation regarding Community action on health services

Royal Philips Electronics welcomes the opportunity to present its views on the importance of the creation of a EU-wide legal framework for health services in Europe. Philips, headquartered in the Netherlands, is a global leader in healthcare, lifestyle and technology, delivering products, services and solutions through the brand promise of "sense and simplicity". Our expertise in medical technology enables innovative solutions for patients and healthcare professionals in areas such as cardiovascular X-ray, digital X-ray and ultrasound, patient monitoring systems, nuclear medicine, cardiology systems and critical care systems.

We note that better regulation and more legal certainty in the area of cross-border healthcare services will help harmonization across Europe of the essential healthcare infrastructure and this will improve patient satisfaction, quality of care and cost efficiency, (partly) enabled by economies of scale for the healthcare industry in Europe.

We argue that cross-border provision of telemedicine, remote care, remote diagnosis and other health related ICT mediated services (hereinafter referred to as connected health) often is the most convenient solution to ensuring that EU citizens have access to the best quality healthcare wherever they are in the European Union. Through Connected Health patients and healthcare professionals can gain access to care and specific medical expertise from within remote regions whilst containing travel costs and allowing as well as ensuring efficient use of medical resources.

Any Community action on health services must explicitly deal with the cross-border provision of connected health services on an equal footing with the "traditional" methods of health services delivery.

The cross-border provision of health services, as the Commission Communication rightly points out, raises the bar for Member States' cooperation in an area where traditionally countries still act independently from each other.

Furthermore, cross-border health services, whether provided by traditional or Connected Health means require that both patient and professional can be identified regardless of their country of registration or residence. Accordingly it is a prerequisite of cross-border health services provision that EU-wide interoperable systems are established in the areas of Healthcare Practitioner and Patient identification and authentication, as well as portability of patient information – the capability of it being exchanged and understood across countries.

The cross-border provision of connected health services offers an excellent environment for a cost-effective sharing of patient data – Electronic Medical Records – and remote identification of health practitioners.

However, without commitment from the Member States to achieve some level of harmonization in the representation as well as in the exchange of a patient's medical condition, a safe and effective health service cannot happen.

Cross-border healthcare and particularly cross-border connected care raises important standardization issues which includes but is not limited to standards for eHealth infrastructure, medical terminology standards and unique identification of healthcare professionals and patients.

The Commission should ensure that technology standards are open and support pan-European interoperability to promote a single internal market in connected health services and products, and as appropriate should encourage such interoperability to be addressed beyond Europe also.

Any Community action on health services must address the harmonisation of identification of health practitioners and patients, as well as patients' medical records and medical terminology

Cross-border healthcare and particularly cross-border connected care raises important challenges from the legal and information-sharing point of view. Accordingly we believe that the EU needs to clarify the legal framework of cross border care, whether provided by traditional or Connect Health means, in order to eliminate the current legal uncertainty.

Accordingly we urge the Commission to consider the full legal and technological implications of using Connected Health services across European borders and to ensure that European policy and regulations do not form a barrier to its use.

In particular we urge the Commission to consider the legal questions concerning applicable jurisdiction for liability, licensing and patient access in both traditional and Connect Health cross border health services delivery.

Any Community action on health services must clearly address the issues of applicable jurisdiction, choice of law and licensing, in the cross-border provision of connected health services.

We consider that further Community intervention is needed to promote the debate on topical issues that, once clarified, will increase the availability, accessibility, quality and safety of cross-border connected health services:

- **Standards of care**: while traditional medical practice and malpractice finds its references on widely accepted international standards, cross-border connected health services are relatively new and the absence of accepted practice standards is the current reality. EU-wide agreement on protocols and guidelines needs to be sought, as well as alignment of performance and quality indicators.
- **Reimbursement**: Member States' approaches to connected health services vary significantly, from its non-recognition to its selective reimbursement. This fact raises uncertainty regarding to their reimbursement when these services are provided to foreign patients where the same type of service is not recognized as such in the patient's home country.
- **Professional liability**: healthcare practitioner's responsibility on a cross-border connected health mediated environment requires further clarification and guidance as well as that of the telecommunication intermediaries that may span several countries in the service delivery chain.

The Commission High Level Group on Health Services and Medical Care and the i2010 Subgroup on eHealth should initiate a taskforce to address standards of care, reimbursement and liability in cross-border Connected Health services, the results of which should be integrated in the future EU legal framework for health services.

Philips is ready to further support the Commission in this initiative towards an EU-wide legal framework for Cross-border Healthcare Services.

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