COCIR Contribution to Consultation initiated by DG Sanco regarding Community action on health services*

Released version

COCIR, the European Committee representing the Radiology, Electromedical and Healthcare IT Industry, welcomes the present consultation on health services and recognizes the importance of promoting the debate. 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.

The cross-border provision of telemedicine, remote care, remote diagnosis and other health related ICT mediated services (hereinafter referred to as *connected health*) is, in a number of circumstances, the most convenient solution and the one that better serves the patients and the healthcare systems: access to specific medical expertise; access to care from within remote regions; travel cost containment; efficient use of medical resources.

Any Community action on health services must explicitly deal with the cross-border provision of *connected health* services in par with the "traditional" methods of healthcare delivery.

While the cross-border provision of *connected health* services may introduce specific challenges from the legal and informational point of view other than those already noted in the Commission Communication, we believe that any approach must aim at maintaining its coherence and predictability vis-à-vis the set of cross-border services' possibilities. We expect that in many situations *connected health* solutions will be (and have already been) confronted earlier with legal and other challenges

As much as possible, cross-border *connected health* services must be considered no differently - from a Community action point of view - from the "traditional" methods of healthcare delivery, and in many cases can lead the way.

*(*)*http://ec.europa.eu/health/ph_overview/co_operation/mobility/patient_mobility_en.htm

The cross-border provision of health services, as the Commission Communication rightly points out, raises the bar for Member States' cooperation in areas where traditionally it does not happen. Practitioner's identification and portability of patient information – the capability of it being exchanged and understood across countries - is a key factor that contributes to patient safety and increases the quality of the delivered service.

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 in achieving 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.

Any Community action on health services must address the harmonization of a patient's medical record and the identification of health practitioners and patients and medical terminology

Cross-border healthcare and particularly cross-border *connected care* raises important **legal** issues that the EU needs to clarify in order to eliminate the current uncertainty.

- **Jurisdiction and choice of law**: when healthcare is assessed remotely, across borders, in case of litigation, the application of the E-Commerce Directive, the Brussels regulation the Rome convention and the Rome II text results on uncertainty, namely in the country of origin / destination principles
- **Licensure**: it is not generally clear whether a practitioner would need to be licensed in Member State A to remotely assist – from Member State B - patients domiciled in Member State A.

Any Community action on health services must clearly address the issues of applicable jurisdiction, choice of law and licensure 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 it references on widely international accepted standards, cross-border *connected health* services are relatively new and the absence of accepted practice standards is the current reality. European 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 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 working task to address standards of care, reimbursement and professional liability in cross-border *connected health* services.

General information about COCIR:

Founded as a non-profit trade association in 1959, COCIR represents the radiological, electromedical and healthcare IT industry in Europe. As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide. COCIR is committed to supporting its members and communicating with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens. COCIR also works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users. We encourage the use of advanced technology to support healthcare delivery worldwide. COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

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COCIR National Associations Members: *AGORIA (Belgium), ANIE (Italy), SNITEM (France), ZVEI (Germany), Spectaris (Germany) FARON (Netherlands), FENIN (Spain), Swedish MedTech (Sweden), AXREM (UK).*