

COCIR contribution on the proposal for a Directive on Patients' Rights in Cross-Border Healthcare

Brussels, 24 November 2008

COCIR represents the European Medical Diagnostic and Imaging, Electromedical and Healthcare IT Industry.

COCIR welcomes the European Commission's proposal for a Directive on the application of patients' rights in cross-border healthcare. COCIR believes that the greater clarity of patients' rights for cross-border healthcare will empower patients, encourage data sharing and best practice exchanges amongst Member States and, in so doing, improve healthcare and ensure its long-term sustainability across Europe.

COCIR key recommendations:

1. We urge the Parliament and Council to recognise their role in supporting patients' rights and access to good quality healthcare and to go as far as possible towards establishing common high level healthcare quality and safety standards throughout Europe.
2. We recommend that the Directive better addresses the challenges of cross border reimbursement, and in particular, that the provisions requiring up front payments by patients be removed. If not, much of the Directive's good intentions may remain unfulfilled.
3. We believe that the Directive's scope must include the continuity of care - from prevention and early diagnosis to treatment and long term care.
4. We recommend the proposal puts stronger emphasis on the fact that reference networks are dedicated to highly specialised healthcare only.
5. Given the important enabling role of eHealth in ensuring cross-border patient rights and beyond, COCIR believes it is important that swift action is taken in various areas among which interoperability. In this respect, we suggest the introduction of a mandatory deadline of 2 years after transposition of the Directive for the European Commission to adopt the necessary interoperability measures for eHealth/Health IT.
6. We urge that medical technology companies, such as those represented by COCIR, are fully involved in the proposed Healthcare Technology Assessment processes both at national and at European levels.

Our detailed comments on the European Commission's proposal are set out below. As the medical technology industry we would be happy to discuss these in more detail with the European Commission, Parliamentarians and other interested parties.

COCIR's detailed observations

1- Quality and Safety Standards

The draft Directive proposes to establish a Committee that will provide guidelines to Member States for high-quality, safe and efficient cross-border healthcare, as outlined in Article 5 of the draft. These guidelines will be based on the Council Conclusions of 2006 on the common principles of quality in healthcare. These principles are referred to many times in the Directive and COCIR is pleased to see them enshrined in law.

The European Commission has stated that it is not intending to legislate on healthcare quality standards. Rather the European Commission expects European Member States to be transparent about the quality standards they apply. COCIR commends these efforts to increase transparency about quality of care. While we understand the complexities of the issues surrounding competency, we would like to invite the Parliament and Council to recognise their role in supporting patients' rights and access to good quality healthcare and go as far as possible towards establishing common high level healthcare quality and safety standards throughout Europe.

COCIR strongly recommends that EU-wide guidelines and the resulting national quality and safety standards should be based on healthcare outcomes and should avoid micro-management of health practitioners, stifling innovation.

One option COCIR would like to propose is the establishment of a "European institute of Health", with national affiliates, which would establish and further develop the best set of performance indicators to be used across Europe. Such an institute could equally foster and publish best practices across Europe for healthcare providers as well as develop a Total Quality Management approach for healthcare providers for continuous improvement, much like or as an extension of the EFQM, European Foundation of Quality Management.

2- Reimbursement

COCIR believes that the mechanism put forward in the proposal for the payment of a patient's treatment in a third party Member State is flawed to such an extent that unless amended, it will undermine the fundamental principle of the proposal to improve access to high quality healthcare to all citizens in the European Union. The proposal that a patient must pay the full costs of treatment, up front, to the country providing the treatment and then claim these cost back from their country of residence is a major barrier to equity of access. It will result in only those able to pay being able to access cross-border treatment and prevent many patients without their own financial means from using options available to richer patients. This is not acceptable and cannot be what the European Commission desires to see as part of the move to single markets within the European Union.

A new mechanism is required which will enable the speedy verification of a patient's identity and entitlement to treatment, confirmation that the treatment sought is reimbursable under terms to be set out by the Directive and the Member State concerned is then directly billed without the need for the patient to pay directly.

The proposal that European Member States will be able to pre-approve treatment and approve only the reimbursement of treatments in other European Member States that the patient would be entitled to in their own Member State also threatens the fundamental purpose of the Directive. Those Member States that restrict citizens' access to treatments those others permit will have no incentive to improve their healthcare system and will be able to continue to deny their citizens access to treatments and technologies that others enjoy. Under this scenario, the proposal will fail to increase the standard of and access to healthcare throughout Europe. To redress this flaw, COCIR recommends that the proposed Quality and Safety Standards referred to above should be incorporated into the Directive's requirements. The European Union must do more to ensure that high quality and accessible healthcare truly is delivered throughout all its Member States.

3- Continuity of Care

Continuity of care in a cross-border setting is difficult but addressing it adequately is essential. The proposed Directive, however, does not address this issue apart from in relation to medicinal products. COCIR welcomes the proposal's call for reinforced cooperation between the different healthcare systems/providers in the EU and urges such cooperation to include measures to achieve effective cross-border communication between healthcare providers at different stages of treatment including long-term care. It is also vital that cross-border continuity of care allows for reimbursement of rehabilitation and chronic disease management in the Member State of affiliation after treatment in another Member State and vice versa, ie, patients should be allowed to seek aftercare in another Member State, having received treatment in their Member State of affiliation.

It is also necessary for the Directive to recognise that healthcare resources are finite. Preventing premature illness, where this is feasible, remains the best option, be it at individual or population level. The proposed Directive remains silent on the important issues of prevention and long-term care. We contend that cross border movement for the purposes of early detection, accurate diagnosis of disease and treatment follow-up through the use of appropriate technologies should be permitted by the Directive.

4- European Reference Networks

The European Reference Networks are a commendable initiative that will enable patients with rare diseases and complications to access the best treatment and care in that field. Reference networks may however not be desirable in the area of major disease burdens and other more common conditions, where the limited resources may be put to better use via investments in quality and innovation in local healthcare systems, to meet local demand. We recommend the proposal puts stronger emphasis on the fact that reference networks are dedicated to highly specialised healthcare only.

5- eHealth

COCIR as does the Lead Market Initiative understands eHealth in a wider sense than currently does the proposed Directive. eHealth covers “the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals; it can also include health information networks, electronic health records, telemedicine services, and personal wearable and portable communicable systems for monitoring and supporting patients” (Accelerating the Development of the eHealth Market in Europe- eHealth Taskforce report 2007 composed in preparation for the Lead Market Initiative). Thus, it can be said that eHealth has a wider scope than only the cross-border supply through telemedicine.

While the potential benefits eHealth could bring are enormous, a number of barriers hinder the introduction of Health IT /eHealth solutions, or prevent from achieving optimal benefits. COCIR therefore welcomes Community harmonisation in the area of cross-border provision of healthcare using ICT. There can be no “safe” mobility of patients throughout Europe without mobility of their medical records and a system to track their treatment and its follow-up as well as payment mechanisms. We believe that this Directive, by giving a mandate to the European Commission to adopt implementing measures, has the potential to overcome market fragmentation and convert Europe’s proven innovation capacity in eHealth into a true EU-wide market for eHealth solutions based on international standards and profiles for eHealth interoperability.

Given the important enabling role of eHealth in ensuring cross-border patient rights, COCIR believes it is important that swift action is undertaken. Significant preparations have already started in this area. We propose a mandatory deadline of no more than 2 years after transposition of the Directive, for the European Commission to adopt the necessary interoperability measures. This will provide legal certainty to stakeholders and help guarantee that the Directive's ambitions will become a reality for Europe's patients. As a practical step, COCIR is also strongly encourages DG SANCO in joining DG INFSO and DG Enterprise in the eHealth interoperability Standards mandate (M403).

We are pleased to see reference to regulation on personal data protection and we would like to see full harmonization in EU and free cross-border intra EU flow of information. Despite Directive 95/46/EC, regulation for electronically exchanging sensitive patient data still differs per country and in some countries it is severely limited.

6- Health Technology Assessment (HTA)

COCIR believes that innovation is the cornerstone of any flourishing healthcare system. Provided that the methodologies chosen will adequately and timely reward innovation, COCIR is fully in favor of a European approach towards health technology assessments, which will do away with current practice whereby each national and even regional healthcare system performs its own HTA, often using different methodologies. This is not only cost inefficient, but also leads to legal uncertainty for providers of innovative technology who may be faced with diverging assessments from region to region. Duplicating HTAs also significantly delays time to market, which for innovative companies, in particular SMEs, is a considerable financial and business burden.

Also, the financing of the burden of proof that a product is clinically and economically viable should be dramatically changed: proof of concept and short, initial clinical trials to demonstrate safety and efficacy should be provided by the product owner; the full evidence based data currently assessed in the latter stages of clinical trials should be collected during the actual initial controlled and reimbursed use of the product. For these reasons, COCIR urges the legislators to ensure that technology companies are fully involved in the HTA process.

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.

COCIR Company Members: Agfa-Healthcare, Aloka, Bosch, Canon Europe, Dräger Medical, GE Healthcare, Hitachi Medical Systems Europe, IBA Ion Beam Applications, IBM, Intel, iSoft, Carestream Health, Fujifilm, Elekta, Medison, Philips Healthcare, Healthvision, Siemens Healthcare, Toshiba Medical Systems Europe

COCIR National Associations Members: AGORIA (Belgium), Assobiomedica (Italy), SNITEM (France), ZVEI (Germany), SPECTARIS (Germany) HHT (Netherlands), FENIN (Spain), Swedish MedTech (Sweden), AXREM (UK), FIHTA (Finland), TipGorDer (Turkey)

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