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Please Tell Us a Little Bit About COCIR – When was it Founded, Who it Represents and Key Areas of Focus / Activity in the European Healthcare IT Sector.

Founded as a non-profit trade association in 1959, COCIR represents the medical technology industry in Europe. As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide.

COCIR moved to Brussels in January 2006, establishing a permanent office in Brussels to better represent the interests and

activities of its members act as a communications channel between its members and the EU institutions and other regulatory bodies.

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. It also cooperates with other organisations on issues of common interest.

As well as communicating with EU policy- makers on economic, regulatory and technical issues related to healthcare, COCIR 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 sector.

In Terms of Research & Development and Gaining Market Access, What do You Consider to be the Biggest Challenges Facing Corporations Involved in European Healthcare IT?

Assuming that Healthcare IT and eHealth are about the same, the challenges in general terms (i.e., not specific to the industry) are formulated regarding barriers:

Organisational fragmentation within and between healthcare organisations

Different organisational settings and responsibilities make it difficult to agree on solutions that encompass the complete care cycle and cut through organisations. For example, it may not be in the interest of one care provider that information will become available to another care provider.

Misalignment Between Investments and Benefits

This is also a result of the 1st barrier. Often, infrastructure investments are needed (e.g. country-wide secure network, patient id, practitioner's id, etc.) but the benefits are in the improved decisions at the point-of-encounter between the healthcare provider and patient. Getting all parties aligned is a major challenge, and it may require a reorganisation of the healthcare system.

In the end, there should be a sound "business case" for every eHealth solution. Note that quite often the so-called "pilot projects" done with funding from the Commission fail after the pilot phase because no sustainable business model is available.

Reimbursement Does not Reward the Use of eHealth

Current reimbursement schemes are often based on the acute care model and the primary care physician model. This does not provide the right incentives to develop preventive schemes, or provide specific care paths for chronic diseases, where eHealth solutions are particularly useful.

Privacy and Security Regulation

For patients, the privacy of their medical information is important. Because eHealth solutions often address crossinstitutional healthcare in non-traditional ways, privacy and security regulations present a huge challenge. However, they are also often used as an excuse not to invest time and effort to find solutions that work within and across member states.

Interoperability Between Different Healthcare Systems

Entering information once, using it many times across the healthcare system: this is the dream of patients and providers. However this requires that terminology and information can be exchanged and understood between different systems.

Many standards exist, some need to be developed. But we should be careful in narrowing the barriers to eHealth to just technical interoperability. If there is a sound business case, interoperability will be developed. If there is no business case, the development of interoperability standards does not help.

Fragmentation of the Market

There are different visions, roadmaps and specifications for eHealth solutions between EU Members States and even within Members States. In this way, we will not get the necessary economy of scale to provide cost-effective solutions.

Absence of Cross-Border Legal Frameworks for Healthcare

Even if the privacy and security regulations are aligned between the Member States, a proper legal framework for cross-border healthcare, such as the recognition of accreditation of healthcare professionals in cross-border eHealth solutions (e.g. tele-consultation or radiology reporting) does not exist.

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What do You Consider to be the Greatest eHealth Opportunities in Europe?

Quality increase, cost reduction, citizen empowerment (to include the following):

– Reduction of errors,

– Improve disease management of chronic diseases,

– More efficient workflow,

– Accessibility and availability of information improves clinical decisions,

– Decision support,

– Home/remote care in an aging society,

– Seamless information transfer between healthcare providers, and

– New clinical applications.

What Role does COCIR Play in Fostering the Harmonisation of European and Global Healthcare IT Regulatory Standards?

COCIR, in the area of Healthcare IT, supports effective worldwide consortium standards; often these consortia have vendors and healthcare providers as members. COCIR companies participate in these standards and guidelines. Positions are also often prepared in COCIR. Examples are Digital Imaging and Communications In Medicine (DICOM) for medical imaging and Integrating the Healthcare Enterprise (IHE), which develops profiles for seamless integration based on existing standards in many clinical areas including: radiology, cardiology, oncology, laboratory information, IT infrastructure and patient coordination. IHE is a worldwide organisation. IHEEurope was started by COCIR, and its secretariat is still managed by COCIR.

In What Ways is COCIR Actively Involved in Promoting & Supporting Sustainable Investment in Healthcare IT Across Europe?

In many ways, because a large and homogeneous European healthcare IT market is a key objective for COCIR, in a

way all our activities contribute to that goal. Examples are:

– Since this year, it has been possible for the new EU Member States to get socalled structural funds not only for the traditional infrastructure, but also for the healthcare infrastructure. COCIR is actively involved in supporting governments to prepare proposals. COCIR also sponsors the European Health Forum in Bad Gastein, especially in a session on structural funds for healthcare.

– By contributing to harmonisation in standards for interoperability and EHR - COCIR is member of the so-called "eHealth Stakeholders Group" (and is a Co-Chair on behalf of the industry) which is initiated by the EU Commission to advise on interoperability between patient summaries, patient id's, practitioner's id's and emergency data sets of Member States. In this, and in other groups, COCIR promotes similar roadmaps and harmonised standards for EHRs in order to support a Europeanmarket with a sufficient scale to develop effective solutions.

– By supporting one European-level healthcare IT conference and exhibition (the World of Health IT), which for the 1st time will take place in Geneva from 10-13 October 2006. Such a conference should stress European-wide solutions.

– By promoting the use of worldwide standards, rather than standards that were developed specifically for Europe.

– By engaging, through IHE, with health care providers and clinicians in order to ensure that healthcare IT solutions are exactly fitting with the requirements in care settings.

– By influencing EU institutions and other governments to remove obstacles for the introduction of eHealth solutions (see previous comments on

the eHealth Stakeholders Group).

– By supporting initiatives that improve the quality of vendor's products in an effective way. An example is the IHE Connect-a-thon, where new interoperability profiles are tested. COCIR supports caution with external certification, because this has not yet proven successful. COCIR companies have extensive experience with self-testing in IHE and DICOM.The DICOM standard for application-level interoperability of medical images is one of the, if not the most, successful medical standard and its functionality belongs to the most complex standards in the world.

What do You Consider to be the Most Important Factors in Bringing Unity to the Fragmented European Healthcare IT Sector?

As with the comments made in question 2, we should support a European-wide market in order to achieve an economy of scale. This is only possible with similar roadmaps for similar EHRs with similar purpose. I use "similar" because "the same" is virtually impossible. The health systems themselves may differ in reimbursement, public / private and regional / national aspects. Therefore, the industry itself can do little, and what can be done is done.The context in which the industry operates needs to change in order to obtain a mature European IT industry. This does not mean that COCIR is only for the big, European-wide players – COCIR also very much supports the SMEs in this healthcare IT field, through its non-corporate members: the national associations.

For more information about COCIR, please consult www.cocir.org.

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