

# **Article 29 Data Protection Working Party working paper 131 on the processing of personal data in electronic health records systems**

## **A response from the eHealth Industry Stakeholders Group<sup>1</sup>**

### **1. Introduction**

The eHealth Industry Stakeholders Group (eHISG), reporting to the i2010 eHealth Subgroup, consists of four Membership organisations as follows:

- The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) - representing 16 large healthcare industries directly, and a further 150 companies indirectly through 10 national associations.
- Integrating the Healthcare Enterprise - an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. (IHE)
- European Health Telematics Association (EHTEL) - representing over 60 eHealth stakeholders across Europe including patient groups<sup>2</sup>, providers and payers.
- Continua Health Alliance (CONTINUA) – representing over 100 companies active in personal electronic healthcare.

All of the members of the group have a significant interest in promoting the development and implementation of EHR Systems in Europe. This paper forms a joint response from the four eHealth Industry Stakeholders Group member organisations, but does not preclude further comment from the individual member organisations of COCIR, IHE, EHTEL and Continua Health Alliance.

### **2. Preamble**

The eHISG warmly welcomes the initiative of the Article 29 Data Protection Working Party (Art.29 WP) to comment on the special data protection issues inherent in the use of Electronic Health Record (EHR) systems.

The eHISG notes that the development and adoption of EHR Systems underpins the modernisation of all European health system so that they may be safer, more accountable, more efficient and more able to meet the rising demands of an aging population.

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1 The eHealth Industry Stakeholders Group consists of COCIR ([www.cocir.org](http://www.cocir.org)), IHE ([www.ihe.org](http://www.ihe.org)), EHTEL ([WWW.EHTEL.ORG](http://WWW.EHTEL.ORG)), Continua Health Alliance ([www.continuaalliance.org](http://www.continuaalliance.org)). The secretariat is held by the COCIR. The Group was brought together in response to a request of DG Information Society to bring the perspective of industrial stakeholder to the eHealth Subgroup of the i2010 High Level Group.

2 It should be noted that this current response has been drafted with the co-operation of the EHTEL industry representatives. The Patients and Citizens Working group of EHTEL have drafted a further response focusing on patient related issues.

The eHISG notes in particular that EHR systems contribute significantly to the goals of the ‘Four Cs of Healthcare’: Continuity, Collaboration, Communication and Confidentiality which reinforce the commitment to the continuity of care, collaboration between health professionals, communication between health professionals and their patients, in an environment which respects privacy and shares confidential information in a manner appropriate to the needs of good healthcare provision.

The eHISG firmly believes that European healthcare institutions must continue to develop and adopt EHR systems, building from the stand alone systems used in most European hospitals to fully integrated and interoperable EHR systems connecting primary, secondary and tertiary care.

The eHISG notes that while some EU Member States have made considerable advances in adopting common EHR systems at national and local level, more legal certainty on the way in which such EHRs may be confidentially shared will do much to ensure that the roll out and adoption of such EHR systems covers all 27 Member States.

The eHISG notes that such legal certainty would encourage market confidence in EHRs both on the part of users at local and national level, and vendors operating at local, national and international level.

The eHISG recalls the *Aho Report on "Creating an Innovative Europe"*<sup>3</sup> of January 2006, which recommended the development of innovation-friendly markets and explicitly acknowledged the importance of information and communication technologies (ICT) in tackling specific challenges within the healthcare sector.

The eHISG also recalls the recent report from the European Parliament inviting “the Commission to encourage the Member States to actively support the introduction of e-health and telemedicine”<sup>4</sup> and calling on the Member States’ governments to actively support the introduction of interoperable and transparent information systems allowing for effective exchange and sharing of information on health between healthcare providers in different Member States.

The eHISG notes that interoperability in this context should be based on open standards which can be implemented by any number of vendors so as to permit vendor choice and competition among alternative suppliers.

The eHISG accordingly calls upon the Art.29 WP to support the Commission in its work on eHealth Interoperability Standardisation to ensure that any standards adopted comply with and support data protection principles

### **3. Specific Comments on Working Paper 131 from the eHealth Industry Stakeholders Group**

The eHISG welcomes the focus of the paper on EHR systems. The eHISG notes in particular that EHR systems can range from complete ‘cradle to grave’ records to summary records held in centralized and decentralised systems for local, national and cross-border use. The eHISG calls

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<sup>3</sup> [http://ec.europa.eu/invest-in-research/pdf/download\\_en/aho\\_report.pdf](http://ec.europa.eu/invest-in-research/pdf/download_en/aho_report.pdf)

<sup>4</sup> Ibid, paragraph 9

upon the ART.29 WP to confirm that the data protection principles apply equally to all such systems, regardless of storage and access systems (local, national or cross-border).

The eHISG notes that data subject consent to processing healthcare data, as provided for in article 8(2) of Directive 95/46/EC on data protection, is complex. It therefore calls upon the Art.29 WP to clarify its understanding of 'freely given consent' in application to EHRs in order that the EHR industry can build more user friendly EHR systems which support healthcare professionals in appropriate use opt-in and opt-out consent systems. More clarity on this matter will allow greater interoperability across EHR systems and will thus support the development of the EHR industry in Europe.

The eHISG notes that the Art.29 WP believes that the legal base in article 8(3) of Directive 95/46/EC for the processing of data in EHR systems has only limited application, because much of the data held may reach beyond the scope of that Article. The eHISG agrees with broad arguments put forward by Art.29 WP and calls upon the Art.29 WP to give further guidance on the types of EHR systems to which the article 8(3) as a legal base may apply, given that this is the legal base used in many Member States currently. Such guidance should address also the application of such principles to primary and secondary use of health data within EHR systems, as well as more clarification on the circumstances in which the legal bases of 'vital interests' may legitimately be used.

The eHISG notes that the Art.29 WP concludes that the adoption of a specific legal framework for EHR systems might be desirable.

The eHISG calls upon the Art.29 WP to clarify that if any such legal guidelines on EHR systems are adopted (at EU or Member State level), they should address all issues pertaining to consent, finality of use, access, security and identification as principles and should leave *de facto* or *de jure* standards to establish the appropriate technical support for those principles

The eHISG would caution very strongly against the adoption of any technology specific legal guidelines. The eHISG believes that the explicit mention of technical applications such as smart cards, centralised or decentralised systems and technical aspects of patient and professional identification are not relevant in this context, and may indeed prove to be a further obstacle to the adoption of EHRs in a context where Member States have differing technological legacies and plans.

The eHISG accordingly calls upon the Art.29 WP to adopt a 'no technology religion' approach in any further work it undertakes in this field and to encourage Member States to be similarly technology neutral.

#### **4. Conclusion**

The eHISG warmly welcomes the Art.29 WP report.

The eHISG stresses that legal uncertainty on matters of data protection in EHR systems will undermine the willingness of the industry to invest in suitable EHR systems, and therefore urges the Art.29 WP to work with the Commission to ensure that any legislation or guidelines which are adopted at EU or Member State level will address any such legal uncertainties.

The eHISG notes the conclusion of the Art.29 WP that specific legislation on EHR systems may be required. The eHISG notes that the adoption of any such legislation is likely to take place at Member State level, not least because article 152 of the Treaty confirms that matters of health service organisation are subject to the principle of subsidiarity.

Nevertheless, and following the European Parliament Resolution of June 2007, cross-border nature of health care requires at a minimum a co-ordination of action at the Community level<sup>5</sup>. The eHISG therefore calls upon the Art.29 WP to actively support the European Commission and Member States in the co-ordination of any such legislation so that a maximum level of EHR system interoperability can be achieved. The eHISG notes in particular that the economies of scale for implementation of EHR systems (and hence less costs for the European citizen) are proportional to the level at which the legislation in different Member States is harmonised.

The eHISG also calls on the Art.29 WP, the European Commission and the Member States to ensure that such legislation reflects the issues as set out in this paper.

Finally, the eHISG calls on the Art.29 WP, the European Commission and the Member States to ensure that, as far as possible, all stakeholders are represented in the drafting of such legislation. Experience has shown that legislation which fails to include all user perspectives is very hard to implement in the health setting. Such user perspectives should include a full range of healthcare professionals (including allied health professionals and social care) patients, payers (public and private) eHealth industry representatives as well as suitably experienced technical and legal experts.

Done in Brussels, June 2007

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<sup>5</sup> The European Parliament at point 12 notes that, "whilst health care systems are not a competence of the Community, issues relating to health care systems, such as access to medicines and treatments, patient information, and the movement of insurance companies and health professionals, have a cross-border character; notes that those issues need to be addressed by the Union".