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COMMISSION OF THE EUROPEAN COMMUNITIES

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Explanatory Memorandum

Scope of the Recommendation

COMMISSION RECOMMENDATION

of 2nd July 2008

on cross-border interoperability of electronic health record systems

Explanatory Memorandum

Scope of the Recommendation

The Commission Recommendation on cross-border¹ interoperability of electronic health record systems (hereinafter referred to as 'the Recommendation') has been drafted as a follow-up to the Community eHealth Action Plan² which, in 2004, defined interoperability of electronic health records as one of the priorities for Member States in the roadmap annexed to the Action Plan.

The Recommendation is intended to support the premise that connecting people, systems and services is vital for the provision of good healthcare in Europe insofar as it is necessary to enable the free flow of patients as well as eHealth³ products and services, and hence may contribute significantly to the establishment and functioning of the internal market.

Recent developments in information and communications technology (ICT) systems and services in different Member States have resulted in a proliferation of incompatible ICT formats and standards in healthcare institutions. The resulting lack of interoperability (the ability to 'talk to each other') between health ICT systems in different regions and Member States causes problems for travelling persons and the health professionals who might treat them⁴.

This lack of interoperability is a particular issue for the use of electronic health record systems (EHR systems), which are used to collect digital information about an individual's medical treatments over a certain period of time, perhaps even a lifetime. Fully interoperable EHR systems should make access to patients' information easier, as well as enhance the quality and safety of patient care throughout the Community by providing patients and health professionals with relevant and up-to-date information while ensuring protection of personal data and confidentiality.

When systems become more interoperable, the need for building safeguards against abuse grows as well. Health records are among the most sensitive records available containing information concerning an individual. The unauthorised disclosure of a medical condition or diagnosis could negatively impact an individual's personal and professional life. Maintaining health records in an electronic form increases the risk that patients' information could be accidentally exposed or easily distributed to unauthorised parties⁵.

Interoperability of EHR systems involves transfer of personal data concerning a patient's health. These data should be able to flow freely from one Member State to another, but at the

¹ For the purpose of this Recommendation, the term "cross-border" should be understood as exchanges between neighbouring and non-neighbouring Member States and their entire territories.

² Commission Communication on "eHealth - making healthcare better for European citizens: An action plan for a European eHealth Area" COM(2004) 356 final. http://ec.europa.eu/information_society/activities/health/policy/index_en.htm

³ For the definition of eHealth, see p.4 of the eHealth Action Plan Communication referred to above.

⁴ See: <http://europa.eu.int/idabc/>, <http://www.i2-Health.org/>

⁵ See, in particular, Article 29 Working Party Working Document 131 on the processing of personal data relating to health in electronic health records (EHR), adopted on 15 February 2007. http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf

same time the fundamental rights of the individual should be safeguarded. The fundamental right to the protection of personal data is essentially based on Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms and on Article 8 of the EU Charter of Fundamental Rights. More precise rules are in particular laid down in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data⁶, and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)⁷.

The Recommendation is intended to provide Member States and their relevant bodies with the basic principles on how to address interoperability in the cross-border setting when necessary for a legitimate medical or healthcare purpose. It addresses the steps required to arrive at this ideal solution, and to avoid potential problems caused by a lack of interoperability of such systems. This deployment will support the free movement of people (patients and professionals) and services and will favour the safety of travelling individuals across Europe. Due to the fact that the basic components that need to be addressed in a cross-border setting (identification, security, legal, organisational, technical and semantic interoperability⁸) apply also on the local, regional and national setting, we believe that this Recommendation will also influence the deployment of interoperable electronic health record systems within Member States.

While the Recommendation is considered especially relevant in a cross-border Community context, it has other very obvious benefits at different levels. These include benefits for all European citizens and health professionals in the immediate local and/or regional setting in which they live and work; funding agencies; health insurers; and members of the European healthcare information technology (IT) industry, for which a more homogeneous eHealth market⁹ could be the result. Indeed, eHealth as a specific domain forms part of a wider Information Society approach that is oriented towards eGovernment and ePublic Services, and new forms of services based on public-private partnerships¹⁰.

The aim is to kick-start an eHealth interoperability initiative in an area of activity and operation that is already relatively well defined, and has been explored in detail by a majority of Member States and by international and European standardisation efforts, among others¹¹. It is also intended that the recommended activities will be applicable and relevant to other eHealth services and applications of high priority, such as e-Prescribing. The Recommendation respects the principle of subsidiarity, acknowledging that Member States have prime responsibility for protecting and improving the health of their citizens. It is – as part of that responsibility – for Member States to decide on the organisation and delivery of their own country's health services and medical care. Interoperable eHealth systems and services do not necessarily lead to harmonisation of national healthcare systems; nevertheless, they are a key element in working towards harmonisation of essential medical information

⁶ OJ L 281, 23.11.1995, p. 31.

⁷ OJ L 201, 31.7.2002, p. 37.

⁸ See: <http://europa.eu.int/idabc/en/document/3761>

⁹ See the Commission Communication on "A lead market initiative for Europe" COM(2007)860 final.

¹⁰ Gartner (2007) Preparation for Update European Interoperability Framework 2.0 – Final report. A Report for DIGIT. 14-02-2007.

¹¹ Examples include DICOM, HL7, and the frequently quoted Integrating the Healthcare Enterprise.

and the accessibility of this information to provide patients with more effective and efficient healthcare, by having timely and secure access to basic, and possibly vital, health information. Thus, they help to ensure the right of access of citizens to preventive health care and the right to benefit from medical treatment, as recognised by Article 35 of the Charter of Fundamental Rights of the European Union.

The Recommendation outlines the general guidelines which should thus apply to all Member States, each of which has its own health system(s) and service(s). The Recommendation also has relevance for the European Economic Area countries, and for the suppliers, buyers and economic stakeholders that operate in the eHealth field within the internal market of the European Union.

1.1. The framework of the Recommendation

The Recommendation is based on Article 211 of the Treaty establishing the European Community but there are a number of relevant texts related to its domain, such as:

- Article 5 of the Treaty establishing the European Community, which focuses on the subsidiarity principle;
- Article 152 of the Treaty establishing the European Community, which ensures a high level of human health protection in the definition and implementation of all Community policies and activities, complements national policies in the public health sphere and respects the responsibilities of the Member States for the organisation and delivery of health services and medical care;
- Article 7 of the Charter of Fundamental Rights of the European Union on the right to respect for private and family life;
- Article 8 of the Charter of Fundamental Rights of the European Union on the right of every individual to the protection of his or her personal data;
- Article 35 of the Charter of Fundamental Rights of the European Union on the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices;
- Conclusions of the Council on Common values and principles in European Union Health Systems¹²;
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Personal Data Protection Directive)¹³;
- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)¹⁴;

¹² OJ C 146, 22.6.2006.

¹³ OJ 281, 23.11.1995, p.31.

¹⁴ OJ L 201, 31.7.2002, p. 37.

- Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (Transparency Directive)¹⁵;
- Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC, laying down a procedure for the provision of information in the field of technical standards and regulations (Information Services Directive)¹⁶;
- Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications¹⁷;
- Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on Electronic Commerce)¹⁸;
- The Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions "eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area"¹⁹;
- The Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions "A Lead Market Initiative for Europe"²⁰;
- The Communication from the Commission to the European Parliament and the Council on the role of European standardisation in the framework of European policies and legislation²¹;
- The Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions – "i2010 – A European Information Society for growth and employment";²²;
- The Communication from the Commission to the European Parliament and the Council on Promoting Data Protection by Privacy Enhancing Technologies (PETs);²³
- European Parliament Resolution of 23 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market²⁴;

¹⁵ OJ L 204, 21.7.1998.

¹⁶ OJ L 217, 5.8.1998.

¹⁷ OJ L 255, 30.9.2005, p. 22. Directive as last amended by Council Directive 2006/100/EC (OJ L 363, 20.12.2006, p. 141).

¹⁸ OJ L 178, 17. 7. 2000, p. 1.

¹⁹ COM(2004) 356 final.

²⁰ COM(2007) 860 final.

²¹ COM (2004) 674 final.

²² COM (2005) 229 final

²³ COM(2007)228 final

²⁴ See:<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0201+0+DOC+XML+V0//EN&language=EN>

- Mandate M/403 EN (2007) Standardisation mandate addressed to CEN, CENELEC and ETSI in the field of Information and Communication Technologies applied to the domain of eHealth.

1.2. Objectives and benefits

While the eventual purpose of the Recommendation is to contribute to the achievement of overall **European eHealth interoperability by the end of 2015**, there is an immediate need to start a dialogue on achieving this goal, with a view to developing a **process** through which the appropriate concrete activities and tasks can be undertaken. In turn, these objectives should be supported by the relevant human, organisational and financial resources. The Recommendation therefore proposes a set of guidelines that ought to be attained by individual Member States to ensure the minimum level of compatibility and communication with fellow Member States. The guidelines address the following **four objectives**:

- (1) **To outline and agree the principles** on which there should be broad agreement and engagement in regard to cooperation on shared and interoperable eHealth information: conditions which were outlined initially in the eHealth Conference 2007 Declaration²⁵. A framework will be created that enables the Member States to participate and to identify an appropriate role for themselves regardless of the particular size or type of country or type of health system. The activities directed to ensure the interoperability of electronic health record systems shall be planned ahead for at least for 5 years to ensure policy consistency²⁶;
- (2) **To enable interoperability between health information shared among different healthcare systems**, which is to be based on a limited range of applications currently existing and in use in different Member States. This approach will be founded on a number of distinct challenges such as resolution of appropriate and secure identifiers for patients, health professionals and institutions. Where appropriate, the steps should make use of existing standards²⁷, and be based on the approaches and achievements of relevant initiatives²⁸. The involvement of a wide variety of user groups in this process is welcomed;
- (3) **To resolve the various challenges of achieving cross-border interoperability of electronic health record systems in the Community** by building appropriate networked systems and services that cover the entire continuum of care, and that are underpinned by the appropriate legal and regulatory, medical and care requirements. The understanding is that the necessary actions will be built on the minimum

²⁵ eHealth Conference 2007 Declaration, 17 April 2007.
http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=3370

²⁶ For example the "English National Programme for IT" involves a 13-year timescale and is perceived as a fundamental enabler of healthcare reform. See also 'eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites':
http://europa.eu.int/information_society/activities/health/docs/publications/ehealthimpactsept2006.pdf

²⁷ European Standardisation Organisations: European Committee for Standardisation (CEN), www.cen.eu, European Committee for Electrotechnical Standardisation (CENELEC), www.cenelec.org, European Telecommunications Standards Institute (ETSI), www.etsi.org, International Organisation for Standardisation (ISO) www.iso.org and other standardisation bodies.

²⁸ Examples of such initiatives include: Integrating the Healthcare Enterprise (IHE), Continua Health Alliance, European Coordination Committee of the Radiological and Electromedical Industry (COCIR), European Institute for Health Records (EUROREC), European Health Telematics Association (EHTEL) etc.

infrastructure and minimum measures required, in line with the principle of proportionality;

- (4) **To assess not only the benefits, but also the barriers, hurdles and potential threats to achieving eHealth interoperability, and to identify the necessary preconditions and relevant incentives to overcoming these.**

The ultimate goal of the Recommendation is, therefore, to contribute to creating a means whereby **authorised health professionals can gain managed access to essential health information about patients, subject to the patients' consent, and with full regard for data privacy and security requirements.** Such information could include the appropriate parts of a patient's **electronic health or medication record, patient summary, and emergency data** accessible from any place in the Community.

The Recommendation is intended to lead **to benefits** that are both **social** and **economic**. Interoperability of electronic health record systems is claimed to be an appropriate means to:

- bring about better quality of treatment because of better information about the patient;
- improve the cost efficiency of medical treatments and thus prevent further rapid growth of health care budget deficits²⁹;
- furnish the necessary data for quality control, statistics and planning in the public health care sector which should also have a positive effect on public health care budgets.

Interoperability of EHR systems will support the concept of more accessible, high-quality, cost-effective and sustainable health services and systems, especially in the context of cross-border citizen and patient mobility³⁰. The potential benefits are by no means limited to those outlined in this text. Rather, **a wide range of benefits, particularly with regard to patient safety, are laid out in detail** in two Commission publications^{31,32}. From an economic perspective, **the potential benefits of interoperable exchange of health-related data** among healthcare institutions are expected to be substantial. Health and healthcare are important not only for each individual but also in **providing important indicators of the state of a society**. **Statistics about health** are an important part of a health information system: for example, in relation to medical research and the combating of chronic diseases and/or pandemics.

²⁹ For many Member States, healthcare budgets may be spread across a range of ministries or authorities that encompass, for example, social care, industry or innovation, education or sport, research, etc. For budgetary purposes, and as a rule of thumb, the earmarking of at least 3,0% of the annual health budget may be considered as a valuable indicator in order to achieve successful eHealth deployment. Despite this, the figure is given as indicative; the actual budgets from which the proposed sum is extracted may differ according to Member State.

³⁰ European Parliament Resolution of 23 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market (2006/2275(INI)).

³¹ European Commission (2006) "Connected Health:Quality and safety for European citizens". Luxembourg: European Communities. http://ec.europa.eu/information_society/activities/health/docs/policy/interoperability_report_final092006-cover.pdf

³² European Commission (2007) "eHealth for Safety - Impact of ICT on Patient Safety and Risk Management" http://ec.europa.eu/information_society/activities/health/docs/studies/eHealth-safety-report-final.pdf

When implementing interoperability of electronic health record systems, it should be pointed out that EHR systems create a significant new risk scenario for processing of personal data concerning health, which calls for new, additional safeguards and counterbalances: maintaining the legal standard of confidentiality suitable within a traditional paper record environment may be insufficient to protect the privacy interests of a patient once electronic health records are put online. EHR systems thus pose significant challenges in ensuring that only appropriate health professionals gain access to information for legitimate purposes related to the care of the data subject³³.

The Recommendation underlines the applicability of Directive 95/46/EC to personal data processed in EHR systems. It reiterates that processing of personal data contained in EHR systems is particularly sensitive and therefore subject to the special data protection rules on the processing of sensitive data. Article 8 of Directive 95/46/EC prohibits in principle the processing of sensitive data concerning health. Limited exemptions to this prohibition principle are laid down in the Directive, in particular if processing is required for specified medical and healthcare purposes.

The Recommendation foresees the adoption by Member States of a comprehensive legal framework for setting up an interoperable EHR system, which should address measures of a technical and organisational nature appropriate for prevention and fight against identity theft and other privacy-intrusive attacks³⁴, avoiding loss or unauthorized alteration, processing and access of data in the EHR system. Integrity of the system should be guaranteed by making use of the knowledge and instruments representing the present state of the art in computer science and information technology. Security and privacy enhancing technologies (PETs)³⁵ should be embedded in the design and implementation of EHR systems before their widespread deployment ("security and privacy-by-design") in order to promote personal data protection. The possibility of using less intrusive alternatives to online access to electronic documents should be considered, and online access to electronic documents containing certain categories of personal data concerning health should be excluded altogether or at least be subject to especially strict online controls.

EHR systems should be construed in a user-friendly way to broaden their application by health professionals and patients. The patients should still have the possibility for alternative (conventional) means to access their personal data concerning health. The necessary costs for achieving cross-border interoperability of electronic health record systems should be seen as an investment into the fundamental rights compatibility, which will be one of the most important prerequisites if EHR systems are to become a success.

1.3. Comments on the Commission's recommendations

Member States are invited to undertake actions at **five** levels. These are the **overall political level**; the **organisational level**; the **technical level**; and the **semantic level**. Underpinning all of these activities is a commitment to various **education** and **awareness raising** mechanisms.

³³ For detailed information see Article 29 Working Party Working Document 131 on the processing of personal data relating to health in electronic health records (EHR), adopted on 15 February 2007. http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf

³⁴ See Commission Communication on a strategy for a secure Information Society, COM(2006) 251 final, 31. 5. 2006.

³⁵ See Commission Communication on Promoting Data Protection by Privacy Enhancing Technologies (PETs) Brussels, 2.5.2007, COM(2007) 228 final.

- **At the overall political level:** To build a political platform that is aimed at setting up the necessary regulatory and financial environment so as to render eHealth infrastructure and services interoperable. This could involve more effective coordination and harmonisation – where necessary – of the Member States’ legislation, and to consider means of incentives to invest in the eHealth area³⁶;
- **At the organisational level:** To agree on an organisational framework for interoperability that recognises the autonomy of each Member State in relation to the development of the relevant eHealth infrastructure and services. It should create a common domain, accompanied by the necessary interfaces, that enables the national domains to interact;
- **At the technical level:** To promote the use of technical standards and architectures, and the **establishment** of common interoperability platforms. To apply the joint or mutually recognised mechanisms for conformity testing and certification as well as techniques and methodologies offered by various industry consortia³⁷;
- **At the semantic level:** To coordinate efforts geared towards semantic activities by agreeing on common **priorities and specific applications**³⁸;
- **At the level of education and awareness raising:** To evaluate, monitor, analyse and reflect on all the intended **developments** and possible others in the eHealth interoperability field, and to consider various education mechanisms.

The Commission will also continue its efforts to coordinate actions and exchange experiences with the Community’s trading partners in the context of open standards to be used for technical and semantic interoperability that will assist in the development of a single market for interoperable products. The Transatlantic Economic Initiative and the Transatlantic Economic Council could provide appropriate fora for such coordinated actions³⁹. In particular, reference to the patient summary, electronic health or medication record, and relationships with, for example, the European Medicines Agency or the United States Food and Drugs Administration, should also be explored.

³⁶ Cohesion Policy financial instruments such as the European Regional Development Fund provide the possibility to invest in eHealth – see the Council Decision of 6 October 2006 on Community Strategic Guidelines on Cohesion, OJ L 291, 21. 10.2006, http://ec.europa.eu/regional_policy/sources/docoffic/2007/osc/l_29120061021en00110032.pdf

The Member States have allocated in their Operational Programmes for 2007-2013 €5.2 billion for investments on ICT services and applications for citizens. Of this amount some €4.4 billion will be invested in Convergence regions and some €147 million are foreseen for trans-national or cross-border activities.

³⁷ For example Q-Rec initiative, see <http://www.eurorec.org> and "Integrating the Healthcare Enterprise-Europe": see <http://ihe-Europe.org>

³⁸ Wherever possible, consider the suitability of international terminologies, such as Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) and terminologies and nomenclatures used for pharmacovigilance and clinical trials (see: <http://www.ihtsdo.org>) and classifications such as WHO International Classification of Diseases (ICD), see: <http://www.who.int/classifications/icd/en/>

³⁹ See http://ec.europa.eu/trade/issues/bilateral/countries/usa/pr010306_en.htm, and http://www.eu2007.de/en/Meetings_Calendar/Dates/April/0430-RAA1.html

Draft

COMMISSION RECOMMENDATION

of

on cross-border interoperability of electronic health record systems

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 211 thereof,

Whereas:

- (1) The strategic initiative i2010 which is an initiative for growth and employment – builds on information and communication technology policies, research and innovation to help achieve the goals of the Lisbon Strategy. The i2010 initiative promotes the building of European Information Society and encourages provision of better public services, including eHealth.
- (2) Resolving existing and future challenges to European healthcare systems is possible, at least partly, through deployment of proven information and communication technology-enabled solutions (eHealth). A major requirement to use benefits of eHealth is improved cooperation regarding interoperability of Member States' eHealth systems and applications. Electronic health record systems form a fundamental part of eHealth systems.
- (3) Electronic health record systems have the potential to achieve greater quality and security in health information than the traditional forms of health records. Interoperability of electronic health record systems should make access easier, and enhance the quality and safety of patient care throughout the Community by providing patients and health professionals with relevant and up-to-date information while ensuring the highest standards of protection of personal data and confidentiality. Enhancing cross-border cooperation in the domain of eHealth requires cooperation between providers, purchasers and regulators of healthcare services in different Member States. At the same time any measure relating to interoperability need not necessarily lead to the harmonisation of laws and regulations of the organisation and delivery of healthcare in Member States.
- (4) Lack of interoperability of electronic health record systems is one of the major obstacles for realising the social and economic benefits of eHealth in the Community. Market fragmentation in eHealth is aggravated by the lack of technical and semantic interoperability. The health information and communication systems and standards currently used in Member States are often incompatible and do not facilitate access to vital information for provision of safe and good quality healthcare across different Member States.

- (5) The Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions "eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area", presented on 30 April 2004⁴⁰, outlines the potential of eHealth systems and major challenges for its wide deployment. The Action Plan outlined in this Communication calls for joint Community and Member States action on interoperability of electronic health record systems.
- (6) The Declaration of the High Level eHealth Conference in 2007 acknowledged the importance of starting joint initiatives among Member States by strengthening a range of activities related to interoperability of electronic health record systems.
- (7) The Commission responded to the report "Creating an Innovative Europe" of the independent expert group with the Communication "A Lead Market Initiative for Europe"⁴¹ that aims at the creation and marketing of innovative products and services in lead industrial and social areas, including eHealth. One of the main targets of the proposed initiatives to boost the interoperability of electronic health record systems, since the health information and communication systems and standards currently used in Member States are often incompatible and thus present a barrier to the emergence of cost-effective and innovative information technology solutions for healthcare.
- (8) The European Parliament, on 23 May 2007, passed a Resolution on the impact and consequences of the exclusion of health services from the Directive on services in the internal market⁴². The Resolution invites the Commission to encourage Member States to actively support the introduction of eHealth and telemedicine, particularly by developing interoperable systems allowing the exchange of patient information between healthcare providers in different Member States.
- (9) The purpose of the Recommendation is to contribute to development of overall European eHealth interoperability by the end of 2015.
- (10) This Recommendation respects and observes the principles recognised by the Charter of Fundamental Rights of the European Union, in particular Article 7 on the right to respect for private and family life and Article 8 on the right of every individual to the protection of his or her personal data.
- (11) Health records are among the most sensitive records available containing information concerning an individual. The unauthorised disclosure of a medical condition or diagnosis could negatively impact an individual's personal and professional life. Maintaining health records in an electronic form increases the risk that patients' information could be accidentally exposed or easily distributed to unauthorized parties.
- (12) Interoperability of electronic health records involves transfer of personal data concerning a patient's health. These data should be able to flow freely from one Member State to another, but at the same time the fundamental rights of the individual should be safeguarded. This Recommendation should therefore be without prejudice to

⁴⁰ COM(2004) 356 final.

⁴¹ COM(2007) 860 final.

⁴² (2006/2275(INI))

the Community provisions on the protection of personal data consisting in particular of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data⁴³, and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)⁴⁴.

- (13) The Commission considers that Privacy Enhancing Technologies (PETs) should be developed and more widely used where personal data is processed through ICT networks in relevant fields such as eHealth.⁴⁵

HEREBY RECOMMENDS:

- (1) This Recommendation provides a set of guidelines for developing and deploying interoperable electronic health record systems, allowing for cross-border exchange of patient data within the Community so far as necessary for a legitimate medical or healthcare purpose. Such electronic health record systems should enable healthcare providers to ensure that a patient receives care more effectively and efficiently by having timely and secure access to basic, and possibly vital, health information, if so needed and in conformity with the patient's fundamental rights to privacy and data protection.
- (2) This Recommendation provides guidance for interoperability of electronic health record systems, including patient summaries, emergency data sets, medication records facilitating ePrescription solutions.
- (3) For the purposes of this Recommendation the following definitions are applied:
 - (a) "patient" means any natural person who receives or wishes to receive health care in a Member State;
 - (b) "health professional" means a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications⁴⁶ or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC;
 - (c) "electronic health record" means a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes;

⁴³ OJ L 281, 23.11.1995, p. 31.

⁴⁴ OJ L 201, 31.7.2002, p. 37.

⁴⁵ COM(2007) 228 final

⁴⁶ OJ L 255, 30.9.2005, p. 22. Directive as last amended by Council Directive 2006/100/EC (OJ L 363, 20.12.2006, p. 141).

- (d) "electronic health record system" means a system for recording, retrieving and manipulating information in electronic health records;
 - (e) "patient's summary, emergency data set, medication record" mean subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription;
 - (f) "ePrescription" means a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC⁴⁷, issued and transmitted electronically;
 - (g) "interoperability of electronic health record systems" means the ability of two or more electronic health record systems to exchange both computer interpretable data and human interpretable information and knowledge;
 - (h) "cross-border interoperability" means interoperability between neighbouring and non-neighbouring Member States and their entire territories;
 - (i) "semantic interoperability" means ensuring that the precise meaning of exchanged information is understandable by any other system or application not initially developed for this purpose.
- (4) Achieving and maintaining cross-border interoperability of electronic health record systems implies managing a continuous process of change and the adaptation of a multitude of elements and issues within and across electronic infrastructures in Member States. These electronic infrastructures are necessary to exchange information, interact cooperate in order to ensure the highest possible levels of quality and safety in healthcare provision to patients. Implementing interoperability of electronic health record systems will require a complex set of framework conditions, organisational structures and implementation procedures involving all relevant stakeholders.
- (a) To achieve this, Member States are invited to undertake actions at five levels, namely the overall political, the organisational, the technical, the semantic and the level of education and awareness raising.
 - (b) Underpinning these activities will be full compliance with national as well as Community legal instruments, in particular for the protection of personal data, including confidentiality and data security. The necessary legal safeguards should be ensured, together with the embedding of data protection safeguards in the design and implementation of electronic health record systems. Furthermore, it is indispensable to develop mechanisms for education of both patients and professionals as well as for the evaluation and monitoring of activities necessary for ensuring the interoperability of electronic health record systems.

The political level of cross-border interoperability of electronic health record systems

⁴⁷ OJ L 311, 28.11.2001, p. 67.

- (5) At the level of political feasibility and commitment to electronic health record systems interoperability, it is recommended that Member States:
- (a) commit politically and strategically to the implementation at local, regional and national level of electronic health record systems that are capable also of interoperating with electronic health record systems in other Member States;
 - (b) engage in active cooperation with other Member States and relevant stakeholders to ensure the adoption and implementation of standards that make the cross-border interoperability of electronic health record systems feasible and secure;
 - (c) implement interoperability of electronic health record systems as an integral part of regional and national eHealth strategies;
 - (d) consider the inclusion of eHealth in national and regional strategies for territorial cohesion and development and analyse the results of already deployed electronic health record systems at the level of eHealth policy and financing possibilities. For the period 2007-2013 the support for developing eHealth interoperability through investments in eHealth and trans-national and cross-border activities is provided within the framework of cohesion policy;
 - (e) analyse the risks, barriers or missing elements in relation to achieving cross-border interoperability of electronic health record systems, and identify the necessary preconditions and relevant incentives to solve the problems;
 - (f) reserve adequate resources, for example by means of direct incentives, to invest in electronic health record systems;
 - (g) recognise that investments in both technical and semantic interoperability can be beneficial in the shorter term, applying a step-by-step approach and examples of best practice, drawing on priorities and expertise of Member States;
 - (h) consider the creation of other financial indirect incentive mechanisms to enable the adoption, acquisition and/or modernisation of interoperable electronic health record systems;
 - (i) plan the activities directed to ensure the interoperability of electronic health record systems ahead for at least five years. Such a timescale is deemed appropriate to ensure policy consistency - which is often a precondition for increasing investment and innovation;
 - (j) accompany implementation of electronic health record systems by strong involvement of users and other stakeholders in establishing adequate governance, management, public-private partnerships, public procurement, planning, implementation, evaluation, training, information and education;
 - (k) raise awareness among relevant stakeholders such as local and regional authorities, health professionals, patients and industry of the benefits and need for interoperability of electronic health record systems.

The organisational level of cross-border interoperability of electronic health record systems

- (6) It is essential to create an organisational framework and process that will enable cross-border interoperability of electronic health record systems. This should be based on a roadmap, developed by Member States, which covers a five-year period and provides details with regard to the following milestones:
- (a) agree on a European governance process to establish guidelines for developing, implementing and sustaining cross-border interoperability of electronic health record systems covering management for reliable identification of patients and authentication of health professionals as well as other relevant issues as described in points 7, 8, 9 and 14;
 - (b) consider policies and incentives to increase demand for procuring eHealth services to enable interoperability of electronic health record systems;
 - (c) analyse the factors which render the standardisation processes leading to higher levels of interoperability of electronic health record systems such a long, complex and expensive activity, and devise measures to speed up these processes;

Technical interoperability of electronic health record systems

- (7) Compatibility of electronic health record systems at the technical level is the essential prerequisite for interoperable electronic health record systems. Member States should:
- (a) undertake a comprehensive survey of existing technical standards and infrastructures that may facilitate the implementation of systems supporting cross-border healthcare and the provision of healthcare services throughout the Community, especially those related to electronic health records and exchange of information;
 - (b) analyse the use of standardised information models and standards-based profiles when developing and implementing interoperable electronic health record systems and services solutions. Consider standardised information models and standards-based profiles to be part of national or regional specific interoperability specifications. Where appropriate, these information models and profiles should make use of existing European and international standards, and be based on the approaches and achievements of relevant industrial initiatives;
 - (c) commit to the development of any necessary additional standards, preferably open standards on a global scale, involving the relevant European and international standardisation bodies in the key areas where shortcomings have been identified;
 - (d) analyse the achievements of the Mandate M 403: "Mandate to the European Standardisation Organisations CEN, CENELEC and ETSI in the field of Information and Communication Technologies, applied to the domain of eHealth" in order to provide optimal technological foundations, infrastructure, safety and regulatory integration in Europe and within global markets.

Semantic interoperability of electronic health record systems

- (8) Semantic interoperability is an essential factor in achieving the benefits of electronic health records to improve the quality and safety of patient care, public health, clinical research, and health service management. The Member States should:
- (a) establish an appropriate mechanism in cooperation with the relevant standards development organisations, the Commission and the World Health Organisation, to involve national research centres, relevant industries and stakeholders in the development of health semantics to advance in implementation efforts of interoperable electronic health record systems;
 - (b) wherever possible, consider the suitability of international medical-clinical terminologies, nomenclatures and classifications of diseases, including those for pharmacovigilance and clinical trials; the establishment of competence centres for multilingual and multicultural adaptation of international classifications and terminologies should also be encouraged;
 - (c) agree on standards for semantic interoperability to represent the relevant health information for a particular application through data structures (such as archetypes and templates), and subsets of terminology systems and ontologies responsive to local user needs;
 - (d) consider the need for a sustainable reference system of concepts (ontology) as a basis for mapping multilingual lexicons that take into account the difference between professional healthcare languages, lay terminologies and traditional coding schemes;
 - (e) support the widespread availability of methodologies and tools for incorporating the semantic content into practical applications as well as the development of relevant human capacity and skills in this domain;
 - (f) demonstrate the benefits and/or shortcomings of current and future systems through scientifically sound evaluation and assessment.

Certification of electronic health record systems

- (9) There is a need for a mutually recognisable conformity testing procedures that are valid throughout the Community or which serve as a basis for each Member State's certification mechanism. Therefore Member States should:
- (a) apply properly the existing eHealth standards and profiles, namely those related to interoperability of electronic health record systems, in order to enhance the confidence of users in those standards;
 - (b) put into place a joint or mutually recognised mechanism for conformity testing and certification of interoperable electronic health records and other eHealth applications, such as the techniques and methodologies offered by various industry consortia;

- (c) consider the industry self-certification and/or conformity testing activities as a mechanism to reduce delays in bringing interoperable eHealth solutions to the market;
- (d) take into account national and international practices, including those which exist outside Europe.

Protection of personal data

- (10) Member States should ensure that the fundamental right to protection of personal data is fully and effectively protected in interoperable eHealth systems, in particular in electronic health record systems, in conformity with Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.
- (11) Directive 95/46/EC applies to personal data processed in application of this Recommendation. Processing of personal data contained in the electronic health records and their systems is particularly sensitive and therefore subject to the special data protection rules on the processing of sensitive data. Article 8 of Directive 95/46/EC prohibits in principle the processing of sensitive data concerning health. Limited exemptions to this prohibition principle are laid down in the Directive, in particular if processing is required for specified medical and healthcare purposes.
- (12) Member States should be aware that interoperable electronic health record systems increase the risk that personal data concerning health could be accidentally exposed or easily distributed to unauthorized parties, by enabling greater access to a compilation of the personal data concerning health, from different sources, and throughout a lifetime.
- (13) Member States should follow the guidance on electronic health record systems provided for by the Working Party set up under Article 29 of Directive 95/46/EC⁴⁸.
- (14) Member States should lay down a comprehensive legal framework for interoperable electronic health record systems. Such a legal framework should recognise and address the sensitive nature of personal data concerning health and provide for specific and suitable safeguards so as to protect the fundamental right to protection of personal data of the individual concerned.

This legal framework should in particular:

- (a) analyse different personal data protection impacts of organisational alternatives for storing personal data concerning health and establish organisational structures for electronic health record systems in view of the specific risks for the rights and freedoms of data subjects, which best reflect the national, regional and local specifications and practices;
- (b) guarantee the patient's self-determination by allowing for the patient's autonomous and freely taken decision, supported by means of user-friendly technology, as to which personal data concerning health are to be stored and

⁴⁸ See at present Working Document 131 of 15 February 2007 on the processing of personal data relating to health in electronic health records.

disclosed to whom in his or her electronic health record unless expressly required by national law. This decision shall be without prejudice to the possibility for the relevant healthcare body or doctor to store this data for treatment purposes;

- (c) establish that electronic health record systems are designed and selected in accordance with the aim of collecting, processing or using no personal data or as little personal data as possible. In particular, use is to be made of the possibilities for pseudonymisation or rendering persons anonymous, in so far as this is possible and the effort involved is reasonable in relation to the desired level of protection;
- (d) provide for an assessment of the information security risks and personal data protection impacts prior to the implementation of an electronic health record system, in view of the specific risks for the rights and freedoms of data subjects;
- (e) clarify the extent to which categories of personal data concerning health should be made available in electronic form or online. In particular, certain categories of personal data concerning health such as genetic or psychiatric data may have to be excluded from online processing altogether or at least be subject to especially strict access controls;
- (f) prescribe that processing of personal data in electronic health records and their systems must be required and carried out only by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person subject to an equivalent obligation of secrecy; ensure a reliable identification of patients and health professionals;
- (g) determine the conditions under which health data contained in electronic health record systems can be lawfully accessed and processed by persons other than the individual concerned, and for what predefined health purposes, including the security that should be assured while processing health data; specify these issues as policies that can be practically applied, technically implemented and enforced, inter alia by the national data protection supervisory authorities;
- (h) ensure that patients are fully informed on the nature of the data and the structure of the electronic health record containing them. Patients should have alternative (conventional) means to access personal data concerning health related to him or her. In this context it is important to ensure that information provided to data subjects uses language and a layout that is easy to understand and is given in an appropriate manner to persons with special needs (e.g. children or elderly persons);
- (i) provide for special measures to prevent patients from being illegally induced to disclose their personal data contained in electronic health record systems;
- (j) make sure that any processing - especially the storage - of personal data in electronic health record systems takes place within jurisdictions applying Directive 95/46/EC or those with an adequate level of protection of personal data;.

- (k) lay down detailed auditing requirements for the purpose of ensuring compliance with data protection obligations, such as reliable system of electronic identification and authentication, data access logging, documentation of all processing steps, duration of maintaining the auditing information, effective back up and recovery systems, and enforce the adoption of these requirements or solutions according to best practices for information handling;
 - (l) guarantee the confidentiality of electronic health record systems as well as provide for appropriate technical and organisational measures, including rules on incident detection and management processes, in case of a breach of security or identity mechanisms leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to personal data transmitted, stored or otherwise processed in electronic health record systems. Incidents or violations should be identified promptly and effectively and measures or solutions should be put in place to manage such incidents, including informing and involving the individuals concerned, the national data protection supervisory authorities, and other appropriate stakeholders.
- (15) Member States should furthermore:
- (a) stimulate the deployment of security-enhancing products, processes and services to prevent and fight identity theft and other privacy-intrusive attacks;
 - (b) ensure that data protection safeguards are embedded in electronic health record systems, including through the widest possible use of Privacy Enhancing Technologies (PETs) in their design and implementation.

Monitoring and Evaluation

- (16) In order to ensure monitoring and evaluation of cross-border interoperability of electronic health record systems, Member States should:
- (a) consider the possibilities for setting up a monitoring observatory for interoperability of electronic health record systems in the Community to monitor, benchmark and assess progress on technical and semantic interoperability for successful implementation of electronic health record systems;
 - (b) undertake a number of assessment activities. These could include defining the quantitative and qualitative criteria for measuring the eventual benefits and risks (including economic benefits and cost-effectiveness) of interoperable electronic health record systems and assessing the benefits and risks achieved by the systems and services developed by such practical demonstrators as the Large Scale Pilot projects ('Pilot Actions A') that are incorporated within the Competitiveness and Innovation Programme ICT Policy Support Programme.

Education and Awareness Raising

- (17) In terms of education, training and awareness raising, Member States should:
- (a) increase awareness about the benefits of and need for standards in electronic health record systems and their interoperability among producers and vendors

of information and communication technologies, healthcare providers, public health institutions, insurers and other stakeholders;

- (b) consider requirements for education and training with regard to health policy-makers and health professionals;
 - (c) Pay particular attention to education, training and dissemination of good practices in electronically recording, storing and processing clinical information as well as in gaining informed consent of the patient and lawfully sharing patient's personal data;;
 - (d) provide parallel information and training, including awareness raising, for all individuals, in particular patients. Such an approach would make for more effective use of health information as patients move between a variety of healthcare providers, along the continuum of care, and receive whenever possible treatment, care and data in their own homes.
- (18) Member States are invited to report, on a yearly basis, to the Commission on the measures they have taken in relation to the implementation of cross-border interoperability of electronic health record systems. The first report should be presented by Member States one year following the day of publication of this Recommendation.
- (19) The Recommendation is addressed to Member States.

Done at Brussels,

For the Commission

Member of the Commission