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<u>DRAFT REVISED</u> DOCUMENT IN PREPARATION OF

DRAFT RECOMMENDATION OF THE COMMISSION

on eHealth interoperability

Text with EEA relevance.

This document is designed and structured using the format of a Commission recommendation, and has received informal commentary from DG INFSO ICT for Health Unit on 11 July, 2007. It continues to follow the agreed content of an earlier 6 June, 2007 text which received substantial commentary from the eHealth stakeholders' (industry and users) group. Earlier, very detailed, commentary had also been received on a preparatory document outline dated 30 April, 2007; that document had been circulated to, and received detailed feedback from, the relevant Member State representative, expert, and stakeholder eHealth groups, and various eHealth projects and studies.

The Commission of the European Communities

Having regard to

The principal relevant Treaty articles:

- Art. 5 of the ECT[i] (which establishes the European Community and focuses on the subsidiarity principle).
- Art. 6 of the EUT[ii] The Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950.
- Art. 12 of the ECT. Within the scope of application of this Treaty, and without prejudice to any special provisions contained therein, any discrimination on grounds of nationality shall be prohibited (equal access to healthcare services).
- Art. 95 of the ECT The Commission, in its proposals … concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.
- Title XIII Public Health, Art. 152 of the ECT (which ensures a high level of human health protection in the definition and implementation of all Community Policies and activities).
- Art. 154-156 of the Treaty (which set the objective of establishing Trans-European networks in the areas of transport, telecommunications and energy. These networks will enable the citizens of the Union, economic operators, and regional and local communities to derive full benefit from the setting-up of an area without internal frontiers).
- Art. 163 of the Treaty (which emphasises the development of research and technological international competitiveness of the European industry).
- Art. 174 of the ECT Community policy on the environment shall contribute to pursuit of the following objectives….protecting human health.

Various other documents:

- The Charter of Fundamental Rights of the European Union (EU) (see in particular Art. 35 on health care) which recognises that having access to high-quality healthcare when and where it is needed is a priority issue for European citizens.
- Directive 95/46/CE of the European Parliament and of the Council of 25 October 1995 on the protection of individuals with regards to the processing of personal data and on the free movement of such data.
- Directive 2002/58/CE 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).
- 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).
- Directive 2006/24/CE of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of

public communications networks and amending Directive 2002/58/EC.

- Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on recognitions of professional qualifications.
- Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provisions of information in the field of technical standards and regulations.
- Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 on Information Society Services.
- Council Regulation (EEC) No. 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community.
- Regulation (EC) No. 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.
- Council Resolution of 28 October 1999 and its Conclusions of 1 March 2002 on the role of standardisation in Europe.
- COM(2002) 263 final *Europe 2005 action plan*.
- Conclusions of the Council of the European Union on patient mobility and health care developments in the European Union (19 April 2004).
- The Framework and Recommendations stated in the report produced by the Unit responsible for Interoperable Delivery of European eGovernment Services to public Administrations, Businesses and Citizens (IDABC) on the European Interoperability Framework (2004).
- Comité Européen de Normalisation (CEN)/European Committee for Standardisation) Workshop Agreement (CWA) 15 264 - Part 1: *eAuthentication: Architecture for a European interoperable eID system within a smart card infrastructure* (April 2004).
- COM(2004)674 final Communication on the *Role of European standardisation in the Framework of European policies and legislation*.
- COM(2004)356 final: *e-Health – making healthcare better for European citizens: An action plan for a European e-Health area*, and particularly the eHealth action plan which occupies the final three pages of the document.
- COM(2005)229 final *i2010 – European Information Society 2010 - strategic framework*.
- eGovernment Communication on *Interoperability for Pan-European eGovernment Services*, 2005
- 2006/2275 (INI) Provisional edition. *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*.
- M/403 EN (2007) *Standardisation mandate addressed to CEN, CENELEC and ETSI in the field of Information and Communication Technologies*.

And the relevant jurisprudence:

- For example, Case C-120/95 Decker [1998] ECR I-1831; Case C-158/96 Kohll [1998] ECR I-1931; Case C-368/98 Vanbraekel [2001] ECR I-5363; Case C-157/99 Smits and Peerbooms [2001] ECR I-5473; Case C-56/01 Inizan [2003] ECR I-12403; Case C-385/99 Müller-Fauré and Van Riet [2003]; Case C-8/02 Leichtle [2004]; ECR I-2641; ECR I-4503; Case C-372/04 Watts [2006].

Whereas

1. The European Union Member States have the prime responsibility for protecting and improving the health of their citizens and, as part of that responsibility, it is for them to decide on the organisation and delivery of health services and medical care.

2. When exercising these competences, Member States nonetheless have to comply with Community law, including the case law formulated by the Court of Justice of the European Communities.

3. Given the rising health care costs at the national level and cross-border dimension of health care, there are a number of examples in the health area on which Member States cannot act alone effectively and where cooperative action at the level of the Union is indispensable.

4. While health care systems are not a competence of the Community, issues relating to healthcare systems, such as access to medicines and treatments, patient information, and the movement of insurance companies and health professionals, have a cross-border character and therefore those issues need to be addressed by the European Union[iii].

5. The level of cross-border health care in the European Union is relatively small – less than 1% of total health care – the fundamental non-discrimination principles on equal access of citizens to services, including healthcare services, contained in the European Community Treaty, shall be guaranteed.

6. Given the sensitive nature of healthcare information, and the high degree of reliance of health professionals on data available in reliable health records, the issues of integrity, security, privacy and confidentiality are of particular significance and must be clearly addressed.

7. Growing use of networking and computing for healthcare information processing calls into question national and international borders and the access of citizens to health information. Use of eHealth systems and services is set to increase with the application of the full mobility of citizens, the forthcoming liberalisation of services (although it at present excludes health services), deployment of new medical technologies and techniques through information and communication technologies (ICT), and enlargement of the European Union.

8. Given the complex character of healthcare (high costs, and the need for quality, patient safety, adequate organisation and delivery, cross-border care, reimbursement, and liability), eHealth provides one of the most important solutions to address the cost and quality of healthcare. The enabling technology of telemedicine, as a special eHealth service, would not create an extra financial burden as it would depend on a voluntary basis from services providers. It would also present another alternative to the existing health system which is currently largely based on non-electronic platforms (*additionality*).

9. Recent evidence suggests that the health ICT industry has the potential to be the third largest industry in the health sector with a global turnover of €50-60 billion, of

which European activity could represent one third. By 2010, a double digit growth rate in the industry of up to 11% is foreseen[iv].

10. It is important that the fundamental principles that underpin healthcare systems in Europe – universality, solidarity, equity, financial stability and sustainability – continue to be supported through eHealth and through the interoperability of its systems and services.

Presents

An initiative – **a European Commission Recommendation** (hereafter referred to as 'The Recommendation') – that supports the premise that connecting people, systems, and services is vital for the provision of good healthcare in Europe. The lack of interoperability in systems and services has long been identified as one of the major challenges to the wider implementation of the Union's eHealth applications. The opportunities and positive benefits of achieving interoperability are ultimately considerable, whereas various barriers and challenges act as impediments.

This Recommendation outlines a set of recommended guidelines for good practice on eHealth interoperability. The Recommendation is addressed to all the **Member States**, but it also has relevance for the **European Economic Area (EEA) countries**, and for the appropriate **industries** and **stakeholder associations** that work in the eHealth field. While the Recommendation is considered especially relevant in a cross-border European context, it has, moreover, very obvious benefits for all European citizens and health professionals in the immediate district, local, and/or regional level where they live and work.

The overarching notion is of a European service space in which, and through which, European citizens and their designated health professionals can access the necessary health services. eHealth as a specific domain forms part of a larger Information Society approach that is oriented towards eGovernment, and ePublic Services, and new forms of services based on public private partnerships[v], [vi]. This increasingly popular approach to access to services needs to be both useful and usable in a seamlessly safe and secure manner, and allow its users to access different applications according to relevant, and different, circumstances.

The requirement for eHealth interoperability is perceived as being based fundamentally on the citizen or service need. It is considered as having importance and benefits for both in-country and in-region health systems and services. The interoperability of eHealth systems and services is principally required in **four specific circumstances** between the health systems of different Member States, whether those systems are organised in a centralised or a decentralised manner:

- When an individual citizen is travelling in another Member State and is then taken ill. While the numbers are relatively small as a percentage of total healthcare activity, the life-affecting urgency (e.g., emergency circumstances) may be considerable in a high proportion of these cases;
- When a citizen exercises the right to travel to a different Member State in order to receive the health service of his or her choice;

- When health services are sought remotely using electronic means, either by a citizen or by a health professional in the form of store-and-forward diagnostic service or real-time communications.
- In transnational settings where, in effect, a local health economy crosses a single border. Here local agreement is likely to be necessary and to take place on a much wider range of issues than simply interoperability. For instance, it may also include referral thresholds, admission rights, liability and recompense, and reimbursement.

This Recommendation is complementary to a number of other instruments that include potential **legal and regulatory change, the pursuit of effective standards, and the open method of coordination**, that are currently either in use or under consideration in the European Union. While the contents of the Recommendation are not binding on Member States, they reflect a consensus on good practice developed with feedback from the Member States themselves and a range of other stakeholders, including policy-makers, the healthcare and the eHealth industries, healthcare professionals, funding agencies, and healthcare insurers. Hence, the Recommendation is intended to facilitate a process which will lead to the development of even further good practices.

Hereby recommends that

Since eHealth is essential to providing quality healthcare, **an interoperability framework** in which health information can be transferred securely, and with patients' consent, is also vital. Although **interoperability is not a goal in itself**, since the Member States are now directing their health policies to subscribe to a paradigm of common visions, common values, and eventually common standards[vii] with regard to health service provision throughout Europe, a definitive focus is now required on eHealth interoperability.

Hence, **to achieve a vision of good healthcare throughout Europe, healthcare systems and services and other providers will no longer work entirely in isolation, but will need to collaborate as teams**; and, increasingly, by developing constructive, dynamic, and interactive relationships with patients. In a growing number of situations, it will be advisable, better, or necessary to do this beyond national and linguistic borders. **Information and communication technologies (ICT) for health – more frequently known as eHealth – can facilitate this cooperation**. The interoperability of the resulting eHealth systems and services will enable these processes even further.

Therefore, the ultimate goal of this Recommendation is to contribute to enabling the provision of a means of **authorised healthcare professionals to 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 record, patient summary, and emergency data** from any place in Europe: within countries, in cross-border regions, and between countries.

1. Definitions and scope

While the two key definitions of eHealth and interoperability are outlined here, a number of other important definitions are included only in annex (see Annex 2).

1.1 Definitions

eHealth is taken to cover 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 also includes health information networks, electronic health records, telemedicine services, and personal wearable and portable communicable systems for monitoring and supporting patients. The specific focus in the case of eHealth interoperability is on **electronic health records, patient summaries,** and **emergency data sets**.

The notion of **eHealth interoperability** used here is not only the technical definition of the term that relates to connecting systems and exchanging information, but also seeks to recognise the concept of connecting people, data, and diverse health systems, while particularly taking into account the relevant social, political, regulatory, business/industry, and organisational factors.

For this purpose, a specific definition of interoperability has been selected: "Interoperability means the ability of information and communication technology (ICT) systems and of the business processes they support to exchange data and to enable the sharing of information and knowledge". The term originates from the European Interoperability Framework (EIF) (2004:5) Interoperable Delivery of European eGovernment Services to public Administrations, Business and Citizens (IDABC) Programme of the European Commission.[viii]

1.2 Scope

The scope of the Recommendation refers specifically to **electronic health records** and their subset, or extract, **patient summaries**. This orientation is intended to kick start the interoperability initiative with an area of activity and operation that is already relatively well defined and has been explored in some considerable detail by at least a core range of Member States in the European Union. Limiting the scope of the Recommendation in this manner does not preclude that the recommended activities will also be applicable and relevant to other eHealth applications of high priority, such as **ePrescribing**. Although ePrescribing draws on the same set of principles and practices, achieving interoperability in this domain may include facing an additional set of regulatory, infrastructural, and market challenges.

2. Principles

This Recommendation acknowledges 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 country's health services and medical care. Today, there is relatively little harmonisation among healthcare systems in Member States. However, even when they exercise their own competences, Member States have to comply with Community law.

Member States are currently trying to improve their healthcare systems as best they can on their own. Even though Member States act independently in organising their healthcare systems, there are a number of similar factors and challenges facing them which underline the scope for potential European cooperation. It is difficult and inefficient to continue in circumstances in which 27 Member States work in isolation to enhance their individual healthcare systems and services. eHealth is therefore seen as an important means of facing these common challenges by using a shared and mutual approach. It is also considered to provide an accessible, quality-based, and cost-effective alternative to more conventional forms of healthcare.

This Recommendation therefore draws on high-level European policy agreements on eHealth collaboration in order to prepare the ground for operational-level interoperability of electronic applications in health. On the one hand, the Recommendation is addressed to those Member States which have already implemented a health ICT infrastructure, and eHealth services, and which desire to collaborate with other Member States. On the other hand, the Recommendation is also directed at Member States which intend to implement an interoperable eHealth service or services, and/or architecture, and have not yet done so. It is considered to be crucially important to include in these arrangements those Member States which are still at a very early stage of development of a notion of interoperability for their own eHealth services. The guidelines to be developed should apply to all Member States which each have their very different health systems and services.

3. Objectives

While the eventual purpose of this Recommendation is to contribute to the achievement of a **European health information space by the end of the year 2015**, there is an immediate need to start a stakeholder dialogue on achieving this goal. Key to this orientation is the need to develop **a process** that undertakes the appropriate concrete activities and tasks. In turn, these should be supported by the relevant human, organisational, and financial resources. Hence, the seven objectives of this initiative are intended to be:

1) **To propose a set of guidelines that will outline the appropriate level of interoperability** in terms of eHealth needed to be taken by individual Member States to ensure the minimum level of compatibility and communication with fellow Member States.
2) **To provide Europeans with the appropriate kinds and levels of healthcare**, by using the appropriate and supporting forms of eHealth.
3) **To outline and agree the principles** on which there should be broad agreement and engagement to reach a shared and interoperable eHealth information space: conditions outlined initially in the eHealth Conference 2007 Declaration[ix]. A framework will be created that enables all 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[x].
4) **To base the process on an open form of consultation and mutual collaboration** with and among the Member States. The steps necessary need originally to be based on a political commitment on the part of the Member States. However, the actual steps – which will be undertaken *in tandem* – will start at a high conceptual level, and will increasingly shift towards technical development and concrete solutions. The legal or regulatory, business and/or

organisational, applications, and technical solutions are to be guided by and be based on a set of relevant use cases, that are dependent on a thorough definition of user requirements and process re-engineering.

5) **To focus on interoperability between health information shared among different healthcare systems**, and to be based on a limited range of applications in current existence and use in different Member States. This approach will be founded on a number of distinct challenges e.g., resolution of appropriate and secure identifiers for patients, health professionals, and institutions. The steps will be premised on the prevalent standards, existing and useful good[xi] practices, exemplars, case studies, and models.
6) **To resolve the various challenges of achieving eHealth interoperability in Europe** by building appropriate networked systems and services that cover the entire continuous chain of the provision 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 infrastructure and minimum steps required.
7) **To assess the barriers and hurdles** implicit in achieving eHealth interoperability, and **to identify the necessary pre-conditions and relevant incentives to overcoming these**.

4. Benefits

A shift towards eHealth interoperability in the European Union accrues a set of fundamental benefits to the individual nations and to the Union itself. Overall, eHealth interoperability supports the concept of more accessible, high-quality, cost-effective, economic, and sustainable health services and systems, especially in the context of cross-border citizen and patient mobility[xii]. eHealth interoperability provides considerable opportunities to European citizens, patients, healthcare professionals, Member States, and industry. While the proposed Recommendation will be advantageous to the free circulation of people, goods and services, it may also benefit healthcare professionals and public authorities by lowering the acquisition costs for the components of eHealth infrastructures and services. More effective cross-border contacts and exchanges are likely to be both a driver and a result of eHealth based on the practical exchange of data and information. **A wide range of benefits** are laid out in detail in two ICT for Health Unit publications[xiiixiv].

In particular, a major benefit of eHealth interoperability lies in **improving patient safety**. The need to manage health risks both within and outside clinical settings, and along the full continuum of care, is now a priority issue on the international health policy agenda. From an economic perspective, **the potential value of interoperable exchange of health-related data** among healthcare institutions is expected to be substantial. Finally, health and healthcare are not only important for each individual but also in **providing important indicators of the state of a society or community**. Statistics about health are an important part of a health information system. The **ability to share relevant information at a pan-European level to the appropriate authorities and decision-makers** would be a helpful outcome that can emerge from the introduction and expansion of eHealth interoperability.

5. Background

Resolving contemporary and future challenges to European healthcare is conceived of as at least partly possible through the growth in interoperability of the Union's health systems and services, particularly using electronic means. Member States are increasingly interested in focusing on a similar, and possible even the same, set of clinical applications, and their eHealth support. Hence, a number of Europe-wide developments are outlined in Annex 5 as **background** support for the proposals made in the Recommendation.

These developments include an assessment of major challenges to European health services, which are judged to be composed of many that affect the **provision, continuity, equity, quality, cost, and safety** of European healthcare. They indicate a growing concern with eHealth interoperability that dates back to at least 2002. A long history of funding of research and development in ICT for health formed the basis for the focus on implementation and deployment which underpins the action plan for a **European eHealth Area** of 30 April, 2004[xv]. This **eHealth action plan** (2004) was one of a trio of Communications[xvi] launched in spring 2004 which provide substance for the proposed initiatives on eHealth interoperability. And, indeed, that called implicitly for joint European Union and Member State action to **find suitable approaches or guidelines on the interoperability of eHealth systems**. The eHealth Conference 2007 Declaration[xvii] again acknowledged the importance of starting such **joint initiatives in a phased and structured collaboration among the Member States** by initiating and/or strengthening a range of six well-defined activities. More recently, the European Commission response to the Aho[*xviii*] report' on *Creating an Innovative Europe*[*xix*] is a new initiative – called the Lead Market Initiative – aimed at the creation and marketing of innovation products and services in promising industrial and social areas. Chief among the areas of European industry ripe for further development is eHealth; one of the four key areas targeted for action in a proposed programme to support **eHealth as a lead market** is **eHealth interoperability**.

The Health Council Conclusions of 2 June 2004 were followed by three years' of dedicated work by the high-level group on health services and medical care. A public consultation on community action in the field of healthcare launched in late 2006 has now been finalised[xx]. Many contributors to the consultation emphasised that eHealth could help to solve a variety of problems apparent in both the health systems of the Member States and also in cross-border healthcare provision. Efforts to **improve the interoperability of eHealth tools should focus on areas where the added value of increased interoperability can be expected to be the highest.** More generally, there was a concern to identify and measure the factors that facilitate the adoption of broader eHealth solutions (such as the development of case studies that demonstrate the relative advantages of eHealth). More recently, on 23 May 2007, the European Parliament passed a Resolution on health services in relation to the internal market. The Resolution highlighted the importance of such **eHealth applications** as electronic patient identification; electronic reimbursement requests; online health systems; and telemedicine, particularly in relation to the cross-border provision of care (Principles 8 and 9)[xxi].

The establishment of a **dedicated health information space** poses many challenges, including in particular the challenge of interoperability between systems and applications and a services-oriented architecture which is able to accommodate a wide

number of dispersed applications in the field of healthcare where the number of such applications is growing daily[xxii]. The political and policy developments described here are also taking place in the context of a 2007-based agreement on the part of major information and communications technologies' companies to define how a **services-oriented architecture** can be adopted in terms of applications and technologies serving healthcare. This new type of architecture gives European healthcare systems the opportunity to develop a European health information space with interoperable applications and services. The proposed architecture could be developed by a wide range of software companies that span a coverage of the whole spectrum of health information. The notion has advantages for both large-scale industry and small- and medium-sized enterprises.

6. Actions on the part of the European Commission, Member States, and stakeholders

Building on these **principles, objectives**, and **background**, the Recommendation seeks to allot various responsibilities to both the European Commission and to the Member States. These endeavours are largely at a high, strategic, level and involve a resolution of the political/legal and regulatory aspects of the challenges that face the proposed activities to achieve eHealth interoperability. The two main levels of decision-making that underpin the actions outlined in the Recommendation, are therefore at both the European level, and the Member States' level. In particular, the Member States are invited to undertake actions at four levels. These are the **political/legal level; the organisational level; the application level (which includes semantics), and the technical level (which includes architecture)**. Underpinning all of these is a commitment to evaluation and monitoring of the activities.

- **At the political/legal level:** To build a political platform that is aimed at setting up the necessary legal and regulatory environment so as to render eHealth infrastructure and services interoperable. This could involve more effective coordination, and harmonisation – where necessary, of their legislations.
- **At the organisational level:** To agree on an organisational framework for interoperability that recognises the autonomy of each Member State in what concerns the development of the relevant eHealth infrastructure and services, but creates a common domain with the necessary interfaces to enable the national domains to interact.
- **At the application (including semantic) level:** To coordinate efforts towards semantic activities by agreeing on common priorities (through so-called 'use cases') and to share these results and experiences.
- **At the technical (including architectural) level:** To promote the use of technical standards and architectures, and the establishment of common communication platforms.

Precise roles for a wide variety of stakeholders, including European industry, through such mechanisms as Integrating the Healthcare Enterprise, will also be considered particularly within the organisational, application, and technical domains. The areas to be covered in these next phases of activity by all the parties concerned are outlined in detail in Annex 1.

7. Implementation mechanisms

The Recommendation will be rigorously followed up in the meetings of the i2010 sub-group on eHealth, its attached expert group on eHealth interoperability, and the various, supporting, stakeholders' groups. It will also have a major influence on the eHealth part and future directions of the Competitiveness and Innovation Programme (CIP) of 2008 and 2009, and thereafter.

Focused sessions at appropriate conferences are foreseen in order to follow up on the Recommendation in other arenas. These events can be seen as supporting an observatory mechanism with annual checkpoints at which all the relevant stakeholders can be invited to discuss progress and experiences.

The need is also recognised to maintain liaison in this field with other appropriate task forces, workgroups, and coordination and support actions that work in a number of related domains (e.g., the health systems working party, and the Article 29 Working Group), but especially the relevant industrial and standardisation bodies[xxiii]. Among the latter are both formal committees and working groups and informal arrangements, such as the Integrating the Healthcare Enterprise, with its emphasis on testing, validation, and certification (described further in Annex 4).

8. Annexes

Annex 1: Proposed actions

Many of the proposed activities which follow are directed particularly to the Member States. However, when appropriate, responsibilities and tasks are also identified as being conducted by both the European Commission and the Member States together. The relevant industries and appropriate stakeholders should also be involved at the appropriate levels and in the appropriate activities.

1. The overall (political/legal) level of eHealth interoperability

To build a political platform that is aimed at setting up the necessary legal and regulatory environment so as to render eHealth infrastructure and services interoperable. This could involve more effective coordination, and harmonisation – where necessary, of the Member States' legislations.

At the overall level of feasibility of and commitment to eHealth interoperability, there is a need for **Member States** to:

- Commit politically and strategically to eHealth and eHealth interoperability at all the relevant levels.
- Implement eHealth as an integral part of national strategies.
- Reserve adequate resources to invest in the eHealth area (including time, management capabilities, and financial resources). For budgetary purposes, and as a rule of thumb, the earmarking of at least 2.5% of the annual health budget may be considered as valuable indication. A dedicated proportion of this sum should be dedicated specifically to eHealth interoperability. Where appropriate, the possibilities offered by such financing mechanisms as the structural funds and/or the IDABC programme in this domain should be considered.
- Plan ahead for at least 5-7 years (this is intended to ensure policy consistency – which is often a precondition for increasing investment and innovation –, and also due to the substantial sunk costs and long cycles of return on investment of some eHealth projects).[xxiv]
- Along with other user requirements, consider interoperability from the design phase of all health-related investment, including education, professional training and physical infrastructure.
- Build on stakeholder involvement, public-private partnerships, and public procurement in the health sector to promote and roll out interoperable eHealth solutions.
- Accompany eHealth implementation by a strong involvement of users and other stakeholders in planning, design, validation, implementation, evaluation, training, information and education, and change management.
- Set up adequate governance and monitoring mechanisms.

1.1 Privacy and confidentiality

Under the umbrella of the requirements for an appropriate legal and regulatory framework for eHealth interoperability, a number of initiatives – particularly in

relation to privacy and confidentiality issues – are outlined here. There is a need for the following to:

- **Member States:** Identify the relevant, different stakeholders (e.g., national health services, national statistical institutes, hospitals, social services, physicians, general practitioners) and assess what kinds of data and access they need.
- **Member States:** Explore, commit to, and put into place proven, robust, and appropriate means to ensure privacy protection design, processes, technologies, validation and certification to treat and protect all personal data.
- **Member States:** Formulate clear agreements concerning the process by which citizens can give and revoke consent to access to or transfer of information, including the ability to designate any data as sensitive and which must be given special treatment.
- **Member States:** Formulate clear agreements on how to handle data that may be subject to specific constraints within administrations (e.g., mental or sexual health information).
- **Member States:** Identify under which conditions or events health data can be accessed, by whom, and the confidentiality to be assured while accessing and/or transmitting health data.
- **Member States:** Identify auditing/tracing needs (e.g. data access to be logged, and logged information) and how long the auditing/trace information must be maintained.
- **Member States:** Promote the adoption at the national level of good practices, solutions, data formats and interchange protocols and interfaces.
- **Member States:** Enforce the adoption of measures and solutions that are able to ensure the confidentiality, integrity and availability of health information, as well as access control and restrictions.
- **Member States:** Enforce the adoption of auditing/tracing measures and solutions according to good practices available for data handling.
- **Member States:** Give adequate consideration to the mandatory reporting of contagious diseases, of potential health threats and of statistical data for public health monitoring in general (including disease, professional and other relevant registries).

2. Creating the organisational framework (or process) for eHealth interoperability

To agree on an organisational framework for interoperability that recognises the autonomy of each Member State in what concerns the development of the relevant eHealth infrastructure and services, but creates a common domain with the necessary interfaces to enable the national domains to interact,

It is essential to create an organisational framework (or 'process') that will enable eHealth interoperability. Various possibilities for the initiation of this process, with the involvement of the relevant stakeholders, are outlined. In initiating the basic pillars, processes and structures of eHealth interoperability in Europe, the following activities are considered necessary:

- **European Commission and Member States:** Develop and agree a roadmap that reflects the above 5-7 year timeline[xxv].

- **Member States:** Agree on relevant use cases and user requirements, identifying the patient data fields that have to be allowed to move data seamlessly between Member States[xxvi].
  - Agree on the minimum requirements for the legal framework allowing for interoperability (namely on a cross-border level).
  - Agree on and create the basic privacy, security, authentication, and traceability framework allowing for interoperability, namely at a cross-border level.
  - Agree on guidelines concerning accountability, liability and follow-up.
  - Agree on the general vision concerning the road ahead as far as nomenclatures, classifications, registries, accreditation and semantic interoperability are concerned.
  - Agree on the common principles concerning identification of patients, health professionals, and health institutions independent of particular carriers[xxvii]. Discuss and determine whether this notion of identification should be based on a federated model or a common model across the whole of the European Union.
  - Explore the use of the European health insurance card as a common approach to facilitating patient mobility in accordance with the eEurope 2005 plan, approved by the Seville European Council and suggested by the Parliamentary Report on patient mobility and healthcare developments in the European Union.[xxviii]

3. Applications (including semantic) interoperability

To coordinate efforts towards semantic activities by agreeing on common priorities (through so-called 'use cases') and to share these results and experiences.

To ensure the application-based and semantic interoperability of eHealth systems and services in Europe, the following approaches are proposed:

- **Member States**. To agree on standards for semantic interoperability that will be used to represent the relevant health information involved (such as coding and terminology standards). This work should be undertaken with the appropriate international and European standardisation bodies.[xxix] The timing of this work involves two periods: firstly, an exploration of the relevant groundwork for a common terminology framework based on relevant use cases; secondly, discussion on an appropriate business model that would be implemented over the five-year period 2010-2015.[xxx]
- **Member States**. To consider the establishment of an appropriate mechanism consisting of national research centres, appropriate industries, and stakeholders involved in the development of health ontologies and semantics to further advance scientific and technical work in the applications field (including semantics).
- **Member States**. To consider the need for:
  - Multi-lingual dictionaries adapted to the health care domain that take into account the difference between professional healthcare languages and lay terminologies.

- Services and tools for cross-language information retrieval, translation and provision of abstracts and extracts of healthcare-related information (including extracts from patient records).

4. Architectural and technical interoperability

To promote the use of technical standards and architectures, and the establishment of common communication platforms.

The following actions are proposed in relation to architectural and technical interoperability. Issues relating to security, certification and accreditation are treated as sub-sections of this level of interoperability.

In all cases, where appropriate, there should be an agreement to undertake the actions necessary with the appropriate standardisation bodies and with industry.

- **Member States.** Undertake a comprehensive survey of existing technical infrastructures that support health systems and services throughout the European Union. Identify the providers (including the companies involved) of these eHealth systems and services solutions.
- **Member States:** Explore together the barriers, hurdles, or missing elements implicit in achieving eHealth interoperability, and identify the necessary pre-conditions and relevant incentives for achieving eHealth interoperability.
- **Member States**. Take into account and use to the maximum scope the existing standards in the eHealth area related to electronic health records and exchange of information. Bear in mind, in particular, the notions of scalability and extendibility.
- **Member States**: Agree on the application of a minimum number of standards appropriate to eHealth systems and services.
- **Member States**: Commit to the steadfast development of additional standards, preferably on a global scale, in the key areas that are identified as gaps or missing elements.
- **Member States**. Where appropriate, apply as good practice the achievements and lessons learned from the Large Scale Pilots on 'EU wide implementation of patients' summaries/Emergency Data Set to support continuity of care' and 'Electronic medication records' and 'EU wide implementation of ePrescription solutions to support continuity of care.
- **Member States**: Explore, in addition, the possibilities offered by portable data sets, diagnostics- and process-specific component interoperability, and a 'health broker' solution, for example, as a means of adopting or applying a service-oriented architecture.

4.1 Security

Security-related issues are regarded as being of considerable importance. They can primarily be associated with three areas of concern: identification, authentication and authorisation. Access to a carrier can involve identification and authentication that uses diverse mechanisms:

- **Member States:** *Identification*. Electronic health cards cannot be the only identification mechanism to be explored, given that several Member States

have not adopted them. Multiple methods should be adopted. The analysis should be sufficiently general and flexible to enable each Member State to adopt the most appropriate approach for itself and, at the same time, to assure interoperability and mutual recognition of national identities. Among the possible mechanisms to be considered are: cards, tags, bar coding, mobile telephonic equipment, and other devices.

- **Member States:** *Authentication and authorisation*. There is a need to review the existing methods of authentication and authorisation in such a way as to assure the required controls and access restrictions and, at the same time, minimise the amount of configuration data and systems management effort. Electronic identity cards may play a larger role here.

4.2 Certification and accreditation

A preference is agreed for certifying the organisation of the exchange and sharing of data. At the level of certification and accreditation of eHealth interoperability in Europe, it is considered that there is either a need for a single certification process that is valid throughout the European Union or a means of mutual recognition of each Member State's certification mechanisms:

- **Member States**: To put into place a joint or mutually recognised mechanism for certification of interoperable electronic health records and other eHealth applications.
- **Member States**: To explore methods and procedures of accrediting healthcare professionals who develop or who use interoperable eHealth systems and services.
- **Member States**: industry self-certification should have as an objective to reduce delays in bringing interoperable eHealth solutions to the market.
- **Member States**: To explore the pre-requisites for the reliable exchange of medical data that ensure well-managed healthcare systems, and thereby not only support but ensure the quality requirements for any system that is connected to a national/international healthcare infrastructure, such as up-time, response-time, log-in, maintenance, up-to-datedness of information.

5. Monitoring and evaluation

At the level of monitoring and evaluation of eHealth interoperability in Europe, there is a need for:

- **Member States and the European Commission**. Consider the possibilities for setting up a European Union interoperability observatory, in which healthcare interoperability would be included.
- **Member States and the European Commission**. Strengthen and expand the opportunities for annual checkpoints at which all the relevant stakeholders are invited to share experiences, progress, and good practices.
- **Member States and the European Commission**. Both parties should define the quantitative and qualitative criteria, and milestones, to measure the progress of the interoperability of eHealth (in particular for electronic health records) and the benefits achieved by the systems and services developed by the Large Scale Pilots. Continuous evaluation of both systems and their management should be integrated in any proposed scheme. These figures

should be available both on a country-by-country basis, and collectively. Comparison with other countries internationally is also favoured.

- **Member States**. Should identify and measure the factors that facilitate the adoption of eHealth solutions in general. This would involve the development of case studies that demonstrate the relative advantages of eHealth, identify and ensure compatibility with existing systems and procedures, minimise complexity for the various users of the systems, and ensure both the trialling and observing of eHealth innovations.
- **Member States:** Assess the eventual benefits, including economic benefits and cost effectiveness, of increasing eHealth interoperability throughout health services across Europe.
- **Member States:** Assess the impact of interoperable eHealth solutions on the streamlining and evolution of the cross-border provision of eHealth services during the implementation of interoperable eHealth solutions.

Annex 2: Definitions

This annex contains below definitions and further information on various concepts.

Citizens and patients:
Both the terms **citizen** and **patient** are also used when considering eHealth connectivity. In the case of the provision of healthcare through electronic means, it is considered that a **citizen** is someone who, while not actively in need of immediate healthcare, has a legitimate desire to access health information in general and/or his or her own health information specifically. A **patient,** on the other hand, implies a person with a health problem who is actively seeking or receiving healthcare. Unanticipated or unexpected medical occurrences may quickly, however, transform a citizen into a patient.

eHealth interoperability:
The notion of eHealth interoperability used here is not only the technical definition of the term that relates to connecting systems and exchanging information, but also seeks to recognise the concept of connecting people, data, and diverse health systems, while particularly taking into account the relevant social, political, regulatory, business/industry, and organisational factors.

For this purpose, a specific definition of interoperability has been selected: "Interoperability means the ability of information and communication technology (ICT) systems and of the business processes they support to exchange data and to enable the sharing of information and knowledge". The term originates from the European Interoperability Framework (EIF) (2004:5) Interoperable Delivery of European eGovernment Services to public Administrations, Business and Citizens (IDABC) Programme of the European Commission.[xxxi]

A distinction is made between two possible approaches to ensuring interoperability:

- by defining common interfaces between products and services from different suppliers.
- by setting up middleware[xxxii] between eHealth network or systems from two or more autonomous jurisdictions. The focus on jurisdictions here is on national

eHealth systems, although it can also be appropriate to regional, community, or hospital, systems.

The former approach is overall considered to be more powerful and longer-term. However, whatever is effective among or between jurisdictions must presumably also be excellent within and across Member States. The latter, second, approach can therefore be considered as providing an interim, implementation set of steps towards the eventual achievement of the first approach.

Electronic health record:
An electronic health record consists of 'digitally stored health care information about an individual's lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times'.[xxxiii]

Electronic health records are used as the basic underlying concept to underpin a seamless and interoperable exchange of health information across Europe that will require common structures and ontologies.

The single most important characteristic of an electronic health record is its ability to share information among different authorised users. In technical terms, this requires both the interoperability of information in the electronic health record and the interoperability of electronic health record systems which exchange and share this information. The sharing of patient electronic health record information between different electronic health record systems and different health organisations will almost certainly take place in a distributed processing environment. The electronic health record is just one of the key elements in a comprehensive health information system.

Ontologies:
Within a domain of discourse, such as the clinical or health domain, an **ontology** is the representation of the entities, ideas and events, together with their properties and relations. These are structured according to a system of categories. An ontology represents knowledge that formally specifies agreed logical theories for an application domain. It is more abstract and generic than a data model, which is often grounded in the organisation and business processes of a particular enterprise. The process of creating an ontology for a specific domain is known as 'ontology engineering'. This involves tasks such as eliciting knowledge from experts and workers in the field, analysing this information so as to identify entities, concepts, attributes and relationships, and structuring and encoding these so that the result can be used to model knowledge within that domain. See also relevant information on **semantics**.

Patient summary:
A patient summary is defined as a clinical document that is stored in repositories with cumulative indexing systems and secure access by authorised personnel. In liaison with the Competitiveness and Innovation Policy Support Programme, it can be understood as **a minimum set of patient data** which would provide a health professional with essential information needed in the event of unexpected or unscheduled care.

Semantic interoperability is considered to be the ability of two or more computer systems to exchange information and have the meaning of that information accepted and automatically interpreted by the receiving system.

Services-oriented architecture:
A services-oriented architecture uses loosely coupled devices to support the requirements of business processes and users in environments where services are made available as independent applications that can be accessed without knowledge of their underlying platform implementation. This approach has gained good support in the health sector, not least because it provides greater interoperability alongside some protection from lock-in to proprietary vendor software.

Annex 3: Current and previous European projects

This annex will continue to be completed with information from other pertinent projects as and when it is provided.

Several of the activities outlined in this Recommendation can be based on progress already made within the context of various European Commission co-financed projects (in Directorate-General (DG) Information Society and Media (INFSO), DG Employment, Social Affairs and Equal Opportunities (EMPL), DG Health and Consumer Protection (SANCO) and DG Directorate-General Taxation and Customs Union (TAXUD), and so on) which have reported or continue to report their results. Examples from DG Health and Consumer Affairs need still to be added. Examples include the following:

DG EMPL

- The Electronic Exchange of Social Security Information (EESSI) project of DG EMPL, that is currently closing its feasibility study stage, and that is enabling Member States to exchange data among social security institutions about mobile citizens. The concepts underpinning the project have been adopted by the Ministries in charge of social security in all Member States.

DG INFSO

- **i2Health - Interoperability Initiative for a European eHealth area:** http://www.i2-health.org/ was an eTEN co-financed project that identified the requirements and submitted recommendations for the deployment of interoperable eHealth infrastructures and services for trans-European use through the definition of a generic eHealth interoperability framework and common approaches to both patient and health professional identifiers and ePrescribing.
- **Netc@rds**. This project, which is at a pilot stage, has been co-funded by the eTEN programme. It is enabling health professionals to verify online the validity of social security/health insurance cards issued in another Member State and hence the entitlement of patients to benefit from social protection.
- **Q-Rec - European Quality Labelling and Certification of Electronic Health Record systems (EHRs)** http://www.eurorec.org/projects/qrec.cfm In the first quarter of 2007, this European Commission-financed specific support action reported on its findings, identified possible activities with regard to

conformity testing and accreditation schemes relating to eHealth, and made recommendations on which are considered to be the most appropriate mechanisms to be adopted.

- **RIDE - A Roadmap for Interoperability of eHealth Systems in Support of COM 356 with Special Emphasis on Semantic Interoperability:** http://www.srdc.metu.edu.tr/webpage/projects/ride/ Follow-up of the findings and recommendations of the RIDE integrated project, a project which has investigated the various approaches in all the Member States to eHealth systems and services that are implemented at local levels. Its final report highlights European good ('best') practices with such interoperability domains as: identification of patients, identification of health professionals, eHealth data messaging architectures, and electronic health record sharing architectures.
- **SAPHIRE - Intelligent Healthcare Monitoring based on Semantic Interoperability Platform:** http://www.srdc.metu.edu.tr/webpage/projects/saphire/index.php The results of the SAPHIRE[xxxiv] project, an eHealth co-financed integrated project, may prove a useful guide to authorisation-related issues. Within the scope of this project, implementation of the SAML enhanced client and proxy (ECP) profile and OASIS extensible control markup language specification (XACML) based authorisation (XUA) mechanism was undertaken for the Integrating the Healthcare Enterprise (IHE) Cross Enterprise Document Sharing (XDS) profile. Recommendations were also made relating to the Cross Enterprise Document Sharing (XDS) profile.
- **SHARE - Supporting and structuring Healthgrid Activities and Research in Europe:** http://www.cems.uwe.ac.uk/cccs/project.php?menu=off&name=share Follow-up of the findings and recommendations of the SHARE specific support action final report with regard to the task outlined in the eHealth action plan to deploy health information networks and outline a roadmap for HealthGrid development.

DG SANCO
Examples of relevant projects need still to be added here.

DG TAXUD

- The secure interoperability architecture defined in the context of the New Computerised Transit System (NCTS) project of DG TAXUD, that is currently at an operational stage, that is enabling Member States to exchange data between customs offices about the movement of goods in transit in order to fight against fiscal fraud.

Annex 4:

Hence, a number of Europe-wide developments are outlined here as **background** support for the proposals made in the Recommendation.

Major challenges to health services: Among this decade's major challenges are many that affect the **provision, continuity, equity, quality, cost, and safety** of European healthcare. Europe's peoples are ageing. At the same time, whatever their

ages, Europeans are increasingly moving around the Union for reasons of travel, study, work, and retirement. Europe's citizens and patients are asking to be better informed on healthier lifestyles in order to live healthier lives, and are requiring that this be combined with the availability and provision of better, higher quality, and more cost-effective healthcare. These demands place considerable pressure on Europe's nations' health authorities and policy-makers. At the same time, the demands offer considerable opportunities to European industry to help in the creation of a prosperous, sustainable, and internationally competitive Europe-wide market for eHealth applications and health technologies.

A concern with eHealth interoperability: eHealth interoperability within and among European and national health systems and health providers became a major area of concern and policy attention through the eEurope 2005 action plan and its associated programme during the period 2002-2005[xxxv]. A central, originating document was the 2003 Final report of the Health Telematics Working Group of the High Level Committee on Health, which addressed extensively the challenge of sharing health data, and was set up by the Directorate-General for Health and Consumer Protection[xxxvi]. A variety of other European documents concentrate on this priority issue; among them the Ministerial Declaration on eHealth announced in Brussels on 22 May, 2003[xxxvii] and the conclusions of the 2 June, 2004 health risk management workshop[xxxviii]. A long history of research and development in ICT for health (comprised of almost two decades of research programmes, and pilot activities - many of which are now well advanced in several European Member States), and more than €550 million funding formed the basis for the focus on implementation and deployment which underpins the action plan for a European eHealth Area of 30 April, 2004[xxxix].

An eHealth action plan: The eHealth action plan (2004) was one of a trio of Communications launched in spring 2004 which provide substance for the proposed initiatives on eHealth interoperability. They were based on a desire to resolve the growing challenge of patient mobility in Europe[xl] *via* solution-building methods based on the open method of coordination. The April 2004 Health Council especially noted the relevance of ICT in the field of health-related mobility issues, since they enable particular health services to be provided across borders and – *via* use of the Internet – enable a wider understanding of health-related issues[xli]. The eHealth action plan (2004) called implicitly for joint European Union and Member State action to find suitable approaches or guidelines on the interoperability of eHealth systems.

A European health information space: The eHealth action plan enables the European Union to achieve the full potential of eHealth systems and services in a European eHealth Area. This concept is based on ideas explored in more detail in the 2005-launched strategic framework called *i2010 – European Information Society 2010*, which sets out as a priority the completion of a Single European Information Space, the promotion of innovation, and the strong support for the inclusion of all European citizens, topics which are all at the heart of eHealth interoperability.

Engineering eHealth in Europe: In 2005, therefore, the European health and information technology ministries agreed to work together in a coordinated and structured way on eHealth interoperability. At the eHealth 2005 conference, the Ministers committed to raising awareness of the pressing need for 'a more integrated

and interoperable European health information space'. The eHealth Conference 2007 Declaration[xlii] acknowledged the importance of starting such joint initiatives in a phased and structured collaboration among the Member States. The Member States, European Economic Area countries, and the Commission services committed in this declaration to initiating and/or strengthening a range of six activities based on their combined engagement: a European-wide means of organising; national eHealth roadmaps; innovative eHealth services; a combination of standardisation and safety in eHealth; and involving and supporting the eHealth industry and other stakeholders. This concern can be perceived as part of a global concern with electronic support for health services[xliii].

Innovative eHealth: a European market: The January 2006, so-called 'Aho[xliv] report' on *Creating an Innovative Europe*[xlv] recommended the development of innovation-friendly markets in a more targeted way. The report's stated aim was to create the necessary conditions to translate aspects of both technological and non-technological innovation into commercial products. The report acknowledged explicitly the importance of ICT in the healthcare sector, and identified eHealth as a potential lead market for Europe[xlvi]. In response to the Aho Report, the European Commission proposed a new initiative – called the Lead Market Initiative – that is aimed at the creation and marketing of innovation products and services in promising industrial and social areas. Chief among the proposed areas of European industry which are ripe for further development is eHealth. One of the four key areas targeted for action in a proposed programme to support eHealth as a lead market is eHealth interoperability. The Initiative provides an important parallel initiative to this Recommendation, although with a greater focus on industry and enterprise.

Cross-border healthcare – the appropriateness of eHealth: The Council Conclusions of 2004 have been followed by three years' of dedicated work by the high-level group on health services and medical care. A public consultation on community action in the field of healthcare launched in late 2006 was finalised[xlvii]. Many contributors to the consultation emphasised that eHealth could help to solve a variety of problems apparent in both the health systems of the Member States and also in cross-border healthcare provision. It was considered that efforts to improve the interoperability of eHealth tools should focus on areas where the added value of increased interoperability can be expected to be the highest. More generally, there is a concern to identify and measure the factors that facilitate the adoption of broader eHealth solutions (for example, the development of case studies that demonstrate the relative advantages of eHealth).

European Parliament Resolution: On 23 May 2007, the European Parliament passed a Resolution on health services in relation to the internal market. The Resolution highlighted the importance of such eHealth applications as electronic patient identification; electronic reimbursement requests; online health systems; and telemedicine, particularly in relation to the cross-border provision of care (Principles 8 and 9). It underlined that, while patients must benefit from an equal access to treatment nearest to their home and in their own language, Member States should also provide access to health services to both public or private patients who are residents of another state on a basis of equality (principles 13 and 14)[xlviii].

Annex 5: Selected eHealth interoperability initiatives

Besides the various European standardisation initiatives, two international initiatives are particularly highlighted here as examples of useful committees and processes: the United States Health Information Technology Standards Panel Technical Committee, and the Integrating the Healthcare Enterprise.

Health Information Technology Standards Panel Technical Committee

This Technical Committee founded in the United States of America provided a useful mechanism for selecting the most appropriate standards to implement use cases provided by the Office of the National Coordinator (ONC) for Health Information Technology. It is often known by its abbreviation HITSP. Following the elaboration of the particular use cases, the technical committee:

- provided a listing of
  - all standards that satisfy the requirements implied by the use cases
  - all assumptions made in creating the pool of standards
  - the use case-related open issues identified while developing the pool of standards;
- provided a description of
  - all duplications and overlaps among standards for the use cases
  - all the gaps, including missing or incomplete standards;
- submitted recommendations for resolving the gaps and overlaps to the Healthcare Information Technology Standards Panel Technical Committee for review;
- received and resolved comments from the Healthcare Information Technology Standards Panel Technical Committee and submitted them for approval;
- evaluated and selected the specific standards to meet the requirements of the use cases; and produced 'Selected Standards' reports for each of the selected use case in five different technical domains.

Integrating the Healthcare Enterprise

Integrating the Healthcare Enterprise http:// www.IHE-EUR.fr/ accelerates the adoption of the standards needed to support exchange of health records between different actors. In Europe, more than 75 companies and many end-user societies (such as radiology, laboratory, and cardiology societies, other national, health-related organisations, and universities) participate in the Integrating the Healthcare Enterprise validation process in five different technical domains. This process, that includes both testing and validation, is well known. It is considered to be a mature process that ensures the provision of the continuity of information throughout the entire care process. It is based on four distinct steps:

- Identify interoperability problems.
- Specify integration profiles.
- Test systems at an annual Connect-a-thon.
- Publish integration statements for use in requests for proposals.

The technical frameworks are publicly available in several domains. Other technical frameworks are currently under development in areas such as pathology, ophthalmology, pharmacy, and patient care devices.

Integrating the Healthcare Enterprise is an independent organisation which preserves the autonomy of European countries. Each country can define its own national extensions to the protocols and infrastructures, if necessary, and can use the process for their own purposes. Integrating the Healthcare Enterprise provides a pragmatic and effective process for testing the exchange of electronic healthcare records between actors inside a European interoperability certification process.

[i] ECT-1997 The consolidated version of the Treaty establishing the European Community

[ii] EUT-2001 EU Treaty 2001

[iii] European Parliament Resolution of 23 May 2007, point 12.

[iv] Datamonitor 2007- *Trends to watch: Healthcare technology*

[v] European Commission (2007) *Draft of the ICT PSP work programme – Version 3*. Competitiveness and Innovation Framework Programme (CIP). May 2007.

[vi] Gartner (2007) *Preparation for Update European Interoperability Framework 2.0 – FINAL REPORT*. A Report for DIGIT. 14-02-2007

[vii] See for example the Health Council outcome of 30 November, 2006.

[viii] http:// www.i2-Health.org/. This definition has been selected from a range of definitions presented in a deliverable produced by the i2Health project entitled *Comprehensive Overview of Interoperability Definitions and Sub-Definitions* that was completed in August 2005.

[ix] eHealth Conference 2007 Declaration, 17 April 2007. http://ec.europa.eu/information_society/activities/health/docs/events/ehealth2007/eh_declaration20070417_en.pdf

[x] Examples could include whether: a) the method of introducing the health information system is top-down or is bottom-up; b) the health information system model of the particular Member State is, in technical terms, distributed, centralised, or consists of a combination of approaches that are both distributed and centralised. (A scenario could be envisaged in which a group of states which share a common language or have close historic or cultural ties might choose to collaborate and/or share systems. Also, rather than providing an all-Europe solution, bi-lateral arrangements among Member States could be considered where appropriate); and/or c) health information system or service is organised at a more regional or local level of granularity, and the method of building health information is integrated locally.

[xi] Good practices were formerly referred to as 'best' practices, an expression which is now out of favour due to its deterministic overtones.

[xii] See particularly the principles of the 23 May 2007 European Parliament Resolution.

[xiii] European Commission (2006) *Connected Health. Quality and safety for European citizens.* Luxembourg: European Communities.

[xiv] This second document is currently in draft form, and provides an overview of eHealth interoperability (July 2007).

[xv] COM(2004)356 final. *e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area.*

[xvi] COM(2004) *Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union*.

[xvii] See http://ec.europa.eu/health-eu/news/ehealth/ehealth2007_en.htm

[xviii] Esko Aho chaired the working group which first drafted and published this report on innovation in Europe. It is his name which has since been used to refer to the report.

[xix] See http://ec.europa.eu/invest-in-research/pdf/download_en/aho_report.pdf

[xx] SEC (2006) 1195/4 of 26 September 2006. European Commission, Health and Consumer Protection Directorate-General, *Summary report of the responses to the consultation regarding 'Community action on health services'*.

[xxi] http://www.europarl.europa.eu/

[xxii] For a short overview of the main considerations of a services-oriented architecture, see the Legally eHealth study final deliverable: *Final recommendations on Legal Issues in eHealth*.

[xxiii] See M/403 (EN) (2007) *Standardisation mandate addressed to CEN, CENELEC, and ETSI in the field of Information and Communication Technologies*; CEN/ISSS (2005) on the need to establish a stakeholder platform that identifies agreement on policy priorities for ICT standardisation.

[xxiv] Purely as an example, the English National Programme for IT strategy involves a 13-year timescale and is perceived as a fundamental enabler of healthcare reform.

[xxv] The purpose of the Roadmap will be to support the thinking and management of the process of developing eHealth interoperability in Europe. It should provide a complete overview of the tasks to be achieved and allow the stakeholders and constituents to see the whole range of activities involved in achieving eHealth interoperability, including the identification of actions and activities that have not

necessarily been considered to date. The Roadmap needs to define the way ahead, and thus it should incorporate a clear workplan, timelines, agenda, and 'to do' list. Aligned with it, there needs to be an agreed process for tracking results, monitoring progress, updating any changes or new orientations, and ensuring quality control. One of the main challenges of commitment towards achieving eHealth interoperability in Europe will be to outline the formal decision-making approach, and the methods for obtaining agreement and consensus, among the European Commission services and among the twenty-seven Member States of the Union. The Roadmap will be prefaced by a description of the political task needed to manage this process.

[xxvi] The approach followed by the Office of the National Coordinator (ONC) for Health Information Technology, in the United States of America, and its associated Healthcare Information Technology Standards Panel Technical Committee(s) (HITSP) may prove useful in this regard.

[xxvii] A carrier is any technological means through which data is made available to a system. Whereas several European Member States currently focus on the notion of electronic health cards, particularly the electronic European Health Insurance Card, there can be many different carriers like: mobile telephones, handheld and laptop devices, chips and communication services.

[xxviii] 2004/2148 (INI).

[xxix] Wherever possible, the suitability of such international classification standards as the World Health Organisation's ICD-10, and other classifications like SNOMED CT, MeSH, UMLS, and the various new patient safety terminologies, should be considered.

[xxx] An appropriate mechanism to support such a discussion could involve setting up a Web-based shared workspace application that enables exploration of semantically-based health-related applications and solutions by researchers and practitioners.

[xxxi] http:// www.i2-Health.org/. This definition has been selected from a range of definitions presented in a deliverable produced by the i2Health project entitled *Comprehensive Overview of Interoperability Definitions and Sub-Definitions* that was completed in August 2005.

[xxxii] In this context, middleware is defined as a bridge in lay language.

[xxxiii] See Iakovidis, I. (1998) Towards Personal Health Record: Current situation, obstacles and trends in implementation of Electronic Health Care Records in Europe. *International Journal of Medical Informatics*. 52 (128), 105-117.

[xxxiv] See http://www.srdc.metu.edu.tr/webpage/projects/saphire/

[xxxv] Further detail on the background and processes involved in the development of the importance of eHealth interoperability is outlined in *Connected Health.* European Commission (2006) *Connected Health. Quality and safety for European citizens.* Luxembourg: European Communities.

[xxxvixxxvi] European Commission (2003) *Health Telematics Working Group of the High Level Committee on Health – Final Report*. Luxembourg, 04/2003. HLCH/2003/1/7.

[xxxvii] eHealth 2003 Ministerial Declaration, Brussels, May 22, 2003: http://europa.eu.int/information_society/eeurope/ehealth/conference/2003/doc/min_dec_22_may_03.pdf/

[xxxviii] See http://europa.eu.int/information_society/activities/health/events/2004events.htm

[xxxix] COM(2004)356 final. *e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area.*

[xl] COM(2004) *Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union*.

[xli] Council of the European Union (2004). *Conclusions of the Council on patient mobility and health care developments in the European Union. Brussels*, 19 April, 2004. 8524/04. SAN 64

[xlii] See http://ec.europa.eu/health-eu/news/ehealth/ehealth2007_en.htm

[xliii] WHO Declaration WHA 58, 2006: http://www.who.int/gb/ebwha/pdf_files/WHA58/

[xliv] Esko Aho chaired the working group which first drafted and published this report on innovation in Europe. It is his name which has since been used to refer to the report.

[xlv] See http://ec.europa.eu/invest-in-research/pdf/download_en/aho_report.pdf

[xlvi] An outline of possible actions to be undertaken in the eHealth domain is in the process of drafting. It is provisionally entitled (May 2007) *Draft Report from the eHealth Task Force. Accelerating the Development of the eHealth Market in Europe*.

[xlvii] SEC (2006) 1195/4 of 26 September 2006. European Commission, Health and Consumer Protection Directorate-General, *Summary report of the responses to the consultation regarding 'Community action on health services'*.

[xlviii] http://www.europarl.europa.eu/