Response from Oracle Corporation to the European Commission's Consultation on Health Services

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Introduction

The Oracle Corporation supports the European Commission in its efforts to ensure safe, high quality and efficient health care for citizens across Europe.

Oracle is the world's largest enterprise software company. Our products allow organisations to manage, share and protect information. We have extensive experience as a partner and ICT provider to healthcare providers, administrators and payors throughout the European Union. We welcome the opportunity to respond to the Commission's 26 September 2006 Communication regarding action on health services and hope to work with the Commission and member state authorities as they seek to enhance access to healthcare regardless of national boundaries and provide the best quality health care opportunities for « patients without borders ».

Our response does not seek to address the legal questions raised in the consultation document. Rather, based on our experience, we would like to focus on those areas where European action can add value to efforts undertaken by Member States and specifically respond to Questions 8 and 9.

The European citizen must be at the centre of healthcare policy. However, information is at the core of diagnosis, healthcare delivery and administration. Member States, regions and local entities across Europe are developing systems to better manage healthcare related information. If these systems are to work together (interoperate) and enable relevant health related information to follow the citizen or care deliverer across Europe, European authorities should take the lead to ensure that an appropriate pan-European information infrastructure is put in place to support our cross border health services objectives.

An Information Infrastructure to Support Cross Border Healthcare Services

Secure, reliable and rapid access to comprehensible information is a prerequisite for quality healthcare, whether in a local or cross border scenario. Accurate and complete patient medical records can significantly enhance the appropriateness and quality of healthcare. Efficient and error-free handling of related administrative data can expedite payment and reimbursements and increase the efficiency of healthcare administration.

Four scenarios for cross border health care have been identified in the consultation document.

- Cross-border provision of services; telemedecine services, remote diagnosis and prescription, laboratory services
- Use of services abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment, 'patient mobility')
- Permanent presence of a service provider such as local clinics of larger providers
- Temporary presence of persons (health professionels moving temporarily to the Member State of a patient to provide services)

Oracle and our partners have defined the necessary components of an information infrastructure to enable cross border healthcare applicable to each of these four scenarios. Our contribution to the health services consultation will focus on European policies necessary to put in place the information infrastructure to enable cross border health services and, as we conclude at the end of this submission, enable the « patient without borders » .

Cross-border Healthcare IT Infrastructure - Overview

A. Central *Repository*

The **cross-border healthcare IT infrastructure** should enable healthcare data from any number of disparate healthcare providers to be consolidated in a Central Repository.

The **cross-border healthcare IT infrastructure** should be based on an industry standard information model. The most widely used industry standard information model has been developed by the Health Level 7 organisation.

The **cross-border healthcare IT infrastructure** will consist of a number of systems that will communicate using various different messaging formats. The Health Level 7 organisation has constructed an industry standard Reference Information Model to facilitate the message development process. The Health Level 7 – Reference Information Model is a vendor independent standard available for wide implementation by various vendors. Such an open standard permits healthcare providers and payors to procure relevant solutions from a variety of vendors, maximising competition, choice and flexibility for future evolution of the IT infrastructure.

In addition to providing a data consolidation platform, the **cross-border healthcare IT infrastructure** must provide a framework for the rapid development and deployment of new centralised healthcare solutions across the European Union. The deployment of centralised services will enable common clinical processes to be introduced across all care providers to care for patients across borders by different healthcare organisations.

The healthcare information consolidated within the Central Repository will include both administrative and clinical information from all healthcare provider organisations.

The Central Repository proposed as the foundation of the **cross-border healthcare IT infrastructure** will enable the consolidated data to be made available to care providers using a portal that would be developed on the central repository. This portal will be able to be deployed in a number of different ways:

- Web-based applications for care providers (e.g. Hospitals, GPs, Clinics etc.)
- Wireless / Handheld devices (e.g. Community care workers, Accident and Emergency etc.)
- Industry Standard Messaging (e.g. Citizens (i.e. SMS))

The approach of enabling the existing healthcare information systems to integrate with the Central Repository will protect the investment that the European Union and Member States have already made in healthcare information systems.

Moreover, this **cross-border healthcare IT infrastructure** could also offer the possibility to deploy information systems supporting efficient and safe specialised diagnosis or care in smaller member states where it would otherwise be impossible because there is an insufficient volume of patients to maintain the specialist skills of health professionals or to justify investment in the necessary equipment.

The strategy of integrating the existing healthcare information systems with the Central Repository will:

- Provide an initial foundation for the sharing of clinical information across care providers located in the European Union
- Enable the incremental development of a longitudinal clinical record for all European citizens
- Protect the investment already made across the Member States in the existing healthcare information systems
- Support enhanced clinical decision support and business analysis

B. Messaging Standards for an IT Infrastructure

The **cross-border healthcare IT infrastructure** should receive and transmit information with the existing healthcare systems using open, industry standard healthcare messages (i.e. Healthcare Level 7 version 3 messaging (HL7 v3).

HL7 v3 represents a significant departure from the previous messaging standards defined by the Health Level 7 organisation. HL7 v3 messaging reduces ambiguity. HL7 v3 messaging provides flexibility by using a well defined methodology for building standard terminologies to an industry standard reference information model. HL7 v3 messaging is the most definitive message standard to date.

The major vendors in the healthcare information systems marketplace are adopting the Healthcare Level 7 messaging standard, which will mean that new systems purchased for these major suppliers will be able to integrate with standards based **cross-border healthcare IT infrastructure facilitating the development of a single European healthcare area, facilitating equitable access to healthcare information regardless of location within the EU.**

A number of the existing healthcare information solutions may not be capable of generating industry standard messages. Therefore, the **cross-border healthcare IT** architecture will incorporate an Integration Engine that will provide the transformation from the legacy message formats (e.g. flat-files, vendor specific message formats or early versions of HL7) into HL7 v3.

A replacement strategy for those healthcare information systems that are not capable of generating or receiving the appropriate messages or data sets with the Central Repository will need to be agreed.

The deployment of a **cross-border healthcare IT infrastructure** that consolidates data from the existing healthcare information systems in this way will enable:

1. Existing and new healthcare information systems to be incrementally connected to the **cross-border healthcare IT infrastructure** avoiding the need to replace all of the existing healthcare information systems from day one
2. The connections of similar healthcare information systems to the **cross-border healthcare IT infrastructure** to be rapidly replicated (e.g. Hospital and GP systems)
3. The existing healthcare solution to integrate with the **cross-border healthcare IT infrastructure** irrespective of the nature of their native technology, operating systems or hardware platform

C. Core Services

In addition to acting as a central repository, the **cross-border healthcare IT infrastructure** must provide some core services to enable the consolidation of healthcare information across the European Union.

The core services are as follows :

Person Consolidation
The information stored in the **cross-border healthcare IT infrastructure** must be citizen centric. Therefore, the **cross-border healthcare IT infrastructure** must provide the capacity for information from disparate systems to be consolidated around a specific Person record. The **European Health Insurance Card** could correspond to a summary of this consolidated information for emergency situations or disconnected health professionals or organisations.

Standard Data Model
The **cross-border healthcare IT infrastructure** must enable data to be stored in accordance with an industry standard information model. The Health Level 7 – Reference Information Model (i.e. HL7 RIM) fully supports the storage of data in a structured and non-proprietary fashion.

Data Normalisation
The **cross-border healthcare IT infrastructure** must enable data to be "normalised" using industry standard terminologies (e.g. ICD 10, SNOMED, LOINC and OPCS4 etc.) as well as locally defined terminologies (e.g. country specific terminologies). The **cross-border healthcare IT infrastructure** should provide the capability for terminology mediation.

Integration with Legacy Systems
The existing healthcare information systems (e.g. Hospital Information Systems, Primary Care Systems, Community Systems and A&E Systems etc.) that support the clinical and business processes in the care setting (e.g. hospital, primary care settings etc) must update the **cross-border healthcare IT infrastructure** using industry standard healthcare messages. Where the existing healthcare information systems are not capable of updating the **cross-border healthcare IT infrastructure** using healthcare industry standard messages, an integration solution must be used to convert legacy data formats to the standard defined in the **cross-border healthcare IT infrastructure**.

Support the Development of New Applications
The **cross-border healthcare IT infrastructure** must provide the ability for the rapid development of new healthcare information systems that will support the **European eHealth programme** (e.g. Patient Summary, Emergency Record and ePrescribing). The administrative and clinical data that have been consolidated from the disparate systems in the **cross-border healthcare IT infrastructure** must be able to be accessed by the new healthcare information systems. Health professionals moving temporarily to another country could access the **cross-border healthcare IT**

infrastructure to continue to deliver care when patients are transferred from another Member State to their own Member State.

Information Management
The **cross-border healthcare IT infrastructure** must be populated with normalized data and must support management reporting. The information stored within the **cross-border healthcare IT infrastructure** should include all data required to support European reporting requirements. The **cross-border healthcare IT infrastructure** must enable a data warehouse to be created of fully anonymised data to support secure business intelligence using industry standard tools.

Technical Platform
The **cross-border healthcare IT infrastructure** must be delivered on a scalable, fault-tolerant technology platform, which is proven to deliver the performance requirements of such an infrastructure project.

D. Generic Technology Requirements

The **cross-border healthcare IT infrastructure** should be based on a technology framework that has the following characteristics:

Scalable
Managing health information for a large population at a pan-European level will require database technology that is able to manage very high volumes of information.

Robust
A **cross-border healthcare IT infrastructure** as a basis for managing the patient record must be robust. Such an infrastructure will need to be mission-critical in a healthcare environment as systems failure could be potentially life threatening. Therefore, the technology foundation must provide high levels of availability and eliminate any single points of failure.

Secure
Personal health information is highly sensitive in nature. Individuals are concerned to know that only authorised persons will have access to their health record. The technology infrastructure for the **cross-border healthcare IT infrastructure** must ensure that data is stored securely and can only be assessed by authorised persons. Access to data should be fully audited. The **European Health Insurance Card** is the key vehicule for security with the appropriate PKI solution included in the **cross-border healthcare IT infrastructure**.

Able to evolve
A **cross-border healthcare IT infrastructure** must be able to integrate with existing IT systems to support the management of health data. It must protect current investments, as well as being able to evolve to support new projects in a cost effective manner.

Growth
The **cross-border healthcare IT infrastructure** will support the Central Repository for healthcare information collated over a number of years. The underlying technology architecture should not only be proven to scale, but also evidence the ability to incrementally grow as and when required.

The technology on which the **cross-border healthcare IT** solution is based should enable hardware and software elements to grow without the need to reconfigure the entire system to take account of technology developments or system growth. The **cross-border healthcare IT infrastructure** should incorporate facilities to integrate seamlessly with existing systems making full use of available standards for integration. It should also be based on a technology that limits the cost of ownership by having specific facilities to reduce the burden of maintenance and for which there is a large body of people with the necessary technical skills to manage it.

Fully featured
The **cross-border healthcare IT infrastructure**'s ability to manage information demands more than a simple database:

- The data managed will consist of both structured and unstructured information
- The infrastructure will be required to store data, communicate and exchange it, query and report on it, analyse and data-mine it.

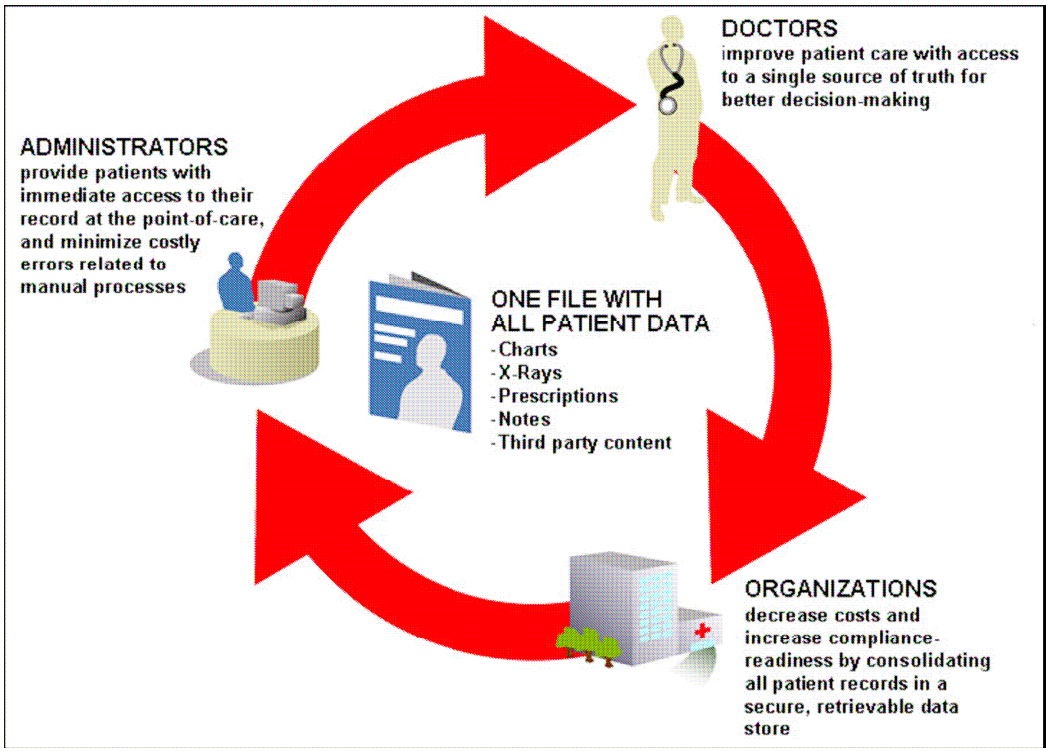
Incorporate new technology advances
Technology is rapidly evolving. The **cross-border healthcare IT infrastructure** should be based on a platform that is able to evolve to take advantage of new technical advances. Good examples include:

- The use of wireless technology to enable patient health information to be delivered at the point of care whenever and wherever it's needed.
- Radio Frequency ID (RFID). RFID can be used to label and track many items critical in healthcare including patients, test samples, healthcare equipment, consumables, etc.

Support for Collaboration
The **cross-border healthcare IT infrastructure** supports the ability to enable healthcare professionals to collaborate and share information in a highly effective manner. The infrastructure should enable collaboration in a variety of ways, including sharing information electronically in real time, communicating information electronically using email and making knowledge available as a centrally stored resource. The infrastructure should enable collaboration to:

- Be message based
- Use internet technology securely and reliably

Terminology Management
The **cross-border healthcare IT infrastructure** must enable standard sets of terminologies to be used for the normalisation of data. The **cross-border healthcare IT infrastructure** should enable standard terminologies (e.g. ICD10, HL7 terminologies, SNOMED. LOINC and OPCS4) and the cross-maps between these terminologies to be managed (e.g. SNOMED to ICD10 cross map).



Conclusion

Oracle endorses the objectives of the consultation and appreciates the opportunity to share with the Commission our views on the appropriate information infrastructure which will assist the European Union in making cross border health services a reality for Europe's citizens. The right to access or deliver health services on a cross border basis is not sufficient if the appropriate infrastructure is not in place.

As explained in the attached annex, actions to create this infrastructure at a European level can make a difference in the lives of Europeans. « Patients without Borders » should be our objective. Leadership and coordination at a European level can make Patients without Borders a reality.

Cross border health services and the underlying essential information infrastructure will bring important and tangible benefits for Europeans through :

- Enhanced quality of patient care
- Greater access to medical information and specialist care in smaller member states which may lack the resources and critical mass to develop national healthcare IT infrastructures
- Greater efficiencies across the EU in the use of resources dedicated to healthcare

Annex :

Our Vision : The « Patient without Borders «

'Patients without borders' was a term coined by Bernard Kouchner, former French Health Minister and creator of Doctors without Borders. Oracle endorses this « without borders » concept in the broadest terms. Healthcare related borders should be broken down not only between member states, but also between Europe's regions, hospitals, home care and primary care, healthcare, life sciences and research. Today, links sometimes exist between these entities but they are weak and inconsistant.making healthcare inefficient and expensive.

Many reforms and political decisions have been taken to develop more cooperation through « connected health – like « initiatives :

- Health Infoway in Canada
- HealthConnect in Australia
- Connect for Health in UK (NHS)
- DMP and DCC in France
- NHIN and RHIOs in US
- EGK in Germany
- Diraya in Spain (Andalusia)
- In Italy (Lombardia)
- and in many of the newer EU member states.

What is a 'Patient without Borders' in action ?

NC is a 38-year-old businessman with no known health problems. He resides in Cologne. His mother has been scheduled to undergo major surgery (total hip replacement) at a hospital in Munich; she will need to have units of whole blood on reserve in the Munich Blood Bank. On February 14, NC donates blood at the Munich blood bank. As part of the process, a CBC (complete blood count = hemogram) is obtained. NC's hematocrit (one measure of the quantity of his red blood cells) on February 14 is 45 (a normal hematocrit for a man.)

NC is an avid tennis player. He normally plays tennis quite regularly. In recent weeks, his right shoulder has been so painful that he has had to limit his tennis game. On February 21, NC visits his general practicioner in Cologne. After taking a history and examining NC, Dr. Falke prescribes Sulindac 200 mg twice daily for the pain. Sulindac is a member of the category of drugs known as non-steroidal anti-inflammatory drugs (NSAID's.) It is often effective for joint pain that arises from athletic activity. NC discovered that the Sulindac gave him substantial relief and, with his doctor's agreement, continued to take it. His tennis game was restored.

NC's business often requires that he travel. On April 21, NC traveled to Toronto. He spent 3 days in Toronto visiting customers. On April 25, he returned to Germany, arriving at Frankfurt Airport in the morning. On the flight over, NC asked the flight

attendant for some aspirin. He had not felt particularly well the morning of the flight and, after take off, he began to feel as if he had a temperature. In conversation with the flight attendant, NC was reminded that he has some joint pains. During the flight, he started having spells of coughing that were noted by the flight attendant.

At Frankfurt Airport, NC was met by a team of people who were responsible for screening passengers from SARS infected areas that appeared to be at risk for SARS. Because the WHO had lifted its travel advisory for Toronto, the flight attendant had notified the Frankfurt Airport monitoring team. NC was taken to an area of the airport where a small clinic had been organised. After a thorough examination (including chest x ray and blood tests), NC was not felt to have SARS, and he was released to complete his journey home to Cologne. In his hurry to get through the process (he was now 3 hours late in getting home), NC failed to mention that he was taking Sulindac for his shoulder pain. Among his laboratory studies was an hematocrit of 40 (normal for a man.) Nurse Moltz at the Frankfurt clinic also recommended taking aspirin to reduce his fever.

Without a **cross-border healthcare IT infrastructure** that contains a repository of critical clinical information, no one would be able to quickly detect that NC was in serious danger – not from SARS, but from gastrointestinal bleeding. Between February 14 and April 25, NC's hematocrit had dropped more than 10%. Since both hematocrit values were in the normal range, neither test would have triggered an alert by itself. Between February 14 and April 25, NC began taking Sulindac, an NSAID that can cause gastrointestinal bleeding. Moreover, the recommendation to take aspirin by Nurse Moltz at the Frankfurt Airport clinic magnifies the hazard because aspirin also is associated with gastrointestinal bleeding. By itself, the Sulindac drug order would not have triggered an alert.

How 'Patient without Borders' Becomes Reality

The most efficient and practical way for concerned clinicians to author rules that would efficiently detect danger in a combination of three "normal" events is to have the clinical information from those events in **a cross-border healthcare IT infrastructure**. For evidence-based medicine and transactional decision support systems to work efficiently, rules must be able to "reason" over the patient record. It is impossible to reason over records in a distributed system and still retain any semblance of adequate performance. With **a cross-border healthcare IT infrastructure** that includes core clinical information populating a schema of a standard information model, a rule (triggered by updates to NC's record in the system) could reason over NC's record and discover that Dr. Falke and/or NC should be notified about the potential for gastrointestinal bleeding. A simple study to detect gastrointestinal blood loss could be quickly obtained. If such a test were positive, NC would be advised to stop taking Sulindac.

Cross-border healthcare information infrastructure will enable NC to be a 'Patient without Borders' with corresponding increases in quality care and reduced rates of diagnostic errors..