Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

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1 Executive Summary

This final version provides an overview of some of the existing regulations and standards that need to be taken into account for the future deployment of the project's services as well as a brief market analysis. The European legislation will be continuously watched in order to detect new regulations and new initiatives for harmonizing standards in the activities carried out in WP9 and WP12 , which will allow the consortium to react to the market legislative changes and adapt the platform and the implementation of the selected technologies and business models for each country.

2 Glossary of acronyms

AC/DC: Alternative Current / Direct Current

ARH: Regional hospital agencies, France.

ASVG: General Social Security Act

ATC for the active substances of medicinal products

ATR. Annual Technical Review

BMGF: Federal Ministry of Health and Women

CEN: European Standardisation Committee

CENELEC: European Committee for Electrotechnical Standardisation

CHA: Continua Healthcare Alliance

CGM: continuous blood glucose monitoring

DG: Directorate-General

DDS: decision support system

EN: European Standar

EU: European Union

EC: European Commission

EHR: electronic health records

ETSI: European Telecommunications Standards Institute

GP: General Practitioners

GDP: Gross domestic product

HD: Harmonisation Document

IAPO :International Alliance of Patients' Organizations

IHE: Integrating the Healthcare Enterprise

ICPC2 as terminology and classification for use in primary care

ICD-10 as terminology and classification extension linked to the ICPC2

ICT: Information and Communication Technologies (

IHTSDO: International Health Terminology Standards Development Organisation

IS: Impedance Spectroscopy

IEC: International Electrotechnical Commission

ISO: International Standardisation Organisation

HL7: Health Level 7

KMEHR (Kind Messages for EHR) as xml based syntax standard, e.g. for

NHS:. National Health Service. UK

NIR: Near Infrared Spectrum .

OECD Organisation for Economic Co-operation and Development

PCTs: The Primary Care Trusts, UK

SDO: Standards Development Organisations

SME: Small and Medium enterprises

SWOT Strengths, Weaknesses, Opportunities and Threats

SST: Denmark, the National Board of Health

URCAMs: Regional Unions of the Health Insurance Funds. France

XACML: eXtensible Access Control Markup Language

WMA: World Medical Association

WP: Work Package

WHO: World Health Organization

3 Introduction

D2.4 Market and Regulatory Standards Watch Report is part of the WP2 “User Centric Requirements Engineering and Validation” and aims to provide requirements regarding the regulatory and standards aspects as well as market trends related to the potential exploitation of the project’s results. An extensive regulatory and market analysis will be carried out in WP9 “Socio-economic Framework” as well in the Dissemination and Exploitation WP12, specifically within deliverables D9.2 “Regulatory Framework and data protection” and D12.2 Market and Competitor Analysis”

3.1 Purpose, Context and Scope of this Deliverable

This final version completes the draft version submitted at month 12, and it aims at providing initial analysis of the rules imposed by national laws and EU regulation as well as the mandatory standards that REACTION platform have to fulfil. The final version will provide a study of the national/European eHealth initiatives and regulations that could affect the future deployment of the REACTION in each European country.

The final scope of this deliverable is to identify market initiatives and regulations that need to be addressed in each EU member state for the successful deployment of REACTION services. All of these initiatives will be investigated and the specific requirement should be identified and translate into technical requirements in the JIRA application.

3.2 Target Audience

This final version of this deliverable is a public document that aims at eliciting legal and standards-related requirement to the REACTION platform.

3.3 Structure of the Document

The document is structured in two main chapters one devoted to market analysis and other related to regulations and standards description.

3.4 Defining REACTION Services

The REACTION project aims to develop an intelligent service platform providing proficient remote disease management to diabetes patients in different healthcare regimes across Europe. At this moment of the project, main exploitations can be foreseen in terms of platform services and/or in terms of developed sensors.

3.4.1 REACTION as a Diabetes Disease Management Platform

The reaction platform will provide services for disease management such as monitoring of vital signs, context awareness, feed-back to the point of care, integrative risk assessment, event and alarm handling as well as integration with clinical and organisational workflows and external Health Information Systems. The final expected outcome is to improve continuous blood glucose monitoring (CGM) and safe glycaemic control in order to provide better insulin-based therapy and bolus dose adjustments and significantly reduce the risk of long-term complications.

3.4.2 Sensors for Glucose Measurement

In the REACTION environment patients will be continuously monitored with wearable, minimally invasive sensors. IMM and MSG will develop two different sensors subcutaneously applicable for continuous control of blood glucose level. The sensor will work by optical absorption spectroscopy in the near infrared spectrum (NIR). Later on the sensor shall be implemented into a portable sensor unit which will be applied plaster-like by the patient. MSG’s minimum invasive continuous glucose sensor employs transcutaneous fluorescence measurements based on frequency-domain measurements in the near infrared region. Therefore, sensor used in REACTION are medical devices, what it means any instrument, apparatus, appliance, material or other article, whether used alone or in combination,

including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, **monitoring**, treatment or alleviation of disease[1]. Under this definition, not only the sensors but also the software developed during the REACTION project will be considered medical devices.

1 Directive 2007/47/EC. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF

4 Market Analysis

4.1 The EU Health Sector and ICT

The health sector in the European Union (EU) employs almost 10% of the total workforce and corresponds to almost 9% of gross domestic product (GDP)[2]. Health spending is rising faster than GDP and it is estimated to reach 16% of GDP by 2020 in OECD countries[3] . Diabetes Mellitus is a chronic disease that occurs when the production of insulin in the pancreas is impaired. The WHO estimates that diabetes causes about 5% of all deaths globally every year. It is expected that diabetes deaths are likely to increase by more than 50% in the next 10 years without urgent action.

These figures present huge challenges to the sustainability of current health systems unless corrective actions are taken, such as promoting ICTs-based solutions. Medical ICTs hold the promise of revolutionising patient assistance and are considered the main approach for facing European health-related challenges, such as the increase in chronic diseases like diabetes. In 2006, the European E-Health market was estimated worth close to €21 billion[4,5]. The major part (close to 80%) of this market represents generic ICT infrastructure (networks, communication, hardware, software for the back office management).

Recent research has suggested 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 Europe represents one third[6]. By 2010, a double-digit growth rate of up to 11% was foreseen as driven by a search for more productivity and performance[7]. However, this potential growth might not occur if the existing barriers to the market remain, as the lack of real interest of adopting standards. However, all market players and observers agree that eHealth in Europe is set for explosive growth, driven by the need to face the health-related challenges (older population, increase of chronic diseases, shortage of healthcare professionals) and to take advantage of growing new medical information and communication technologies. This potential growth is expected in the specialised eHealth services such as those that will be provided by REACTION platform. Successful commercialisation cannot be achieved based only on providing technical wizardry, commercial success requires end user (patient/doctor) acceptance based on providing simplicity, user friendliness, supporting health care service redesign and above all, improvement with respect to current diabetes (self)-management.

The consortium will analyse the diabetes management market in order to have a clear representation of its structure, its key players and their needs. The market will be continuously watched in order to detect new trends, niches and possibilities, which will allow the consortium to react to the market changes and adapt the platform and the implementation of the selected technologies and business model. A it was mentioned a more detailed market analysis is provided in D12-2 Market and Competitor Analysis.

4.2 Business Model

Diabetes Mellitus management for insulin dependent diabetics has two major tasks: measuring the amount of glucose in the blood at various intervals and, if necessary, administration of insulin to maintain a healthy glucose level, avoiding hyperglycaemic and hypoglycaemic events. For non insulin dependent diabetics it is about lifestyle management. Therefore, also from a commercial point of view it is necessary to distinguish between these two groups.

Monitoring with the REACTION platform may also be of interest beyond that of diabetes patients. If extended to monitoring of patients for other relevant vital signs, other avenues may be exploited, and other possible revenue streams and business models may be defined.

2 Fujisawa R. and F. Colombo (2009), The long-term care workforce: overview and strategies to adapt supply to a growing demand, OECD Health Working Papers n. 44. See also Employment in Europe 2009:

http://ec.europa.eu/social/main.jsp?langId=en&catId=113&newsId=642&furtherNews=yes

3 Source: OECD.

4 http://www.buyusa.gov/northcarolina/exportit.html. US Foreign Commercial Services

5 http://ec.europa.eu/enterprise/policies/innovation/files/swd_lmi_midterm_progress.pdf. Lead Market Initiative for Europe Mid-term progress report

6 Health Information Network Europe (HINE) report 2006 – European eHealth forecast

7 http://ec.europa.eu/enterprise/policies/innovation/files/swd_lmi_midterm_progress.pd. Lead Market Initiative for Europe Mid-term progress report

The first step towards the exploitation of the project results is to clearly identify the expected results that will necessarily comply with the regulations and standards in a fragmented market.

This chapter presents an initial market analysis in order to identify the main stakeholders in relation to diabetes (self)-management. This includes an overview of different national healthcare systems and their financing. The structures of European healthcare systems are diverse, and it is therefore necessary to be aware of fundamental differences. In this initial report the healthcare systems in France and eight of the REACTION partner countries have been outlined. In the final version of this report the remaining two partner countries (Hungary and Switzerland) and a number of other EU Member States will be included, as these will be the main targets for exploitation.

Telemedicine is both a health service and an information society service[8]. As such, it falls under the EC Treaty (Article 49) and additional EU secondary legislation, in particular Directive 2000/31/EC, referred as the "e-Commerce Directive". The e-Commerce Directive defines rules for the provision of Information Society Services[9]. As pure business activity REACTION services have to comply with Directive 2005/29/EC of the European Parliament and of the Council of May 2005 concerning unfair business-to-consumer commercial practices in the internal market (Unfair Commercial Practices Directive). Directive 97/7/EC on the protection of consumers in respect of distance contracts and Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

4.3 National Healthcare Systems

Although there are specific national variations there are some general characteristics as to how the healthcare systems in the EU Member States are organised in relation to financing and provisioning of general healthcare services. Overall, the main difference between the healthcare systems is related to the financing of the systems, which in turn influences how healthcare provisioning is organised. We may therefore distinguish between tax-based systems where the public sector provides healthcare services free at the point of use, and statutory insurance contribution-based systems where there is a mixture of public and private providers and where some services must be paid for at the point of use.

4.3.1 Austria

The organisational structure of the Austrian healthcare system is defined by the interaction of public, private non-profit-making and private profit-making players. There are three levels of organisation, the federal level, the Länder and local community level and the self-governmental level (social insurance and service providers).

At the federal level the main players are the Nationalrat and the Bundesrat (Lower and Upper Houses of Parliament), the Federal Ministry of Health and Women (BMGF) and the social insurance institutions.

The tasks of the Federal Government are largely delegated to the Länder within the framework of indirect federal administration and/or to the self-governing social insurance institutions. However, the Federal Government retains an important role in policy-making and as a supervisory authority for the enforcement of the laws on healthcare provision. It also has important competencies in the training of health professionals. As a supervisory authority, the BMGF monitors adherence to the laws which are implemented by the social insurance institutions and the professional organisations of service providers in order to ensure the provision of healthcare.

The Länder and municipalities play an important role in establishing, implementing and monitoring the various aspects of the public health service. Legislation at Länder level is made by the Länder parliaments, whose members are elected by proportional representation. The state government is the supreme health authority of the Land. It is supported by the office of the state government and by the state health board. There is thus a separate department for health in each state government, which is led by a physician with civil servant status, the State Health Director. The office of each state government has a state health board at its disposal for advisory purposes.

8 As defined by Directive 98/34/EC

9 COM(2008) 689 Communication from the Commission on telemedicine for the benefit of patients, healthcare systems and society

The State Health Funds are public law funds and separate legal entities. Each Land has to establish such a fund. If an agreement is reached between the respective Länder, it is also possible to set up a joint health fund for several Länder.

The management of public hospitals in all the Länder has been outsourced to hospital operation companies organised according to private law, with the exception of Vienna. The organisational structures of these companies differ, but one thing they have in common is that as representatives of the owners they implement the mandate of the Länder to provide healthcare and make strategic decisions on behalf of the Länder

Apart from the hospitals sector, healthcare provision for the Austrian population is organised by negotiations between the social insurance institutions and the professional or statutory representatives of the service providers. Whereas public bodies which exercise sovereign powers have obligatory membership (Physicians' Chambers, Pharmacists' Chambers), statutory representative bodies have no mandatory membership, except for active midwives. However, the latter are still able to conclude collective agreements in some cases.

The social insurance system constitutes an independent area of competence in which legislation and implementation are the responsibility of the Federal Government. The Federal Government has, however, delegated implementation to the social insurance institutions, which are managed as self-governing bodies.

In accordance with the tasks defined by the constitutional and social insurance laws, the financing of healthcare expenditure is pluralistic. Social health insurance, which covers the risk of illness of around 98% of the population, is the most important source of financing. It financed 45% of healthcare expenditure in 2004. Including the expenditure for long-term care (7.7%), 25% was financed from general tax revenue. Including the expenditure on private health insurance, private households financed 25% of health expenditure.

Social health insurance is organised as mandatory insurance. The legal basis for health insurance is provided by the General Social Security Act (ASVG) and the concept of illness it defines, as well as its amendments and the Act on Social Insurance for the Self-employed (GSVG), the Act on Social Insurance for Farmers (BSVG) and the Civil Servants' Health and Work Accident Insurance Act (B-KUVG).

As a mandatory insurance system, the social insurance institutions cover almost all the working population and pensioners. In 2004, 97.6% of the population were covered by social (statutory) health insurance. Since the year 2000, physicians, pharmacists, lawyers, architects, accountants, veterinary surgeons and notaries public can opt for mandatory insurance (opting out in accordance with Section 5 of the GSVG). However, if they opt out, their health insurance cover must be otherwise provided with at least almost equal services, either via arrangements with their professional bodies (particularly taking out private health insurance in a group insurance contract), or through voluntary insurance according to the ASVG or the GSVG.

Multiple insurance is possible in principle. Social assistance claimants and prisoners are not usually covered by social health insurance, but they receive health services from the regional authorities. Access to voluntary insurance is largely unrestricted. Voluntary health insurance is the most common type of voluntary insurance.

Private expenditure particularly includes all direct and indirect cost-sharing. Payments by private households for inpatient services account for the majority of indirect cost-sharing (53%). Of this, around three quarters is payments for "special class" services, the remainder is accounted for by hospital cost contributions. The proportion of health expenditure which is financed via general tax revenue is about 25%.

Public hospitals are funded from social health insurance and by value-added tax revenue (Hofmarcher & Rack, 2006).

4.3.1.1 ICT in Healthcare

In The Austrian Health Reform Act 2005, the use of information technologies in healthcare was defined as a priority. Also, the Health Telematics Act aims at the secure exchange of individual health data. The implementation of the e-card (Health Insurance Card) was completed in 2005. Initially, the e-card was used to verify health insurance entitlement, but in 2006 integration of the hospital information systems began and the plan is to add a range of functionalities which will be offered to e-

card users (European Commission, 2007). Standards currently used in Belgium are ATC, ICPC2, ICD-10, ICD-9-CM, ICD-10-CM, ICD-9-CM and KMEHR

4.3.2 Bulgaria[10]

According to the National Statistical Institute of Bulgaria the country's population is around 7.6 million inhabitants. A high percentage of the population (71%) resides in urban areas. Bulgaria has transformed its centralized, tax-based system into a decentralized and pluralistic compulsory health insurance system. The National Health Insurance Fund (NHIF) NHIF provides most of the funding through the regional health insurance funds; it finances the entire healthcare network for outpatient care and hospitals. All the citizens are covered by the obligatory health insurance system and receive at least the basic healthcare benefits, reimbursement are provided by the NHIF. Private insurance companies are also providing alternative healthcare services, such as treatments that are restricted or not available in the state health insurance. In 2010, the healthcare budget was 4.2% of GDP, what it means around 1.3 billion euro. Bulgaria has 361 medical doctors per 100,000 people, which is above the EU average of 32[11]. Doctors in Bulgaria are trained to a very high standard, though hospitals and clinics in general may not have all the equipment and facilities we would find in Western Europe or in the USA. Despite this, standards of healthcare have improved dramatically since the post-communist restructure.

4.3.2.1 ICT in Healthcare

The Health Ministry is responsible for the implementation of the eHealth Strategy. Currently, there are few telemedicine applications in Bulgaria. It is worthy to mention the ICT system that connects two Obstetrics & Gynaecology departments between two hospitals located in Sofia and Pleven. There is also a pilot project for remote monitoring of chronic heart diseases that monitors around 600 patients. There was also a project for EHR but it was abandoned. Standards currently used in Bulgaria are HL7, IHE, ICD 9, ICD 10, EN/ISO 13606.

4.3.3 Belgium

The Belgian health system is mainly organized on two levels, i.e. federal and regional. Since 1980, part of the responsibility for healthcare policy has been devolved from the federal Government to the regional governments.

Responsibility for healthcare policy is shared between the federal Government, and the Dutch-, French- and German-speaking community Ministries of Health.

The federal Government is responsible for the regulating and financing of the compulsory health insurance; determining accreditation criteria; financing hospitals and so-called heavy medical care units; legislation covering different professional qualifications; and registration of pharmaceuticals and their price control. The regional governments are responsible for health promotion; maternity and child health services; different aspects of elderly care; the implementation of hospital accreditation standards; and the financing of hospital investment.

Numerous public authorities are responsible for the funding of healthcare and for overseeing its organisation. The division of responsibilities is mirrored by the fragmented structure of the Belgian State. At the federal level the authorities determine the general legislative framework for the health system by issuing laws and by determining the annual budget. The three communities (Flemish, French and German) are autonomous and responsible for health promotion and preventive healthcare, except for certain national preventive measures, such as compulsory vaccinations (e.g., for polio).

With regards to secondary care, the communities are responsible for ensuring the implementation of norms and standards for hospitals and rest and nursing homes that have been set at the federal level.

[10] European countries on their journey towards national eHealth infrastructures. 2011.Final European progress report

[11] Individual eHealth Strategies Country Report (2010), further information, and eHealth ERA Report (2007)

The Belgian health system is based on the principles of equal access and freedom of choice, with a compulsory national health insurance, which covers almost 99% of the population and has a very broad benefits package. Compulsory health insurance is combined with a private system of healthcare delivery, based on independent medical practice, free choice of service provider and predominantly fee-for-service payment. All individuals entitled to health insurance must join or register with one of several sickness funds, which are a non-profit, non-commercial organization.

Patients participate in healthcare financing via co-payments, for which the patient pays a certain fixed amount of the cost of a service, with the third-party payer covering the balance of the amount; and via co-insurance, for which the patient pays a certain fixed proportion of the cost of a service and the third-party payer covers the remaining proportion. There are two systems of payment: (i) a reimbursement system, for which the patient pays the full costs of services and then obtains a refund for part of the expense from the sickness fund, which covers ambulatory care; and (ii) a third-party payer system, for which the sickness fund directly pays the provider while the patient only pays the coinsurance or co-payment, which covers inpatient care and pharmaceuticals.

Most physicians – whether they are GPs or specialists – are paid on a fee-for-service basis. The patient pays the set fee for the consultation directly to the physician, and patients are then directly reimbursed by their sickness funds. Most services are reimbursed at a rate of 75%, so the patient shares 25% of the cost. The fee schedule is negotiated yearly or biennially between representatives of the sickness funds and of the healthcare professionals.

Public sector funding as percentage of total expenditure on health care fluctuates around 70%. Social security contributions and subsidies from federal Government are the main funding sources for the compulsory health insurance system. In 2005, social contributions accounted for 74.8%, state subsidies for 11 .4% and alternative financing (mainly from indirect tax revenues) for 13.8% of the general social security scheme. For the self-employed, shares were 64.5%, 29.1% and 3.4% respectively.

Both in the general system and in the system for the self-employed, social security contributions are related to income and independent of risk. In the employed workers' scheme, there is both an employees' and an employers' contribution. The self-employed pay their own social insurance contributions to their social insurance fund (Dick Corens, 2007).

4.3.3.1 ICT in Healthcare

Belgium's eHealth strategy focuses on using ICT to improve the quality of healthcare delivery, including the exchange and sharing of healthcare information. Basic interoperability has been achieved, and the priority is now on the development of "intelligent" applications (decision support) for general practitioners, and on the structure and codification of patient files for other practices (European Commission, 2007),

4.3.1 Cyprus[12]

The country's population is around 789,300 inhabitants and theaverage life expectancy at birth is 79.2 . The Public health is under the responsibility of the Ministry of Health.

The healthcare expenditure is 6.5% of GDP. The National Health Insurance Fund (NHIF) NHIF provides most of the funding through the regional health insurance funds; it finances the entire healthcare network for outpatient care and hospitals. All the citizens are covered by the obligatory health insurance system and receive at least the basic healthcare benefits, reimbursement are provided by the NHIF. Private insurance companies are also providing alternative healthcare services, such as treatments that are restricted or not available in the state health insurance. In 2010, the healthcare budget was 4.2% of GDP, what it means around 1.3 billion euro. Bulgaria has 361 medical doctors per 100,000 people, which is above the EU average of 32[13]. Doctors in Bulgaria are trained to a very high standard, though hospitals and clinics in general may not have all the equipment and

[12] European countries on their journey towards national eHealth infrastructures. 2011.Final European progress report

[13] Individual eHealth Strategies Country Report (2010), further information, and eHealth ERA Report (2007)

facilities we would find in Western Europe or in the USA. Despite this, standards of healthcare have improved dramatically since the post-communist restructure.

4.3.1.1 ICT in Healthcare

Cyprus's eHealth strategy has been a priority from 2005, but it still in the process of deployment. Therefore, the use of ICT technologies for healthcare applications is still pending of being developed. However a there is national strategic program that aims to cover eHealth services. In fact, the Ministry of Health aims to push ICT adoption during the next coming years with the objective of deploying electronic health record system.

4.3.1 Czech Republic [14]

The country's population is around 10.300.000 inhabitants and theaverage life expectancy at birth is 78. Public health is under the responsibility of the Ministry of Health. In 2008 the healthcare expenditure was 7% of the GDP (OECD). The Czech republic healthcare system is public funded and is financed by statutory health insurance payments to the health insurance, additionally taxes and patients payments covered the total expenditures.

4.3.1.1 ICT in Healthcare

ICT technologies for Healthcare are used widely in Czech Republic, especially for patients' data storage and for supporting clinical decision. Transference of EHR is not common but there are initiatives for providing tools to the doctors for using EHR. A specific multidisciplinary department, the Interdepartmental Committee for eHealth deals with all issues related to the deployment of eHealth initiatives.

4.3.2 Denmark

Denmark implemented a structural reform in 2007, which had implications for the structure of the healthcare system. All residents enjoy free access to health services. The main feature of the Danish healthcare system is a decentralized responsibility for primary and secondary healthcare. There are three administrative levels: the State, the regions and the municipalities, each with clearly defined responsibilities. The state (as in the Ministry of Health) is responsible for national health policy, financing of the health system, and health insurance. The new regions will be overall responsible for the healthcare system. Regions own and run hospitals, and partly or fully finance private practitioners, e.g. general practitioners (GPs), specialists and physiotherapist. The municipalities are responsible for disease prevention, health promotion, long-term care, rehabilitation, and social care.

The financing of the healthcare system is obtained through earmarked proportional taxation at the national level. 80% of this revenue is redistributed to the regions via block grants, based on objective criteria (social and demographic indicators), and 20% is redistributed to the municipalities which use these funds to co-finance regional hospital services for the respective population. Self-employed practitioners are reimbursed by taxes and user charges. There are very few private hospitals and clinics in Denmark. These are reimbursed by taxes, private insurance and user charges. Pharmacies are privately owned; they are licensed by the State and subject to strict regulations.

There is an increasing level of user payments for healthcare (mainly for pharmaceuticals, dental care and physiotherapy), primarily as a result of a growing private health insurance market, which has been partly established through labour market agreements for groups of employees. In addition, a current trend shows support for introducing more co-payments, such as patient fees for GP consultations. Also, the increasing demand for new healthcare technologies, the aging of the population, and the growing number of patients with chronic diseases might promote political initiatives to reduce access to publicly funded services through new financial and structural reforms.

Trends within the national healthcare provisioning, point towards a decrease in the length of hospitalised treatment and an increase in outpatient treatment at clinics or at home.

[14] European countries on their journey towards national eHealth infrastructures. 2011.Final European progress report

Notably, there is also a trend pointing towards patients becoming more involved with their own healthcare treatment; a development not least due to the increased access to health related information on the Internet, such as the Danish eHealth Portal. (Strandberg-Larsen et al., 2007)

4.3.2.1 ICT in Healthcare

A National Strategy Group has been established for the development of an IT strategy in Health. The National IT Strategy for the Danish healthcare service was later published, which provided a common framework for the full computerization of the health sector for the period 2003-2007. The implementation of electronic health records (EHR) and the spread of EHR within the health system were among the initiatives (European Commission, 2007).

4.3.1 Estonia [15]

Estonia has a population of 1.3 Million inhabitants with an average life expectancy at birth of 75 years. There are 3.41 physicians per 1.000 people, this ratio has been slightly increased, together with the health expenditure (7% GDP) during the past years whereas the number of hospitals' bed per 1000 inhabitant has slightly decreased, and nowadays is around 5.71. Estonia healthcare system has underlined a deep and successful transformation during the last decades, including regulatory and legal reforms. Estonia has now a modern primary healthcare system providing a network of family medicine-centred primary health care, which deals with health prevention issues. There is an official policy focused on public health goals and services. The healthcare system is funded mainly by public budget; taxes and patients payments covered the total expenditures. There are number of agencies dealing with different aspect of the healthcare system such as National Institute for Health Development (NIHD), the Health Board (HB) as well as an the Estonian Health Insurance Fund independent public body. In 2008, Estonia developed a primary healthcare development plan that promotes the organization of the primary care services integrated with specialist and social care in health centers. The health centers are built around family doctors. The reforms have improved the healthcare system, centered it in the primary care, supported by ambulatory services across the country.

4.3.1.1 ICT in Healthcare

Estonia is one of the most advances countries in relation with the implementation of ICTs in the clinical practice. Some key factors underpin the high level of adoption of eHealth, such as Estonia's small population, the impressive economic growth for many years prior to the current downturn, but overall the high investment in Public health in Estonia 2008. General practitioners use routinely computers that are mostly used for storing patients' data. Data consultation and clinical decision support tools are mostly used for supporting diagnosis and treatments. Recently was established the Estonian electronic health record (EHR), with the interesting particularity that t can be accessed by both medical professionals and patients. Unlike most European countries, Estonia has a well developed system of e-prescription covering the whole country making possible that more than 75% of prescriptions are electronic prescriptions. The high interest is the Estonian initiative for storing and sharing images, the Picture Archiving and Communication System (PACS). This system allow physician to share images from different hospitals,

4.3.1 Finland[16]

Finland has a population of 5.4 Million inhabitants with an average life expectancy at birth of 80 years, the healthcare expenditure arise up to 8.2% of the GDP. The Finnish administration is structured at three levels: central, regional and municipal. The municipalities have a great level of autonomy; in fact, they are the healthcare providers, although healthcare policy is regulated by the Ministry of Social Affairs and Health. The healthcare system is mainly tax-based funded and covers the whole population. In addition, there

[15] Koppel, A., A. Leventhal, et al. (2009) Public health in Estonia 2008, An analysis of public health operations, services and activities. Copenhagen, World Health Organization Europe.

[16] European countries on their journey towards national eHealth infrastructures. 2011.Final European progress report

is a private and occupational healthcare system. Hospitals are organized in districts composed by several municipalities.

4.3.1.1 ICT in Healthcare

ICT in Finland is used widely by GPs. It is estimated that 100% of GPs use a computer with internet connexion that is used for storage medical patients' data. CDSS is also widely used and internet is also used for transferring lab results. Currently, there are several initiatives regarding EHR interoperability and ePrescription

4.3.2 France

Jurisdiction in terms of health policy and regulation of the healthcare system is divided between the state (parliament, the government and various ministries) and the statutory health insurance funds. The structure of the public healthcare system can be divided as follows: the state, regional level, departmental level (local communities) and statutory health insurance.

The state regulates the quality of health service organisation, monitors safety, regulates the volume of health services supply and oversees social protection and regulates the healthcare system. The state also sets the ceiling for health insurance spending, approves a report on health and social security trends and amends benefits and regulation. The Government decides the methods of financing and sets tariffs.

The regional hospital agencies (ARH) are responsible for hospital planning (for both public and private hospitals), financial allocation to public hospitals and adjustment of tariffs for private for-profit hospitals (within the framework of national agreements). They bring together, at the regional level, the health services of the state and health insurance funds, which previously shared management of this sector.

The Regional Unions of the Health Insurance Funds (URCAMs) bring together the three main health insurance schemes at the regional level. They coordinate the work of the funds and give impetus to a regional policy of risk management. In relation to the ARHs, whose role is operational, their function is more to influence and stimulate and they do not have authority over the regional and local funds.

The three main health insurance schemes are: 1) The general scheme (Régime general) which covers employees in commerce and industry and their families (about 84% of the population) and CMU beneficiaries (about 1.6% of the population), 2) the agricultural scheme (MSA) which covers farmers and agricultural employees and their families (about 7.2% of the population), and 3) the scheme for non-agricultural self-employed people (CANAM) which covers craftsmen and self-employed people, including self-employed professionals such as lawyers etc. (about 5% of the population).

France's health system is based on a national social insurance system complemented by elements of tax-based financing (especially the General Social Tax) and complementary voluntary health insurance. The Ministry of Finance and Ministry of Social Affairs and Employment holds authority over finances, including the financial administration of the French healthcare system.

The National Health Insurance System (NHIS) guarantees universal access to healthcare for the whole population resident in France. The CNAMTS (Caisse National d'Assurance Maladie des Travailleurs Salaries) accounts for 80% of the NHIS. It covers mainly employees in the commercial and industrial sectors, as well as their families. The remaining 20% of the NHIS consists of funds for agricultural workers, independent professions, civil servants, doctors and students.

The national funds of the three main health insurance schemes also conclude agreements with self-employed healthcare professionals practicing privately: general practitioners, specialists, dental surgeons, nurses, physiotherapists, biologists, midwives, speech therapists, orthoptists and ambulance personnel. These agreements concern the conditions and level of charges for treatment. Home care is delivered by self-employed professionals or by specialised home care services (European Commission, 2007).

4.3.2.1 ICT in Healthcare

The French eHealth strategy focuses on using ICT for optimisation and reengineering of the healthcare system. eHealth has already been implemented at both local and regional levels. A national eHealth virtual community has also been realised through the national mapping of all eHealth

initiatives. Some of the eHealth implementations include the CPS (Carte de Professionnel de Santé – Health Professional Card), a microprocessor card whose functionalities include identification, authentication and electronic signature of health professionals, and a microprocessor card (carte Vitale) which contains health insurance data for the insured and their beneficiaries. In the near future, the Vitale card will be replaced by a new one, the Vitale 2 (European Commission, 2007).

4.3.3 Germany

The healthcare system has a decentralized organisation, characterised by federalism and delegation to non-governmental corporatist bodies as the main actors in the social health insurance system: the physicians' and dentists' associations on the providers' side and the sickness funds and their associations on the purchasers' side.

The Ministry of Health and Social Security proposes the health acts that - when passed by parliament - define the legislative framework of the social health insurance system. It also supervises the corporatist bodies and - with the assistance of a number of subordinate authorities - fulfils various licensing and supervisory functions, performs scientific consultancy work and provides information services.

The 292 sickness funds collect contributions and purchase proactively or pay retroactively for health and long-term care services for their members. Since 1996 almost every insured person has had the right to choose a sickness fund freely, while funds are obliged to accept any applicant.

According to figures from 2002, public funds cover 79% of the health expenditure. Of total expenditure, 57% of the funds came from statutory health insurance, 7% from statutory long-term care insurance, 4% from other statutory insurance schemes and 8% from government sources. Private health insurers financed 8%, employers 4% and non-profit-making organisations and households (families) 12%. Most out-of-pocket payments cover purchases of over-the-counter drugs and co-payments for prescribed drugs. On 1 January 2004, co-payments were introduced for outpatient visits and raised for virtually all other benefits.

A survey conducted in Germany in 2002 demonstrated that efficient remote patient management can save approximately 20% of annual treatment costs and between 50-60% of costs due to late stage diseases (Busse & Riesberg, 2000).

4.3.3.1 ICT in Healthcare

Germany has already taken steps towards implementing eHealth services. First of all, the implementation of an Electronic Health Card, which allows patients and healthcare professionals universal access to information, started in 2008 and is ongoing. Moreover, a German eHealth Strategy was published in 2005 which focuses on improving the ICT infrastructure. In particular, an online verification of insurance status including availability of all data for an electronic European Health Insurance Card and the implementation of a private electronic patient record are emphasized in the report (European Commission, 2007).

4.3.4 Greece

The Greek healthcare system is characterised by the coexistence of the National Health Service (NHS), a compulsory social insurance and a voluntary private health insurance system. The NHS provides universal coverage to the population and operates on the principles of equity, equal access to health services for all and social cohesion. In addition, 97% of the population is covered by approx. 35 different social insurance funds (compulsory social insurance), whereas 8% of the population maintains complementary voluntary health insurance coverage bought on the private insurance market.

The Ministry of Health and Social Cohesion decides on overall health policy issues and on the national strategy for health. It sets priorities at the national level, defines the extent of funding for proposed activities and allocates resources. Seventeen regional health authorities (PeSYPs) are given extensive responsibilities for implementing national priorities at the regional level, coordinating regional activities and organising and managing the delivery of healthcare and welfare services within their area.

All NHS staff members (doctors, nurses, dentists, pharmacists and technical and administrative support staff) are salaried government employees.

Primary healthcare in the public sector is delivered through a dual system of primary healthcare centres and hospital ambulatory (outpatient) services, which belong to the NHS, and IKA primary care units, which belong to IKA, the largest social insurance fund.

Secondary and tertiary care is mainly provided in 123 general and specialised hospitals and 9 psychiatric hospitals.The public sector provides about 75% of hospital beds, the 243 private hospitals, mainly general hospitals and maternity clinics, account for 25% of total hospital beds.

Health services in Greece are funded almost equally through public and private sources. Public expenditure is financed by both taxes (direct and indirect) and compulsory health insurance contributions (by employers and insured people). Voluntary payments by individuals or employers represent a very high percentage of total health expenditure (more than 42% in 2002), making Greece's healthcare system one of the most "privatised" among the European Union countries.

The NHS budget is set annually by the Ministry of Economy and Finance based on historical data.

Taxes finance about 70% of all hospital funding, whereas the remaining 30% is derived from a mixture of social security and out-of-pocket payments. Tax revenue is often used to fill the gap between the officially determined level of social security funding (by fixed per diem or per-case fees) and the actual cost of the provided services (WHO, 2004).

4.3.4.1 ICT in Healthcare

The Ministry of Health and Social Solidarity released a national eHealth Roadmap in 2006 which set out priorities, strategies and action plans in relation to the quality and safety of health services. The main strategy is to establish the National Health Information System (NHIS); a national system for organising health related information. A main objective of the NHIS is to implement an Electronic Patient Record system. IASYS is the central IT infrastructure of the NHIS, providing the national interoperability framework intended to enable Greek health organisations to seamlessly access and share health related information (European Commission, 2007).

4.3.5 Hungary[17]

Hungary has a population of almost 10 Million inhabitants with an average life expectancy at birth of 74.79 years. The healthcare expenditure is up to 7.8% of the GDP. The healthcare system is funded by the Health Insurance Fund (HIF), which is primarily responsible for recurrent health care costs. The HIF is able to contract freely with providers, and is supervised by the Ministry of Finance, and it is funded by employers and workers, government's taxes complement healthcare costs. The system covers the whole populations, although certain services require a copayment, such as rehabilitation, dental and drugs. Municipalities have an important role in providing primary care. Hospital are classified in municipal hospitals, county hospitals for secondary care, there are also municipal hospitals for secondary and tertiary care. University and large multi-specialized hospitals are ruled by national government. The National Public Health and Medical Officer Service aims to implement a unified health administration system. The healthcare system is l predominantly public although there is an incipient private services providers

4.3.5.1 ICT in Healthcare

It is estimated that all GP's use a computer and almost 100% use Internet, which is above the European average, EHR is widely used for storing patients data. eHealth services deployment differs among hospitals and even between departments in the same hospital. In terms of telemedicine remote consultation and consultation videoconferences between healthcare professionals and call centres are currently in operation in Hungary. However, these are mostly at the local or regional level and are often used offline whereby the data is then transferred manually into the hospital information system. The development of telemedicine applications has been stalled by the lack of interoperability of systems and other issues. It estimated that up to 80% of GPs practices use DSS for diagnosis and/or

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treatment. Data exchange using internet or private networks is not yet well deployed. Data transfer from labs to GPs and ePrescrition have high potential to be developed in Hungary. There are several planning for fostering eHealth initiatives as well some regional pilots regarding the connexion of local healthcare system. Currently, there is an strong interest on integrating hospital information systems. Large Hospitals have developed some telemedicine programs used at local or regional level but not connected at national level. There is a political agenda for the deployment of eCards.

4.3.6 Ireland[18]

Ireland has a population of 4.5 Million inhabitants with an average life expectancy at birth of 80 years. The healthcare expenditure arises up to 7.2% of the GDP. The Health Service Executive (HSE) is responsible for management of the healthcare services under the Ministry of Health. The Ministry has major responsibilities for health and personal social services. Therefore, municipalities and county has a minor role in providing healthcare services. Part of the primary care is funded by the HSE but most of the patients pay for their care from own funds.

4.3.6.1 ICT in Healthcare

Around 70% of GPs use a computer and the internet. This is used mainly for patients' data storage. Exchange of EHR and ePrescription are not yet deployed in Ireland. There is a long term plan for the deployment of eHealth solutions and some pilots related to EHR are under development.

4.3.7 Italy[18]

Italy has a population of 68.5 Million inhabitants with an average life expectancy at birth of 82 years, the healthcare expenditure is up to 8.5% of the GDP. The Ministry of Health is responsible for defining the healthcare plans at national level, whereas health departments at the regional level are in charge of delivering healthcare services to the citizens. Additionally, they are responsible for legislative and administrative functions, Healthcare is tax funded

4.3.7.1 ICT in Healthcare

It is estimated that 83% of the GPs use a computer and are connected to the Internet. ICT is mostly used for storing administrative data, electronic health records and CDSS are used regularly. ePrescription and exchange of EHR are rarely.

4.3.8 Latvia[18]

Latvia has a population of 2.4 million inhabitants with an average life expectancy at birth of 72 years. The healthcare expenditure is up to 6.5% of the GDP. There is a national central Government and regional governments. The healthcare system has been transformed since independence, and currently is a process of restructuring. Healthcare services are tax-based but private insurance, out-pocket payments are also used. The Ministry of Health has the main role in public health. Regional governments have their own budgets, Hospitals are divided in public and private, large hospitals have provides also secondary ambulatory and emergency care.

4.3.8.1 ICT in Healthcare

The deployment of ICT solutions and infrastructure has an important market in Latvia where there are currently few solutions implemented. The Latvian government, as expressed in the Guidelines for eHealth and which establishes the strategic directives for the development of eHealth initiatives is pushing for a eHealth policy.

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4.3.9 Lithuania[19]

Latvia has a population of 3.4 million inhabitants with an average life expectancy at birth of 72 years, the healthcare expenditure is up to 4.5% of the GDP. The Ministry of Health has a supervision and policy make role, whereas primary healthcare is provided by the municipalities. Healthcare is mainly funded by national taxes. The new legislation translates to the municipalities the responsibility of managing small and medium hospitals.

4.3.9.1 ICT in Healthcare

Around 60% of GPs are using computer and internet for clinical purposes. ICT used mainly for storing patients' data either for administrative or for medical purposes. All healthcare institutions use the computer and the Internet in routine activities. Major institutions provide information thought websites. ICT is mostly used for administrative purposes. Exchange electronic health records ePrescription and Decision Support Systems (DSS) is not very common. There are several initiatives for boosting eHealth deployment. The eHealth strategy was presented by the Ministry of Health to define the E. Health System Development Program for 2009-2015

4.3.10 Netherlands

Municipal health services are arranged in a regional network in the Dutch health system, in regard to public health. All aspects of disease control and health education are included in local public health. University departments in various public health areas, series of national institutes and primary care system all support public health tasks. For the highest level of legislation, budgets and policies in healthcare, the responsibility lies with the Ministry of Health, Welfare and Sport. Local authorities and the Ministry work collaboratively and are both responsible for public healthcare. Health Care Inspectorate is responsible for monitoring and supervision at national and regional level. District or municipal services are being organized by public health. Public health services are focusing on strengthening preventive policies.

GPs are the dominant figures and gatekeepers in the system and they are mainly providing the well developed Primary Healthcare. GPs take care of majority of medical problems which can be seen in the low referral rate. In the medical training process, serious consideration is given to communication skills which results in GPs spending a considerable time talking with patients. Prescription rates are very low (66%) in comparison to other European countries (75-95%). Family physicians constitute largely individual and mainly independent practices in their communities. The role of nurses in general practice has increased in recent years. Approximately 60% of GP practices also contain a GP nurse which results in a specialized personal care for patients.

Hospitals with both inpatient and outpatient facilities which contain medical specialists usually provide the secondary and tertiary care. Private hospitals constitute a significant majority (90%) of hospitals.

Since 2005, Diagnosis Treatment Combinations (DTC) provides the funds for hospital treatment of patients. DTC contains the entire process from diagnosis by a medical expert up to and including any hospital treatment received by the patients. Hospitals are bound to give the treatment that is required by the diagnosis, no cost calculation is taken into consideration, the diagnosis is the decisive factor.

In 2006, the government set a mandatory national health insurance, which is practiced by private insurers. In terms of funding and provision of healthcare, the Dutch government would only intervene if the market were to fail about giving a guarantee for universal access, competition and equity.

4.3.10.1 ICT in Healthcare

There is no national e-Health strategy document for the Netherlands as they don't make a distinction between regular and e/online Healthcare. The aim of Netherlands is to carry out the full accession for the establishment of a complete, all-round eHealth system. However, there is a governmental ICT

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agenda aimed for 2012, which covers issues like healthcare, service guidelines, open source and open standards.

4.3.11 Poland [20]

Poland has a population of 38.1 million inhabitants with an average life expectancy at birth of 76 years. The healthcare expenditure is up to 6.5% of the GDP. Poland has restructured its healthcare sector during the last two decades moving from a centralized system to a decentralized one. The health system is still under restructuration and the Polish government published recently a report "Recommendations of the White Summit Conference". Since 2003 the regional insurance were merged in National Health Fund (NHZ). The Ministry of Health is in charge of the healthcare supervision, the public healthcare system in is funded by the state and by the National health Fund, insurance health is obligatory and account for 9% . In addition to the public healthcare system there are private healthcare institutions to be reimbursed they have to have a contract with the NHZ.

4.3.11.1 ICT in Healthcare

It is estimated that 75% of GP a computer and Internet connection mainly used for patient data storage and administrative issues. There is a potential market for CDSS, ePrescription and for tools for secure medical data exchange. Patient data exchange is relatively wide used for reimbursement purposes. There is a plan to introduce a pilot implementation for e-prescribing the Wielkopolska region. Poland participates in the epSoS project. eHealth policy is relatively new in Poland. The Polish eHealth strategy is focused on facilitating access to information, promoting electronic documentation and promoting medical information systems

4.3.12 Portugal [20]

Portugal has a population of 10.6 million inhabitants with an average life expectancy at birth of 79 years, the healthcare expenditure arise up to 10% of the GDP, WHO ranks its Healthcare system at number 12. Healthcare services are mainly responsibility of the Government but municipalities also play a minor role. The Ministry of Health is in charge of supervising and financing the healthcare system. There are a public a private health systems, citizens are entitled to choose between private and public health coverage. The Serviço Nacional de Saúde depending of the Ministry of Health is in charge of the public healthcare system in Portugal mainland whereas Madeira and Azores have their own healthcare systems. The National Health Plan establishes actions and guidance for improving healthcare system.The public healthcare system is mainly tax-based and provides coverage to all the citizens, complementary private healthcare is paid by individual through private individual health plans. Primary and ambulatory services as well long-term care are among the priorities of the government . There is also a special interest on promoting ICT use in Healthcare.

4.3.12.1 ICT in Healthcare

It is estimated that 90% of GP a computer and Internet connection mainly used for patient data storage and CDSS. There is room for market penetration in ePrescription and secure data exchange tools, so far not very used among GPs. Most hospitals and health centres use electronic applications for prescribing although the same service is not deployed for connecting GPs and pharmacies. The Ministry of Health has not competences for health standards, it is the Instituto of Informatica which acts a as standardization body. There are a number of local telemedicine initiatives, of interest an initiative for deployment a trans-border telemedicine system between North of Portugal and Norwest Spain region of Galicia.

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4.3.13 Romania[21]

Romania is currently in a process of restructuration of its healthcare system Romania currently has a struggling healthcare system which used to be dominated by the state due to communism. Present government introduced a healthcare reform aimed towards improving quality of healthcare and accessibility towards the goal of reaching the same level as EU countries.

Distribution of services remains as a serious problem in Romania. There is a significant difference in terms of the health coverage provided between urban and rural areas. (1.102 pharmacies in rural areas which contains half the population Vs. 3.579 pharmacies in urban areas).

Corruption in healthcare system is another major problem. The government is trying to prevent this and the brain drain of well educated Romanian health personnel by introducing better funding and transparency.

The government is the head of current healthcare system. The government's will is reflected through the conducts of the Ministry of Health (MoH). Control of finances and creation of framework contract are done by The National Health Insurance House (NHIH). District Health Insurance Funds (DHIF) contracts these health services to both private and public healthcare service providers. At the national level, The Romanian College of Physicians also has an influence over the framework.

At the national level, the bodies are responsible for creating healthcare objectives and policies while at local/district levels the organisations have a considerable impact on service modelling. Almost all public healthcare facilities are owned by District councils.

Independent practitioners operating from their own offices and family doctors mainly deliver Primary healthcare services. After the reform, the gatekeepers of the system were assigned as family doctors. Centers for treatment and diagnosis, office based specialists and hospital outpatient department networks provide ambulatory secondary care. State or publicly owned hospitals usually provide tertiary and inpatient care.

There is a need for an overall improvement in all aspects of healthcare system.

4.3.13.1 ICT in Healthcare

Romania's usage of computers for consultation purposes and patient data storage are the areas that stand out as the best eHealth performances. Registration of administrative patient data is about 50% in Romanian practices and the storage for at least one type of medical electronic patient data is about 33% amongst GP practices. eHealth usage in Romania can be seen as a bit low, which can be attributed to the fact that it is a rather newly introduced concept in Romania. Currently there is no reported usage of ePrescribing as well. Unique Integrated Information System (SIUI) which belongs to the Social Health Insurances stands out as one of the most important eHealth projects in Romania. It aids in addressing the complex hierarchical structure of Social Health System of Romania. The aim of SIUI was to become the national health information system which would cover the entire country. Yet there are some doubts about the capability of SIUI in such an ambitious projects as National Health Insurance House doesn't cover all healthcare activities and citizens in Romania.

4.3.14 Slovakia

The basis for financing, organization and management of the country's healthcare system is laid down in the Constitution of Slovakia. Free access to the healthcare system and universal coverage is given free of charge to all citizens and bodies through the mandatory health insurance.
The financial backbone of the healthcare system depends upon health insurance, self payments, social security contributions and extra payments. Economically active immigrants and all permanent residents are expected to contribute to the social health insurance.
Key policy maker and regulator in the system is the Ministry of Health which works in partnership with the Ministry of Finance. Regulation of healthcare providers to guarantee the equal access and participation of all the citizens into the healthcare system is the responsibility of the Ministry of Health (MoH) based on the "Act on Health Care".

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The power to issue licenses for healthcare providers has been largely taken away from MoH and given to local/regional administrations. State owned Health Insurance Company is owned by the MoH. MoH also is responsible for providing and withdrawing permits that grant access to operating all varieties of health insurance companies. The licenses for individual healthcare personnel is provided by Slovak Medical Chamber where as licenses to organizations which provide healthcare are given by local/regional administrators. UDZS, the Health Surveillance Authority is responsible for controlling insurance companies in Slovakia.
Management of specialized institutions (on the state level), central and specialized hospitals are done by MoH. Quality of service control for all varieties of healthcare providers is the responsibility of MoH as well.
Majority of secondary care hospitals and polyclinics have become non-profit public benefit entities. Central government continues to own tertiary care hospitals. Privatization of state owned hospitals is an on-going process which is monitored by the Office of Health Care Supervision.
Recently there have been no reforms in terms of healthcare in Slovakia

4.3.15 ICT in Healthcare

Citizen-centered eHealth strategy is tried to be achieved in Slovakia. On top of developing services another aim of the strategy is to provide support for the health of Slovakian citizens.
Four strategic goals have been determined for eHealth project;

- Secured infrastructure creation in order for the realisation of eHealth mission and vision.
- Normative framework and legislative creation for eHealth services.
- New forms and processes of healthcare and services support via eHealth services.
- Implementation of information systems for services and processes in healthcare system (Financed through public resources).

Minister of Health of the Slovak Republic is the main managing body for the national eHealth programme. All production activities of national eHealth programme are the responsibility of National Health Information Center (NHIC) in Slovakia

4.3.16 Slovenia

National health policy, supervisory and regulatory support to health monitoring and healthcare system is provided and developed by the Ministry of Health (MoH). Primary, secondary and tertiary levels of healthcare are all related to the activities of MoH. Municipalities are responsible for primary care.
Free choice of GP is given to the patients with the limitation of change allowed only once per year. Compulsory health insurance constitutes the backbone of the system (through financing). Salary/income of the insured person effects the contributions. Local and National community budgets pay the contributions for people in need (ex:unemployed). Majority of GPs are employed publicly. Recent years saw the rise of private providers with and without concessions. The first step in any diagnosis is the consultation of patient to the GP. National Healthcare system is currently undergoing some changes during its reformation by Slovenia. Certain initiatives lead the restructuring process of national healthcare. These include; Cancer and chronic diseases like cardiovascular disease and diabetes.
Long waiting times remain as a serious problem that needs to be addressed by Slovenian Healthcare System. Diagnosis-related group (DRG) system is used for;

- Enhancing the quality of treatment
- Introduction of risk-equalization scheme for complementary Voluntary Health Insurance (VHI) providers.
- Payment for hospital services

4.3.16.1 ICT in Healthcare

Current Slovenian e-Health strategy is named as “e-Zdravje 2010” (e-Health 2010). There are three strategic objectives of e-Zdravje 2010. These are the integration of existing information systems on a

national level, dissemination of eCommerce in healthcare to support and promote communication and core information infrastructure set up.

Electronic Administrative Patient Data usage amongst Slovenian GP practices are 86%. Storage of at least one type of medical patient data amongst Slovenian GP practices are 83%. Usage of decision support systems for prescribing or diagnosis purposes amongst Slovenian GPs are 40%.

No institution for eHealth has been established in Slovenia as of now. Also there is no Electronic Health Record (EHR) nor basic patient summary. Preperation process for ePrescription is currently carried out.

“Center for Health Informatics of the Republic of Slovenia” is in the development process. The government wants to create Slovene Health Insurance Card which will contain information about; Patient Summary, Insurance and Personal health data. Main problem with Slovene Health Insurance Card and ePrescription is the law that prohibits storage of data on a national level. Slovenian governing body for health informatics capability is “Health Informatics Standards Board”. No telemedical services are carried out at the national level. Health Insurance Card (HI) is used by patients (includes their medical data and insurance status). Renovation of health cards are planned.Estimated value of Slovenian eHealth project is around 67.7 million Euros and estimated eHealth investment is expected to be 133 million Euros.

4.3.17 Spain

Spain's healthcare system is tax-based, and during the past two decades the responsibility for healthcare has largely been devolved to Spain's 17 regions, the autonomous communities. The Ministry of Health and Consumer Affairs establishes norms that define the minimum standards and requirements for healthcare provision, has regulatory power, sets up information systems and assures cooperation between national health authorities and the autonomous communities. The autonomous communities decide how to organise or provide health services and implement the national legislation. The inter-territorial council (Consejo Interterritorial Del Sistema Nacional de Salud) is composed of representatives of the autonomous communities and the state administration and is in charge of promoting the cohesion of the health system. The role of municipalities is limited to complementary public health functions linked to hygiene and the environment.

Private insurance companies provide complementary healthcare coverage and increasingly play a role in covering services not included in the basic package and designed to avoid waiting lists.

The healthcare system is financed out of general taxation such as value-added tax and income tax but also regionally raised taxes. The regions may modify the rate of taxation at the regional level up to a threshold fixed by the national government. Some autonomous communities also receive grants from the state. Private healthcare financing complements public financing with out-of-pocket payments to the public system (such as co-payments for pharmaceuticals). Patients also pay directly for outpatient appointments. If they have signed with a private insurance scheme, they will receive part or full amount of money paid, depending on the type of insurance (Durán et al., 2006).

4.3.17.1 ICT in Healthcare

The national programme for the healthcare system in Spain is defined in the Plan for Quality in the National Health System. The strategic goals of the Plan for Quality include improving citizen participation in their own healthcare, increasing patient safety through improved quality of care, intensifying healthcare ICT security by continuous assessment, and increasing the use of ICT by adapting the human resources policy to the changing service needs. Within the national health system framework, the regional health authorities are also developing numerous initiatives for improving their healthcare services based on use of new ICT. eHealth services such as electronic health records, medical appointments through the Internet, ePrescription , telemedicine systems and the patient health card are therefore being implemented – to differing extents – in all Spanish Regions (European Commission, 2007). Military healthcare network uses telemedicine supporting ships and displaced military units.

4.3.18 Sweden

The responsibility for health and medical care is divided between the state, county councils and municipalities.

The state, operating on national level, is responsible for overall health and medical care policy through laws and ordinances. The Ministry of Health and Social Affairs is responsible for ensuring that the healthcare system runs efficiently and it is responsible for developments in healthcare.

The 21 county councils are responsible for providing, organising and financing healthcare services. The county councils own and run the hospitals, health centres and other health institutions, even if these institutions are supplemented by private providers which, in most cases, have contracts with the county councils to supply certain services. The county councils decide on the allocation of resources to the health services and are responsible for the overall planning of these services.

The 290 municipalities are responsible for long-term care, care of the elderly and social welfare services. They deliver and finance welfare services such care for the elderly and people with disabilities. They operate public nursing homes and home care services. Half the municipalities in the country have agreed with the county council to take over responsibility for elderly and disabled people living at home. In the other municipalities, such care remains the responsibility of the county councils.

Healthcare in Sweden is mainly financed by local taxation, i.e. municipal, county and parish taxes. The county councils and the municipalities have the right to levy income tax on their residents and to decide the rates of taxation. Local taxes are proportionate to income. Other important revenue sources for the country councils are grants and payments for certain services received from central government. Patient fees amount to 4% of county council revenue.

The National Healthcare System provides coverage for all residents of Sweden and no substitute private coverage is available. However, it is possible to take out a supplementary voluntary insurance which is mainly done by employers on behalf of their employees. It is most often taken out to cover payments for employees' long-term sick leave and/or in order to have faster access to treatment (Glenngård et al., 2005).

4.3.18.1 ICT in Healthcare

In December 2000, Carelink was established to develop the use of IT in healthcare. Carelink also runs a national IT infrastructure for data and telecommunications in healthcare, called Sjunet. Sjunet is the infrastructure for communication of healthcare data and services in Swedish healthcare, including various forms of telemedicine. Sjunet started as a regional project and today, practically all Swedish hospitals and primary care centres are connected. Sjunet is as much a cooperative network as it is a technical communicative platform. eHealth strategies were published in 2006, which aim at improving the conditions for ICT in health and elderly care, and improve eHealth solutions and adapting these to patients' needs (European Commission, 2007).

4.3.19 Turkey

Mixture of public and private organisations, including universities, Ministry of Defence, private health professionals and Ministry of Health (MoH) are responsible for the provision of Healthcare. Ministry of Health consists of 7 General Directorates. Allocation of responsibility is done according to the category followed afterwards by provincial level. Some important features are free selection of GP according to geographical limitations. Access to primary health care is free. Main provider of primary healthcare is the Ministry of Health.

Healthcare services are mostly paid by the revenue of government. Government expenditure on Health constitutes 69% of all investment made in Healthcare where as the private sectors expenditure on health remains at 31%. Decision of using private or public healthcare as secondary or tertiary healthcare is up to the citizen.

GPs can make online and written referrals directly to specialists in secondary and tertiary care providers. To make appointments with public secondary and tertiary providers, citizens can use the Centralized Hospital Appointment System (CHAS) call center service.

The government and local authorities financially support the public hospitals (in their region). Public health centers and province/county health directorates manage the local coordination between hospital care and primary care.GPs are informed about the latest status of their patients via the information sharing done between Family Medicine Information System (FMIS) and National Health Information System (NHIS).

All citizens of Turkey have free access to primary care (even if not covered by social-security system) due to mandatory legal measures. 75% of population lives in urban areas. Healthcare is better mostly in western and urban areas of the country.

4.3.19.1 ICT in Healthcare

National Health Information System (NHIS) is being used since January 2009. Integration of NHIS with Family Medicine Information Systems (FMIS) is one of the major goals of MoH. Saglik-Net ("Health-Net" in Turkish) is used for patient summaries and electronic health reports. Saglik-Net is an integrated communication and information platform that gathers any kind of data from health institutions as soon as they are generated (according to their region). Telemedicine, NHIS, FMIS, CHAS and ePrescription are all parts of Saglik-Net. MoH considers Saglik-Net as an "umbrella" eHealth project which gathers all other projects under its roof. NHIS is currently a data collection system. EHR (Electronic Health Report) sharing at the national level amongst medical professionals is targeted after the e-health law passes in the 2nd phase of NHIS. eDispensation and ePrescription are being piloted.

4.3.20 United Kingdom

The United Kingdom has devolved responsibility for healthcare to its four constituent countries. The four health services operate independently, but there is close cooperation and collaboration. The Department of Health is responsible for the National Health Service (NHS). The Primary Care Trusts (PCTs) are both providers and commissioners for different healthcare services. The PCTs provide primary healthcare services such as district nurses, specialist treatment, health visitors and community nurses. These primary care health teams (including general practitioners) are responsible for providing home-care as well. In general, the district nurse, who works closely with a GP but who is provided (i.e. salaried by) the PCT, assists the GP with providing relevant home-care for patients. As a commissioning body, the PCTs commission healthcare services from the public, private and voluntary sector in order to meet national delivery and service requirements. However, PCT structure is about to change, second version of this deliverable will be updated accordingly.

An increased number of conditions are being dealt with in the community to reduce the costs, reduce distress of patients, improve outcomes and empower patients. Hypertension, diabetes, CHD, COPD and other chronic conditions are targeted for home care management

The NHS is mainly funded through general taxation: direct taxes, value-added tax and employee income contributions. Local taxation provides further funding for social services. Private funding can be broken down into out-of-pocket payments for prescription drugs, ophthalmic and dental services and private medical insurance premiums.

In England, budgets for healthcare are set every three years through negotiations between the Chancellor of the Exchequer and the Department of Health. In the rest of the United Kingdom, the devolved administrations set budgets separately (World Health Organisation, 2004).

4.3.20.1 ICT in Healthcare

NHS Connecting for Health is an integral agency of the Department of Health and is responsible for delivering the National Programme for IT (NPfIT) for the NHS in England. The NPfIT, launched in 2002, is one of the largest public sector health ICT projects in the world and aims to provide authorised access to patient information whenever and wherever it is needed. Some of the initiatives include creating a NHS Care Records Service to improve the sharing of consenting patients' records across the NHS and also provide patient access to their own health records, making it easier and faster for general practitioners and other primary care staff to book hospital appointments for patients, and providing a system for electronic transmission of prescriptions (European Commission, 2007).

4.4 Stakeholders

Before a new eHealth service can be analysed and its business potential assessed, it is necessary to have a complete overview of all possible stakeholders, their motivation and their interaction. In the context of the eHealth business case the following stakeholders have been identified: Healthcare authorities, home care providers, medical device companies, insurance companies, hospital managers as well as patient organizations, regulatory bodies and healthcare authorities influence purchasing decisions. The challenge for successful REACTION's results commercialization is to build relationships with all stakeholders paying special attention to the fact that each national healthcare system within the European Union is different and must be taken into account.

4.4.1 Patients

The patients are the final beneficiaries, but they will also be actives users of the REACTION platform. It is expected they would get the benefits of the developments made in REACTION, since they will be able to improve their disease management and have better control of their glucose levels.

The obvious benefits, or value objects, for the patient of self-management and tele-monitoring are that it can be done at any time and any place. This ensures continuity in the management of the disease, and it allows the patient to live a practically normal life without the restraints of having to go to the doctor to have tests done. The patient is not only mobile but will also save travel time back and forth to the doctor, as well as avoiding being stranded for hours at the health clinic.

Patients will also benefit in terms of receiving more efficient and convenient care and overall better health, thus preventing serious complications.

4.4.2 Patients Associations

Patient organisations have emerged worldwide in the last decades. They are present in every region and country in the Western world and work to represent and support patients, their families and carers for a wide range of diseases. A patient is a person with any chronic disease, illness, syndrome, impairment or disability.

The International Alliance of Patients' Organizations (IAPO) is a global alliance representing patients' organisations working at the international, regional, national and local levels. In Europe alone, more than 625 patient associations are members of the IAPO.

Patient organisations are generally very aware of the key global issues surrounding health technologies. IAPO emphasizes the important issues for patients, giving the patients' perspective. They are normally aware of the potential of eHealth and telemonitoring to patient health outcomes but also advocate concerns such as privacy of personal medical information and maintain that, in addition to patients' rights, they also have responsibilities in their self-management.

The patient organisations are keen to understand the various systems that are already available or under development, and to assist in designing and implementing eHealth solutions.

Patient organisations can be formidable partners in opening the market for telemedicine services, because they have a powerful political agenda and are well recognised in the healthcare systems. However, the problem remains to convince a patient organisation that there are measurable benefits to their members, i.e. to their patients, families and carers. Once that is achieved, the patient organisation can be expected to act in several ways.

Most likely, the patient organisation will contribute to a pilot project with knowledge and evaluation support. They may provide input for patient centric requirements engineering and perform validation and evaluation of the outcome. They can also be extremely supportive post-pilot with dissemination and lobbyism vis-à-vis the strategic healthcare authorities, healthcare commissioners and providers and even the general political establishment.

4.4.3 Healthcare Professionals

Healthcare professionals are needed in any telemonitoring application or service in order to secure the medical and clinical integrity of the service and to minimise risk of malpractice. There are several tasks that require deep involvement of different healthcare professionals:

- **General Practitioners/diabetes experts**

With the introduction of the self-management platform the GPs and diabetes experts are enable to to target those patients that need priority help. They would be also mostly benefited from savings time and reducing paperwork, having all the relevant patient information ready to be checked and analyzed. In addition, REACTION decision support system (DSS) will assist them in the decisions related to the therapy. Home monitoring and reduction of visits by patients in the office would save substantial time. The opportunity to present fast, targeted education in risk assessment and risk profiling will also save considerable time in the clinic. Finally, communication will be facilitated not only between patient and health professionals, but also between professionals (shared care). However, a reimbursement system must be in place in order for the MDs to fully embrace the system.

- **Hospital Professionals/Secondary Healthcare Professionals**

The strategy to move more healthcare services for patients with chronic disease from the secondary to the primary care sector has the potential of reaping enormous benefits. First of all, people having long-term or chronic health problems are twice as likely to be admitted to hospital. Studies have also shown that home monitoring of chronic diseases has the potential to reduce hospital visits by as much as 50% by keeping patients stable through daily monitoring (CTEC, 2009).

- **Nurses**

Nurses operate in different environments from major hospital where there are permanent changes to ambulatory systems where ICT has not impacted yet. Improving daily work by applying ICT will reduce not only nurses' administrative burden and paperwork but also errors making their work more efficient.

4.4.4 Medical Device Manufacturers

During the last decade there have been dramatic changes in the medical device industry. This industry is highly affected by health care policies and regulatory issues as well as by the adoption of new technologies while at the same time unsolved problems as market and regulation fragmentation and lack of real interest of adopting standards remain making the commercialization of new devices increasingly complex. This group has a great weight in providing inputs to the Health authorities for influencing legislation related to regulatory affairs

Medical Device Manufacturers Association	www.medicaldevices.org
Continue Healthcare Alliance	www.continuaalliance.org
AdvaMed (Advanced Medical Technology Association)	www.advamed.org
Association of Medical Diagnostics Manufacturers (AMDM)	www.amdm.org
Medical Device Manufacturers Association (MDMA)	www.medicaldevices.org
Massachusetts Medical Device Industry Council (MassMEDIC)	www.massmedic.com
Life Science Alley	www.lifesciencealley.org
Regulatory Affairs Professionals Society (RAPS)	www.raps.org

Table 1 Medical Devices Associations

4.4.5 Regional/National/European Health Authorities

Their main role is watching over the health issues that affect citizens such as the huge increase in patient numbers, the growing number of chronic diseases and elderly people as well as the ever-increasing demand for a good quality healthcare assistance. Therefore, the health related costs are expected to grow dramatically in the next coming years. It is estimated that OECD countries (Organization for Economic Co-operation and Development) spend currently around 10% of GDP on

healthcare. If this trend continues expenditure would climb to 15% of GDP by 202022, government, health authorities will not be able to sustain this financial burden. As a consequences, policy makers announce every year more steps to limit healthcare spending to a level that states are prepared to finance as well as they are promoting ICT adoption for managing chronic diseases and treating patients outside the hospital environment.

4.4.6 Strategic Health Authorities

In some Member States strategic health authorities are identical to the healthcare provisioning bodies, but in some cases they are separate entities. In France, the state regulates the quality of health service organisation, monitors safety, regulates the volume of health services supply and oversees social protection and regulates healthcare system. In Denmark, the National Board of Health (SST) is the supreme healthcare authority in Denmark assisting the minister for Health and Prevention within the administration of the healthcare service. SST also has information responsibilities vis-à-vis citizens on specific health issues. They follow the population health status through monitoring and evaluation and endeavour to be at the cutting edge of knowledge and expertise. It is their task to set the best possible frames within the healthcare system for the prevention and treatment of illness and provide national guidelines for disease management.

The strategic health authorities may decide to support telemonitoring as a strategic tool, because it supports their plans for disease management. The Danish Agency for Health, for example, is hosting the Danish Centre for Digital Healthcare (www.sdsd.dk). The centre has published the first Danish strategy for digital healthcare: “National Strategy for Digitalisation of the Danish Healthcare Service 2008 – 2012 – to promote public health as well as prevention and treatment.

The strategy calls for a common infrastructure to be established as a foundation for exchanging and sharing data across healthcare sectors. At the same time, a number of specific shared services are to be developed, making data and/or functionality available across the healthcare sector.

In most cases, the shared services will provide both data and functionality – either directly to users, for example via sundhed.dk (the public health portal in Denmark), or via integration with the local solutions of the individual players, which can then make them available to users (for example via integration with EPR, ECR or practice systems). In addition to shared services making data available, it may be relevant to establish shared services making functionality available. For example, “*shared services could make certain telemedicine solutions available to all relevant healthcare users”* (Digital Health, 2007).

As can be seen from this example, some strategic health authorities see eHealth services, which include telemonitoring, as a strategic investment in healthcare which needs to be addressed at the national level rather than by the individual regional healthcare providers. The eHealth platform could also be used to enforce certain national clinical protocols, which are part of a national plan for disease management, and for collecting health data on a massive scale as part of a national programme for monitoring prevalence of e.g. certain chronic diseases.

In any case, it is to be expected that the investment needed to commission and install the service will be funded by the government (i.e. Ministry of Health or similar) and the healthcare providers may use the service, either for free or with a calculated usage fee to be decided as part of the annual budget negotiations.

4.4.7 Insurance Groups

Some Member States have statutory insurance contribution-based systems where there is a mixture of public and private providers and where some services must be paid for at the point of use. This is true for Germany, France and, to some extent, Greece. The statutory health insurance schemes mainly act as purchasers of healthcare services from both public and private providers, albeit they may provide some healthcare services as well (as in Greece). In France, statutory health insurance funds approximately three quarters of total health expenditure, while in Germany statutory health insurance funded approximately 57% in 2002, with other statutory insurance funds contributing 10%.

22 Source: OECD

The issue of cooperation and communication between various healthcare providers, and in-between the public and private sector, plays an important role for the efficiency and quality of healthcare services to the patients.

The statutory health insurance groups have a direct interest and influence on any cost containment effort or efficiency improving methods, including telemonitoring. They have a history of funding large scale pilots to achieve these goals or even carrying out the pilots themselves. Their role in the pilots is often to involve the user groups (patients and healthcare professionals) and recruit patients for the trials and, of course, analyse and evaluate the results.

In the case of telemonitoring, the health insurance groups will be interested in deploying services with a potential for large cost-benefit gains. They may fund both the pilots and, if successful, a collective investment in operational services, perhaps in cooperation with the strategic health authorities.

4.5 Strengths

The foreseen objectives of REACTION will take into account the Multi-sensor Concept to address the influence of the perturbing factors, such as the influence of diet and physical activity, thereby allowing for more reliable monitoring of changes in glucose in daily life conditions.

4.6 Weaknesses

Poor quality or improper working of REACTION services may expose patients to health risks having not only economical, but also legal implications. This is especially important for the sensors under development, which will measure glucose levels, sustaining insulin therapy. The accuracy of the platform for providing dependable measurements should be tested and evaluated prior to launching the product to the market. This implies that the launch of REACTION could be delayed, subject to approval from the National regulatory bodies. Therefore, it is necessary to comply with the highest safety standards, not only for the glucose sensors, but also for all services provided by the REACTION platform.

4.7 Opportunities

In reviewing the biological and technological challenges embodied in glucose level measuring, it is clear that there is a lot to be done, and that relatively modest progress has been made in the last 20 years. This is, from the optimist's viewpoint, an opportunity. And it is fortunate that, just at the right time, technologies based on impedance and near IR spectroscopy are emerging with the promise of answering the needs of this demanding situation. REACTION is aiming to integrate new technologies, applications and tools into a service platform for close monitoring of diabetes patients. The opportunities for market growth are clear, not only for outpatient monitoring. Hospitals are still some way off from taking advantage of the full capabilities of state-of-the-art technologies for managing diabetic patients, and clearly REACTION outputs will bring added benefit and safety to Europe's healthcare systems.

REACTION services should demonstrate compliance with a number of legal and technical standards as well as with ethical issues, mainly related with patients' data protection and patients' privacy.

4.8 Threats

It is difficult to determine what will be the economic and financial return of the REACTION platform. The EU-funded eHealth Impact report and the US Budget Office studies highlight the challenges for financing of eHealth services, especially because of the increasing divergence between the ever-increasing health-related needs and available financial resources[23] which are always under pressure for funding cuts. In any case, potential revenue and margins should be estimated state by state since reimbursement approval rules vary widely from country to country.

Changes in regulations affecting standards at national level could affect REACTION deployment negatively, especially if these potential changes are not in line with the standards adopted for the platform. In the close future, REACTION outcomes may undergo even more detailed analysis for medical suitability, safety, and, cost/benefit assessments. This can delay market launches for months or years affecting negatively services/product expected revenue and margins.

23 Health Priorities in the Aftermath of the Crisis. OECD Health Ministerial Meeting www.oecd.org/health/ministerial

For the successful commercialization of the services and outcomes of the projects, commercial partners need to address these issues as early as possible in the development process.

4.9 Competitors

The healthcare market is a high-technological sector subject to highly regulation and continuous process of innovation. Only four years ago the medical device industry was dominated by US companies, this situation has changed and now medical branches of European companies are playing an important role in this health segment such as Siemens and Philips. In addition to the medical devices, eHealth technologies and Electronic Health Record are segments in what these companies are highly interested. These manufacturers could be seen as competitors or as commercial partners a list of the top 30 companies for years 2006 and 2009 is provided. The highly dependence on the innovation capacity of this market is reflected in the ranking movements from 2006 to 2009.

Ranking 2009	Company Name		Ranking 2006	Company Name	Sales
1.	Johnson & Johnson	$23.6 B	1.	Johnson and Johnson	$17.7B
2.	Siemens Healthcare	$17.4B	2.	GE Healthcare	$12.1B
3.	GE	$16B	3.	Medtronic	$10.1B
4.	Medtronic	$14.6B	4.	Baxter International	$9.8B
5.	Baxter International	$12.6B	5.	Cardinal Health	$9.8B
6.	Philips Healthcare	$11.2B	6.	Tyco Healthcare	$9.5B
7.	Abbott Laboratories	$8.4B	7.	Siemens Medical Solutions	$9.2B
8.	Boston Scientific	$8.2B	8.	Philips Medical Systems	$7.5B
9.	Covidien	$7.8B	9.	Boston Scientific	$6.3B
10.	Becton Dickinson	$7.2B	10.	Stryker	$4.9B
11.	Stryker	$6.7B	11.	B. Braun	$3.9B
12.	B. Braun	$5.8B	12.	Guidant Corp.	$3.6B
13.	St. Jude Medical	$4.7B	13.	3M Healthcare	$3.5B
14.	Cardinal Health	$4.6B	14.	Zimmer Holdings	$3.3B
15.	3M Healthcare	$4.3B	15.	Becton, Dickinson & Co.	$3B
16.	Zimmer	$4.1B	16.	St. Jude Medical	$2.9B
17.	Olympus Medical	$4B	17.	Kodak Health Group	$2.7B
18.	Hospira	$3.9B	18.	Hospira	$2.6B
19.	Smith & Nephew	$3.8B	19.	Fresenius	$2.5B
20.	Toshiba	$3.7B	20.	Smith & Nephew	$2.4B
21.	Synthes	$3.4B	21.	Synthes	$2.1B
22.	Beckman Coulter	$3.3B	22.	Alcon	$2B
23.	Terumo	$3.1B	23.	Biomet	$1.9B

24.	Danaher	$3.1B	24.	C. R. Bard	$1.8B
25.	Alcon	$3B	25.	Terumo	$1.8B
26.	Fresenius Medical	$2.9B	26.	Dentsply International	$1.7B
27.	Biomet	$2.5B	27.	Invacare	$1.5B
28.	CR Bard	$2.5B	28.	Gambro	$1.4B
29.	Varian Medical	$2.2B	29.	Dräger Medical	$1.3B
30	Dentsply International	$2.2B	30	Varian Medical	$1.2B

Table 2 Evolution in the ranking of the top 30 Medical Device companies in the period 2006-2009[24]. Successful companies are the most innovative but also the better adapted to regulations.

Companies specialized in providing specific eHealth services for diabetes management will be analyzed in the final version of this deliverable.

4.10 Buyers

The results from REACTION results could be purchased via public procurements that are awarded by tender. They use to favour solutions that can offer complete packages, interoperability and support. Important buyers would be: hospitals, provincial/national Departments of Health, health insurance companies.

4.11 Barriers

The main constraints identified for the adoption of eHealth services are the fragmentation of the health market, the acceptance of the technology by the end users, the lack of common standards and the financing needed to implement these standards and services in medical IT systems.

4.11.1 Health Market Fragmentation

The health market is a very fragmented market, not only at European level but also at national/regional level. The challenge for commercialize project's results is to establish relationships with all healthcare systems stakeholders, from national to regional/provincial level and offering adaptable and customizable services, coordination of all these activities can be difficult and complex.

4.11.2 Approval of REACTION Services

Complying with European and national regulations and standards will pave the way for commercializing project's results. From the commercial point of view, REACTION services will also have to deal with the regulations concerning business and general consumer protection. In addition, it will be necessary to provide a Declaration of Conformity and for medical devices, depending on their classification, they should be verified by a Certificate of Conformity issued by a Notified Body. Certified medical devices should also have the CE mark

4.11.3 Adoption of REACTION for Hospital Management

Hospital managers are shifting their attention from "price per device" to "price for therapy" as well as outsourcing models for rendering healthcare in order to reduce costs. Therefore, in addition to technological and welfare improvements that the REACTION's services will provide to diabetes patients, we will have to demonstrate the efficiency of the platform in terms of reducing globally the price for treating diabetes patients. Hospitals place public tenders not only for basic hospital supplies but also for more sophisticated technologies

24 Source: The Top 30 Global Medical Device Companies Medical Products Outsourcing

4.11.4 Medical Staff/Patient Acceptance

Successful commercialization of the REACTION's product should provide an improved service with respect the current medical workflows at the same time the technological solution should fit actual necessities in a friendly environment in order to be easy to learn minimizing disturbances.

4.11.5 Conflicting Standards for Data Exchange

The lack of interoperability in ICT systems and services in the healthcare sector has been identified as a major obstacle to the widespread use of eHealth applications in the EU. The REACTION monitoring platform and sensors should comply with existing standards in order to make REACTION services interoperable across different environments as well as with existing technologies.

4.12 Policy Implications

Conflicting ICT standards and fragmented regulations in the health sector are creating problems of interoperability and legal framework for eHealth services and for medical device commercialisation, leading to unnecessarily high costs of health services and missed opportunities for industry development. The development of interoperable healthcare systems across the EU-27 was defined as one of the main priorities of the bloc's eHealth Action Plan for 2010.

One of the most significant barriers identified to the adoption of standards is the adjustments and updates needed in the healthcare systems internal processes to adapt them. This suggests a lack of functionality in some services which are crucial for medical practice, and IT hospital services prefer to focus their efforts on the correct and smooth running of their isolated systems rather than making them interoperable by adopting common standards. This transition from isolated IT services to interoperable systems supposes major efforts and requires extra financial incentives that should be supported by national and European policies, but so far, health authorities have shown little government support for standardisation and lack of incentives to boost medical electronic communications.

5 Standards and Regulations

The healthcare domain has two main characteristics from a commercial point of view; it is a very fragmented and heavily regulated industry, making the healthcare regulatory system complex with many regulatory bodies involved, from International and European to national agencies and private organisations.

Standardisation plays an important role in order to allow new products accessing the EU market, thus increasing trade, innovation and growth. In addition, compliance with existing standards also saves efforts and money since not every technology has to be newly developed from scratch. If there are approved and widely used technologies or standards already in place then these could be deployed or built upon

5.1 Regulation in the European Union

EU governing bodies are aware that regulation plays a major role in the healthcare industry. Therefore, the EU launches directives which are then adopted and implemented by the member countries by transposing them into national laws. The standards are of importance for the design, manufacturing and procurement of medical devices.

Therefore, regulation and standards are closely interrelated:

- European standards and standardisation are based on European legislation
- Only National standards derived from European standards can be used in national legislation
- Healthcare Industry should comply with standards which are harmonised with National and European regulations

5.2 Initiatives to Harmonise Standards for Healthcare

The stakeholders involved in eHealth standardisation are becoming increasingly aware of the need to harmonise standards for the healthcare domain. Therefore, the World Health Organization (WHO), the EU and the Industry have launched initiatives for reaching harmonisation.

European standardisation bodies are harmonised in support of European legislation[25] helping to shape the European Internal Market. In 1991 an agreement on technical cooperation between CEN and ISO (Vienna agreement) was formally approved. The EC supported the creation of a collaborative health standards harmonisation group formed by the International Standardisation Organisation (ISO), the European Standardisation Committee (CEN), and Health Level 7 (HL7). Additionally, harmonised standards for medical devices have been boosted by European standardisation organisations such as CENELEC (see below) and ETSI (see below) on mandates from the EU Commission.

At European level harmonised standards are presumed to comply with the essential requirements of the core legal framework developed by the EC. This core legal framework consists of several directives launched by the EC which must be transposed to national laws by the member states.

5.3 International and European Standards Development Organizations and Other Organizations for the Promotion of Standards

IEC (International Electrotechnical Commission)
IEC is a global organisation that prepares and publishes international standards for electrical, electronic and related technologies. These serve as a basis for national standardisation and as references when drafting international tenders and contracts.

ISO (International Organization for Standardization)
ISO is an international standard-setting organisation composed of representatives from different standards organisations from 157 countries around the world.

ITU (International Telecommunication Union)

25 http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/

The International Telecommunication Union regulates information and communication technology issues, promoting telecommunication infrastructure in the developing world and established worldwide standards.

CENELEC (Comite` Europeen de Normalisation Electrotechnique)

CENELEC's mission is to prepare voluntary electrotechnical standards that help develop the Single European Market/European Economic Area for electrical and electronic goods and services removing barriers to trade, creating new markets and cutting compliance costs.

CEN (Comité Européen de Normalisation)
The CEN is the European Committee for Standardization and was founded in 1961 by national standards organizations in the EU.

ETSI (European Telecommunications Standards Institute)
The European Telecommunications Standards Institute (ETSI) produces globally-applicable standards for Information and Communication Technologies (ICT).

WHO
Through its eHealth Standardization Coordination Group the World Health Organization (WHO) launched the WHA58.28 directive for setting up the basis for deploying eHealth services.

HL7
Health Level 7 is a non-profit organization that promotes the development of international healthcare standards. The term HL7 refers also to some of the standards developed by the Health Level 7 organization for exchanging of electronic health information.

OpenEHR
The openEHR is both a foundation and a standard. The foundation is a not for profit organization that promotes the development and implementation of openEHR standard for seamless exchange of medical electronic information. The openEHR is a open standard medical data exchange that includes archetype methodology for specification of content.

Continua Healthcare Alliance (CHA)
The medical Industry is also aware of the negative economic implications of not having harmonised standards. During the latter years the industry has been more deeply involved in standardisation initiatives, giving rise to the Continua Healthcare Alliance. CHA develops and designs guidelines for building interoperable sensors, home networks, e-health platforms, and health and wellness services. It promotes the use of ISO 11073 family of standards.

Integrating the Healthcare Enterprise (IHE)
IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information, promoting the use of standards such as HL7 and DICOM.

5.4 Standards and Regulations for Patient Safety, Data Protection and Privacy

The exchange of health information is subject to privacy and legal issues. Information related to the patients' medical condition, billing information, and medical advice is considered highly sensitive. It is mandatory that these data will only be accessible to authorized personnel. It is also important to keep data integrative avoiding any kind of manipulation or data corruption.

Declaration of Helsinki
A set of ethical principles proposed by the World Medical Association (WMA)

European Convention on Human Rights (ECHR)
This is an international treaty for protect fundamental human rights. Article 8 of the ECHR provides a right to respect for a citizen's "private and family life, his home and his correspondence".

ICH guidelines
The International Conference on Harmonisation (ICH) is a joint initiative of the regulatory authorities of Europe, Japan and the United States aiming to make recommendations for achieving harmonisation in the requirements for product registration.

Good Clinical Practice (GCP)
Good Clinical Practice is an international quality standard provided by the International Conference on Harmonisation (ICH). Good Clinical Practice guidelines include protection of human rights.

HIPAA Privacy Rule (USA)

The privacy rule of the Health Insurance Portability and Accountability Act is a US law protecting the privacy of individually identifiable health information. It sets USA standards for the security of electronic protected health information.

OECD Guidelines Governing the Protection of Privacy and Trans-Border Flows of Personal Data

The OECD defines the following recommendations for protection of personal data:

1) Notice: data subjects should be given notice when their data is being collected
2) Purpose: data should only be used for the purpose stated and not for any other purposes
3) Consent: data should not be disclosed without the data subject's consent
4) Security: collected data should be kept secure from any potential abuses
5) Disclosure: data subjects should be informed as to who is collecting their data
6) Access: data subjects should be allowed to access their data and make corrections to any inaccurate data
7) Accountability: data subjects should have a method available to them to hold data collectors accountable for following the above principles.

The spirit of these principles is at the core of European directives related to data protection.

Directive 95/46/CEE

This directive regulates the processing of personal data whether or not the processing is automated.

Directive 2002/58/EC

This directive concerns the processing of personal data and the protection of privacy in the electronic communications sector. This directive could be considered the most important one related to data privacy, and it has direct implications for REACTION services which must comply with all aspects of this directive, especially those related to the security in storage, management and transmission of sensitive information to ensure confidentiality and data privacy. In addition, patients will be empowered to decide what information will be transmitted, and prior consent will be necessary for collecting, storing and transmitting any personal data.

Directive 2006/24/EC

This directive amends Directive 2002/58/EC for harmonising public security and personal privacy. It establishes the category of data to be stored and the security requirements for retained data.

EU Council Recommendation on General Patient Safety Issues

This document provides recommendations for improving patients' safety in all EU Member States, through sharing information, best practice and expertise.

ISO 27002

ISO 27702 code of practice describes best practices for information security.

EN 14485:2003

This health informatics standard provides guidelines for the security of personal identifiable health information in the case of international distribution of this information.

EN 12251:2004

This health informatics standard provides guidelines for authentication of individual users working with healthcare IT systems, by improving the software procedures linked to the management of user identifiers and passwords. It does this without using additional hardware facilities. This standard applies to electronic patient records and patient administrative systems.

CEN 15299:2006

This standard discusses the procedures for identifying patients and related objects.ISO 14971.

ISO 13485:2003

This is a standard for quality management system requirements for regulatory purposes.

ISO TR 14969:2004 Medical Devices

Guidance for quality management systems on the application of the above ISO 13485:2003

IEC 80001 1

Standard for risk management for IT networks incorporating a medical device

IEC TR 80002 1
Standard for software risk management

EN 1041:2007
Standard for specifying the minimum information supplied by the manufacturer of medical devices

EN ISO 14155
Standards for clinical investigation of medical devices for human subjects

EC 62366 Medical Devices
Application of usability engineering to medical devices

IEC 60601-1:2005
Standard for general requirements for basic safety and essential performance for medical electrical equipment

IEC 61508-3:1998
This Standard provides specifications for ensuring functional safety of electrical/electronic/programmable systems. It also provides software requirements and methods for the determination of safety integrity levels.

IEC 80001
Developed by the ISO /CEN joint group, this standard establishes the risk management procedures for IT-networks incorporating medical devices.

Proposal IEC TR 80002
This is a guidance proposal for applying ISO 14971 to medical devices software

AES
AES stands for Advanced Encryption Standard. It is a standard for secure data transmission

TDEA
TDEA stands for Triple Data Encryption Algorithm (Triple Data Encryption Standard (3DES)). It is a standard for secure data transmission

SHA
Secure Hash Function it is part of a family of algorithms published by the National Institute of Standards for computing message digests.

MD5
MD5 stands for Message-Digest Algorithm 5. It is a standard for secure data transmission

OASIS v2.0
OASIS v2.0 of XACML (eXtensible Access Control Markup Language) is a standard for secure data transmission

EPAL
Enterprise Privacy Authorization Language is a standard for secure data transmission

5.5 Standards and Regulations for Medicals Devices

EU Medical Device Directives
The objective of the EU medical device directives is to ensure safety and proper running of medical devices and at the same time facilitate trade and international commercialization in the European Economic Area. The EU medical device directives have been transposed to national regulations, and in many cases they are transposed almost verbatim. These directives are The Active Implantable Medical Devices Directive 90/385/EEC, the Medical Devices Directive 93/42/EEC and the In-Vitro Diagnostic Medical Devices Directive 98/79/EG.

Directive 90/385/EEC (AIMD)
The Active Implantable Medical Device (AIMD) Directive 90/385/EEC was implemented in 1993 and applies only to active devices that are intended to be permanently implanted into humans.

Directive 93/42/EEC (MDD)
Until recently, Medical Device Directive (MDD) 93/42/EEC was the key directive on regulation of medical devices. As of March 2010 the key directive is 2007/47/EEC, see below.

Directive 98/79/EC (IVDMD)

This directive covers devices used in vitro for the examination of a specimen derived from the human body, including reagents, instruments and specimen receptacles. The In Vitro Diagnostic Medical Devices Directive introduced for the first time common regulatory requirements dealing specifically with the safety, quality and performance of in vitro diagnostic medical devices (IVDs), thereby bringing them in line with other medical devices. This directive applies not only to the sensors that will be developed during the project but also to the software, since the revised definition of a medical device includes stand-alone software and states that when software is used in combination with a device which is 'intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes' it will be considered a medical device covered by the directive.

In addition glucose sensors developed within the project should follow the guides provides by the Good Design Practice appointed by Alexander and Clarkson 1999 and comply with the European Medical Device Directive (MDD) as well as the US food and Drug Administration (FDA).

Directive 2007/47/EEC
This directive amends directive 93/42/EEC, and its compliance is mandatory from 21 March 2010. It provides alignment of directive 90/385/EEC with directive 93/42/EEC. Additionally the directive provides regulation of medical software, which is considered a medical device only if it is intended for diagnosis or therapy.

ISO/IEEE 11073 Personal Health Data (PHD)
ISO/IEEE 11073-20101:2004 provides the upper layer [i.e., open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications.

5.6 Standards for Data Interoperability

ISO/TR 18307
This standard describes the key characteristics for interoperability and compatibility in exchanging medical information.

CEN 13606
This standard proposes a scheme for designing Electronic Health Record (EHR) for data exchange among different systems.

HL7
Standards developed by ANSI for medical information exchange.

SNOMED
SNOMED is a systematically organised clinical terminology allowing indexation, storage and aggregation of unambiguous clinical data.

DICOM
DICOM stands for Digital Imaging and Communications in Medicine. It is a standard for managing digital medical images defining the protocols for exchanging them. European CEN has contributed to DICOM through EN 12052.

OpenEHR
OpenEHR provides descriptions for managing, storing, retrieving and exchanging health data.

5.7 Standards and Regulations for Healthcare Software Systems

IEC 62304
This standard defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes.

IEC TR 800021:2009 Medical Device Software
This standard provides guidance on the application of ISO 14971 to medical device software.

CEN/TS 15260:2006
CEN/TS 15260:2006 Health informatics: Classification of safety risks from health informatics products.

ISO/IEC 27000-Series
ISO/IEC 27000-series: LIS Information security management systems.

ISO 27799:2008 CEN

ISO 27799:2008 CEN Health informatics: Information security management in health using ISO/IEC 27002 (ISO 27799:2008).

ISO/IEC 27799
ISO/IEC 27799, Health informatics: Standard for information security management in health using ISO/IEC 27002 (ISO 27799:2008).

EC 62304
IEC 62304, Ed. 1: Medical device software. Software life cycle processes, computer software.

CEN/TR 15640
CEN/TR 15640 CEN Health informatics: Measures for ensuring the patient safety of health software.

CEN/TS 15260
CEN/TS 15260 CEN Health informatics: Classification of safety risks from health informatics products.

CEN/TR 27809
CEN/TR 27809 CEN Health informatics: Measures for ensuring the patient safety of health software.

CEN/TS 25238
CEN/TS 25238 CEN Health informatics: Classification of safety risks from health informatics products.

ISO/IEC 90003:2004
ISO/IEC 90003:2004 Software engineering: Guidelines for the application of ISO 9001:2000 to computer software.

IEC 60601
This is a harmonised standard for electrical programmable systems.

5.7.1 Standards for Service-Oriented Architecture

A service-oriented architecture (SOA) is a flexible set of design principles used during the phases of systems development and integration. A deployed SOA-based architecture will provide a loosely integrated suite of *services* that can be used within multiple business domains.SOA also generally provides a way for consumers of services, such as web-based applications, to be aware of available SOA-based services. SOA defines how to integrate widely disparate applications for a world that is Web-based and uses multiple implementation platforms. Some generally accepted standards and protocols applying to SOA are listed below.

SOAP
Simple Object Access Protocol (SOAP) is a protocol for structured information exchange in distributed systems.

CMA
Contest Management Architecture (CMA) has been established by the Clinical Context Object Workgroup (CCOW).

XML
Extensible Markup Language is a simple, but very flexible text format derived from the ISO 8879 SGML format.

WSDL
Web Services Description Language (WSDL) is an XML-based format for describing network services in a structured manner.

WS-Security
WS-Security is an extension to SOAP which applies confidentiality and integrity to the basic Web Services Messaging infrastructure.

UML
The Unified Modeling Language (UML) aims to specify, visualise, construct and document software intensive systems.

5.8 Barriers for eHealth Standards Adoption

The European Commission, DG Enterprise & Industry has published "Special Study No. 1, 2008 ICT standards in the health sector: current situation and prospects". In this study a number of barriers for adopting eHealth standards was identified and classified in four groups:

1) Political barriers: Fragmented market with different needs and priorities, lack of financial support for adoption of standards

2) Standards Development Organisations (SDO) barriers. They seek positive returns for their efforts

3) Company barriers: Like SDOs, ICT firms seek positive returns from their standardisation efforts

4) ICT health user barriers. Need of financial investment for adapting current system.

5.9 Healthcare Regulatory Agencies

Many factors make health related provided services development and subsequent commercialization challenging, including the ethical and research governance involved in studying users as well as the inevitable time and financial constraints.

Information concerning the availability of standards can be obtained either from the Standardisation Organisations or from the national standardisation bodies listed here[26]. National European regulatory agencies responsible for medical devices are listed in Annex 1.

5.9.1 European Medicines Agency (EMA)

The European Medicines Agency (EMA) is a decentralised body of the European Union, located in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency is responsible for the scientific evaluation of applications for European marketing authorisations for both human and veterinary medicines (centralised procedure). Under the centralised procedure, companies submit a single marketing-authorisation application to the Agency. Once granted by the European Commission, a centralised (or 'Community') marketing authorisation is valid in all European Union (EU) and EEA-EFTA states (Iceland, Liechtenstein and Norway).

All medicines for human and animal use derived from biotechnology and other high-tech processes must be approved via the centralised procedure. The same applies to all advanced-therapy medicines and human medicines intended for the treatment of different diseases, auto-immune and other immune dysfunctions, and viral diseases, as well as to all designated orphan medicines intended for the treatment of rare diseases.

The Agency also plays a role in stimulating innovation and research in the pharmaceutical sector. The Agency gives scientific advice and other assistance to companies for the development of new medicines. It publishes guidelines on quality-, safety- and efficacy-testing requirements. A dedicated SME Office, established in 2005, provides special assistance to small and medium-sized enterprises.

5.9.2 The Heads of Medicine Agencies (HMA)

The Heads of Medicines Agencies is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of Medicinal Products for human and veterinary use in the European Economic Area. The Heads of Medicines Agencies is supported by working groups covering specific areas of responsibility and by the Heads of Medicines Agencies Management Group and Permanent Secretariat.

The Heads of Medicines Agencies co-operates with the European Medicines Agency and the European Commission in the operation of the European Medicines Regulatory Network.

26 Further information about standards can be found at http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

5.9.3 FDA

The Food and Drug Administration (FDA) is the agency of the United States Department of Health, providing regulations and supervisions for the protection of public health.

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7 Annex I. National Regulatory Agencies for Medical Devices

In the following table all the EU National Agencies are listed.

Country	Agency Name	Address	Web Page
Austria	Agentur für Gesundheit und Ernährungssicherheit GmbH	Schnirchgasse 9; 1030 Wien; Austria	www.ages.at
Belgium	Federal Agency for Medicines and Healthcare Products (FAMHP)	Place Victor Horta 40/40; Bruxelles - 1060	www.fagg.be
Bulgaria	Bulgarian Drug Agency	26, Yanko Sakazov Blvd.; 1504 Sofia	www.bda.bg
Cyprus	Ministry of Health (Cyprus)	7 Larnakas Avenue; Lefkosia 1475, Cyprus	www. phs.moh.gov.cy
Czech Republic	Státní ústav pro kontrolu léciv	Šrobárova 48 - Praha 10; 100 41	www. sukl.cz
Denmark	Laegemiddelstyrelsen	Axel Heides Gade 1, DK-2300 Copenhagen S., Denmark	www.laegemiddelstyrelsen.dk
Estonia	Ravimiamet	1 Nooruse Str; Tartu - 50411	www. sam.ee
Finland	Lääkelaitos	Box 55; Helsinki 00301 - Finland	www. nam.fi
France	Agence Française de Sécurité Sanitaire des Aliments	BP 90 203 Javené; Fougères Cedex 35302; France	www. anmv.afssa.fr
Germany	BVL - Bundesamt für Verbraucherschutz und Lebensmittelsicherheit	Diedersdorfer Weg 1; Berlin 12277; Germany	www. bvl.bund.de
Greece	National Organization for Medicines	284 Messogion Avenue – Holargos – Athens 155 62; Greece	www. eof.gr
Hungary	National Institute of Pharmacy	H-1051 Budapest, Zrínyi u. 3.	http://www.ogyi.hu
Iceland	Lyftasjofnun, Icelandic Medicines Agency (IMA)	Box 180; IS - 172 Seltjarnarnes;	www. lyfjastofnun.is
Italy	Ministero della Salute	Piazzale Marconi 25; Roma 00144; Italy	www. sanita.it
Ireland	Irish Medicines Board (Bord Leigheasra na hÉireann)	The Earlsfort Centre Earlsfort Terrace; Dublin 2; Ireland	www. imb.ie
Latvia	Valsts zalu agentura	Jersikas iela 15; Riga 1003	www. vza.gov.lv
Liechtenstein	Liechtensteinische Landesverwaltung, Amt für Gesundheit	Äulestrasse 512, Postfach 684, FL-9490 Vaduz	www. ag.llv.li
Lithuania	State Medicines Control Agency	Traku 9/1 – Vilnius - 01132; Lithuania	www. vvkt.lt
Luxembourg	Ministère de la Santé	Villa Louvigny - 1er étage Parc de la Ville - Allée Marconi - 2120; Luxembourg	www.ms.etat.lu

The Netherlands	College Ter Beoordeling van Geneesmiddelen	Kalvermarkt 53; Den Haag 2511 CB; The Netherlands	www.cbg-meb.nl
Malta	Medicines Authority	198 Rue D'Argens - Gzira GZR 003; Malta	http://www.sahha.gov.mt/
Norway	Statens Legemiddelverk	Sven Oftedals vei 8, N - 0950 Oslo; Norway	www. legemiddelverket.no
Poland	Urzad Rejestracji Produktów	Leczniczych 41 Zabkowska Street – Warszawa - 03-736; Poland	www.urpl.gov.pl
Portugal	Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.	Parque de Saúde de Lisboa - Avenida do Brasil, 53 1749-004 Lisboa - Portugal	http://www.infarmed.pt
Romania	Ministerul Sănătății	Intr. Cristian Popişteanu, nr. 1-3, sector 1, cod 010024, Bucurest	http://www.ms.ro
Slovak Republic	State Institute for Drug Control	Kvetná 11 825 08 Bratislava 26 Slovak Republic	http://www.sukl.sk
Slovenia	Javna agencija Republike Slovenije za zdravila in medicinske pripomočke	Einspielerjeva ulica 6- Ljubljana 1000; Slovenia	www.jazmp.si
Spain	Agencia Española de Medicamentos y Productos Sanitarios	Parque Empresarial Las Mercedes 8 – Madrid 28022; Spain	www. agemed.es
Sweden	Läkemedelsverket – Medical Product Agency	Dag Hammarskjölds väg 42; Uppsala 751 83; Sweden	www.mpa.se
United Kingdom	Medicines and Healthcare products Regulatory Agency	Market Towers 1 Nine Elms Lane London SW8 5NQ	http://www.mhra.gov.uk

Table 3 List of European National Regulatory Agencies for Medical Devices