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Study on Legal Framework of Interoperable eHealth in Europe

NATIONAL PROFILE MALTA

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1 Documents

1.1 Applicable Documents

[AD1]	Services Contract 30-CE-0162056/00-04

1.2 Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf
[RD2]	eHealth Action Plan, Progress Report http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf
[RD3]	Recommendation of the Commission on eHealth interoperability, http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf
[RD4]	Database of European eHealth priorities and strategies (Empirica), http://www.ehealth-era.org/database/database.html (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, http://www.euro.who.int/observatory/Hits/TopPage
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, http://www.euro.who.int/observatory/Publications/20060522_4
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report:

	http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_survey_final_report.pdf, Country profiles: http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm
[RD9]	Communication from the European Commission, "A Community framework on the application of patients' rights in cross-border healthcare", 2 July, 2008, http://ec.europa.eu/health-eu/doc/com2008415_en.pdf
[RD10]	Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, http://ec.europa.eu/health-eu/doc/com2008414_en.pdf
[RD11]	European Commission, IDABC, eID interoperability for public government services (with country profiles): http://ec.europa.eu/idabc/en/document/6484/5938
[RD12]	European Commission, IDABC, eSig-Web (Electronic signatures applications in public government services – country overviews): http://ec.europa.eu/idabc/en/chapter/6000
[RD13]	Legally eHealth, Study on Legal and Regulatory Aspects of eHealth,http://www.ehma.org/projects/default.asp?NCID=140
[RD14]	Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML
[RD15]	Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf
[RD16]	International Encyclopedia of Medical Law (editor: Herman Nys), http://www.ielaws.com/medical.htm, (with country monographs)

2 Glossary

2.1 Definitions

In the course of this Study, a number of key notions are frequently referred to. To avoid any ambiguity, the following definitions apply to these notions and should also be used by the correspondents.

- **Authorization:** refers to:
  - the permission of an authenticated entity (e.g. a person) to perform a defined action or to access a defined resource/service
  - or: the process of determining, by evaluation of applicable permissions, whether an authenticated entity is allowed to perform a defined action or has access to a defined resource.
- **Data authentication**: information provided for verification, with more or lesser degrees of certainty, of the origin and the integrity of data.
- **eHealth**: a very broad term that encompasses many different activities related to the use of the information and communication technology (ICT) for healthcare. Many of these activities focus on administrative functions such as claims processing or records storage. However, there is an increasing use of e-health related to patient and clinical care.
- **Electronic health record**: a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes;
- **Electronic signature**: data in electronic form which are attached or logically associated with other electronic data and which serve as a method of data authentication.
- **ePrescription**: a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC47, issued and transmitted electronically
- **Healthcare**: the prevention, treatment, and management of illness and the preservation of mental and physical well being through the services offered by the medical, nursing, and allied health professions. Health care embraces all the goods and services designed for people’s health, including preventive, curative and palliative infections, whether directed to individuals or to populations.
- **Health professional**: a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of

Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC.

- **Identification**: using claimed or observed attributes of an entity (e.g. a person) to distinguish the entity in a given context from other entities it interacts with (= entity authentication).
- **Identifier**: attribute or set of attributes of an entity (e.g. a person) which uniquely identifies the entity in a given context.
- **Identity management**: Identity management (ID management) is a broad administrative area that deals with identifying entities in a system (such as a country, a network, or an enterprise) and controlling their access to resources within that system by associating user rights and restrictions with the established identity.
- **Patient**: any natural person who receives or wishes to receive health care in a Member State;
- **Patient summary**: subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription;.
- **Registration**: process in which a partial identity is assigned to an entity and the entity is granted a means by which it can be authenticated in the future.
- **Telemedicine**: exchange of medical information from one site to another via electronic communications with the purpose to improve patients' health status.

2.2 Acronyms

CBSS... Crossroads Bank for Social Security

EHR... Electronic Health Record

eID .... Electronic Identity

eIDM .... Electronic Identity Management

GP... General Practitioner

...

HiT.. Health in Transition

......

OCSP .... Online Certificate Status Protocol

PKI....................................... Public Key Infrastructure

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NRN...................................... National Register Number

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SIS.. Social (security) Information System

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SSCD .... Secure Signature Creation Device

SSIN..................................... Social Security Identification Number

....

TTP .... Trusted Third Party

3 Introduction

3.1 General overview of the Maltese healthcare system

A comprehensive overview of the Maltese healthcare system can be found in the Maltese HiT country report published by the European Observatory on Health Care Systems http://www.euro.who.int/Document/E67140.pdf. However, this document is dated 1999 and hence, various other Policy documents have been used to update the information provided in this report, reference to which can be found in section 1.2 of this report.

The Health of the Maltese Nation

The Maltese population presently exhibits a relatively high health status. In a national health interview survey, conducted in 2002, a relatively high proportion of respondents (73 per cent) stated they were in good or very good health. Life expectancy at birth in 2003 was 80.43 years for females and 76.39 years for males. However, statistics show that circulatory disease is the leading cause of death, accounting for 44 per cent of deaths. Cancers currently account for 24 per cent of deaths with lung cancer as the commonest cancer killer in men (7.6 per cent of all deaths) while breast cancer is the commonest cancer in women (4.4 per cent of all deaths). Mental health is another important chronic condition.

Primary, Secondary and Tertiary Care

The public health care system provides a comprehensive basket of health services to all persons residing in Malta who are covered by the Maltese social security legislation. In addition, the health care system also provides all necessary care for special groups such as irregular immigrants or foreign workers who have valid work permits. No user charges or co-payments apply. Government primary health care services include general practice, community care, immunization services and the school health service. Health services provide extensive preventive services, such as Well Baby clinics, Well Woman clinics, routine blood pressure and cholesterol check-ups, smoking cessation clinics, screening for glaucoma, monitoring of diabetes and opthalmological check-ups. A few services including elective dental services and coverage of formulary medicines are means-tested.

The private sector acts as a complementary mechanism for health care coverage and is financed through private health insurance and out of pocket payment. The two systems of general practice function independently from one another. It has been estimated that the private sector accounts for about two thirds of the workload in primary health care.

Acute hospital care now takes place at a newly constructed Mater Dei Hospital, which is the main acute general hospital in Malta. The Maltese government has heavily invested in the construction of this hospital. The new hospital project has a total floor area of 232,000m² and approximately 8,000 rooms. It allows for a complement of 804 inpatient beds and 107 day beds. There are 38 inpatient wards distributed among medicine, surgery, critical care, obstetrics, gynecology, pediatrics and specialized units including neurosurgery, burns and plastic surgery and acute psychiatry. The hospital is shortly also due to be used as a teaching facility by the neighboring University of Malta. Expenditure on the Mater Dei Hospital represented one third of Government's capital outlay in 2005 and contributed to an estimated 56 per cent of the nominal growth in investment expenditure by Government.[1] Another 85 beds are available at the Sir Paul Boffa Hospital, which has oncology and dermatology units, and 259 short or long stay beds are available at the Gozo General Hospital. At Mount Carmel Hospital there are 563 psychiatric beds (short or long stay), while in the Zammit Clapp Hospital there are 60 specialised geriatric rehabilitation beds.

The Government caters for the special needs of the elderly through a specialized Department which runs residential homes for the elderly in various localities, the largest of which is the Saint Vincent de Paule, a facility with over 1,000 beds at Luqa. Other services in this field include the Home Help Service (for a nominal charge the elderly person is helped with the household chores and the shopping), the Meals on Wheels service (hot meals are delivered to the house of elderly people), the Handyman Service (household maintenance is carried out free of charge for elderly persons with a low income), and the Telecare services.[2] In 2006, the Maltese Government announced plans to create a new 288-bed Rehabilitation Unit which would provide various rehabilitation services. Malta has three private hospitals: St. Philip's Hospital in Santa Venera (75 beds), Capua Palace Hospital in Sliema (80 beds) and St. James Hospital in Zabbar (13 beds).

Figure 1.0: Surgical Operations Register St Luke's Hospital

[1] ***Securing Our Future, Pre-Budget Document 2007.***

[2] This is a telephone system which makes it easy for elderly persons to summon help in case of a medical emergency.

Human Resources for Health

The health sector is one of the largest employers in Malta. The employees form part of the Public Service. Besides health professionals, various categories of support staff ranging from auxiliary workers to clerical workers to engineers make up the health care workforce. 55 per cent of the total government expenditure on health goes towards the salaries for human resources in health care. In the year 2003, the rates of health professionals per 100,000 population were as follows: doctors: 315, dentists: 42, nurses: 577, midwives: 31 and pharmacists: 201.[3]

Health Financing

The National Health Service is funded from general taxation. The Government recurrent expenditure budgeted for health services in 2006 is almost 80 million Maltese Liri (around 186 million €), which constitutes around 10% of the Government's total recurrent expenditure. It is difficult to estimate the proportion spent on primary care as many services at Health Centres are provided by secondary care physicians on a part-time basis. Resource allocation is carried out in the Ministry of Finance, the Ministry for Health and the Health Division (Head Office).

In Malta there is no obligatory health insurance, as there is a national health service (free at the point of delivery) covering the whole resident population. All workers and employers pay National Insurance contributions on a weekly basis, but this money goes to finance welfare services in general (e.g. pensions) and not health services in particular. It is the exception for an employer in Malta to offer health insurance as an employment benefit. A number of residents purchase private health insurance on a voluntary basis; the proportion of the population availing itself of this option is growing. Many people also choose to make use of the services of private general practitioners and specialists on a direct fee-for-service basis.

[3] Source: WHO-EURO Health for All statistical database (www.who.dk).

Pharmaceutical Services

The Government, through its Pharmaceutical Services, supplies a specific list of pharmaceuticals free of charge to all in-patients in Government hospitals. Other persons entitled to free medicines include:

- ***Schedule II patients***

These patients benefit under the Medical Aids grant under the Social Security Act. Entitlement is based on an assessment of the total income. A pink form, which is issued from the Department of Social Security, is given to all certified beneficiaries.

- ***Schedule V patients***

Any patient suffering from a condition which is listed under the fifth schedule of the Social Security Act can benefit from this service. This schedule refers to a series of diseases and conditions in respect of which free medicines are provided irrespective of financial status.

Also benefiting from free pharmaceuticals are members of certain religious orders; inmates of charitable institutions; certain grades of Health Service employees; members of the Police Forces below a certain grade; refuse collection employees; prisoners; persons injured on duty; and military personnel. Some of these persons are entitled by virtue of their eligibility for a “pink form”.

Policy documents

In the late 1980s and early 1990s, policy makers within the Ministry of Health promoted changes in health services strategy aimed at transforming the existing Department of Health into a more decentralised Health Division. The Ministry started to introduce self-management and autonomy in certain health care services. The principle of subsidiarity was introduced and clear lines of accountability were enforced. There was the start of an evolution from a centralised department providing for all the health needs of the population to one where the main focus was of regulator and purchaser of the services, and not the actual service provider.

Health Vision 2000

This document, approved by Cabinet in 1994 and published in 1995, encompassed the national Health for All Policy, based on WHO principles. Ten years on it still serves as a point of reference for current health policy initiatives and reforms. It covered three domains: Diseases, Risk factors, Health sector reform. The most important diseases and risk factors were identified using a priority setting approach. The individual areas are now being tackled separately in detail and policy documents on prevention and management of road traffic accidents and asthma were drawn up in conjunction with the relevant sectors. The objectives for health sector reform are also highlighted in *Health Vision 2000*.

Mental health policy

This document outlines the strategy for reform in mental health care highlighting the importance of multi-disciplinary work and the shift towards community based care. Despite being approved by Cabinet, the reforms in this area have proceeded at a slow pace.

3.2 The use of ICT in the Maltese healthcare sector

General Overview

ICTs started to be applied in Malta's health sector in the 80's, when the first Computer Centre was opened next to St Luke's Hospital. In 1992, Government approved a national health information strategy that envisaged the creation of several information systems to support health care delivery and health service management. The largest of these was the Healthcare Information System to be implemented in phases across all of the public hospitals and health centres in Malta and Gozo. The first PAS modules, i.e. the Patient Master Index and the File Tracking system, went live in April 1997, followed by the Outpatients Booking and Registration module in 1998, the Inpatients Admissions, Discharges and Transfers module in 1999, and the Patient Billing and Accident and Emergency modules in 2001.

Other systems

Although the Healthcare Information System was large in scale and scope, it was not the only health computing system being developed. Several other IT systems were developed. These included the Blood Transfusion System, the Medical Stores system, the Schedule V system, and corporate systems (payroll, personnel, departmental accounting, stock control, e-mail). Other systems developed more recently include a Cardiac Investigation and Patient Records (CIPR) System, a Child Health Surveillance System (CHESS), a Public Health complaints system, a Diabetes Management System, a Radiology Reports database, the Central Sterile Services Department System, as well as off-the-shelf Access Accounts Dimensions software for accounting and Dakar for human resource management. In 1997-98 a pilot telemedicine project was carried out to provide a teleconsultation service between Gozo General Hospital and St Luke's Hospital. Though this was technically a success, the facilities did not enter mainstream service.

In the year 1996, the Ministry of Health was one of the first Government ministries to create an Internet presence, through a website developed by the Department of Health Information hosted on the magnet.mt domain. Over the years this was developed and in 2001 was migrated to the gov.mt domain as part of Government's programme to develop its corporate e-Government identity. In 2004, the site was upgraded and migrated to www.sahha.gov.mt [4].

In the year 2000, the Department of Health Information launched its first intranet, called HealthWeb, which was an important step forward in intra-departmental communication. This was developed over the years and provides health employees, wherever they work in the Government Health service, first hand access to policies, circulars, reports, statistics and other information resources. Another Intranet service in operation is Kura (the Maltese word for "care"), that is aimed specifically at the healthcare providers at St Luke's, Mater Dei and Boffa Hospitals.

Malta's first e-Health portal

The then Ministry for Investment, Industry and IT, working in collaboration with the Ministry of Health, Care of the Elderly and Community Care (MHEC) targeted a number of healthcare and health promotion services as services to be made available to the public electronically via the development of an e-Health portal.[5] These have been included in the National ICT strategy and were deployed early in February 2006. The services include:

- Online application for a European Health Insurance Card (EHIC);
- Online information on pharmacies open in Malta and Gozo;
- Online registration to become a potential blood donor;
- Online application to attend a weight reduction clinic;
- Online application to attend a smoking cessation clinic;
- Online public health complaint registration and the possibility to submit a complaint;
- Online application to attend a sexual and reproductive health counselling session and to consult an adviser in this respect;
- Online request for advice with respect to genito-urinary health problems;
- Online application for Out-Patient appointments and the possibility to schedule, reschedule and cancel appointments;
- Online access to an electronic library for patients.

[4] *Saħħa* is the Maltese word for "health"

[5] See: "EU funding program for a new national health information system in Malta", paper published by the MIIIT in June 2004

3.3 National eHealth strategy

The National eHealth Vision and Strategy for Malta is currently being drafted. The information contained in the following section emanates from a close look at the Draft Strategy[6] and other policy documents of the Maltese Government including Budget and Pre-Budget Programmes and Malta's Operational Programmes 2007-2013. The vision for eHealth for Malta is that

> *eHealth will lead to better communication between all stakeholders in Malta's healthcare system, throughout the whole process of healthcare delivery and health service management. Through facilitated and improved human, organisational and technical communication, healthcare in general will be more efficient, of better quality and accessible to all, whilst respecting the privacy of individuals*.

The eHealth vision will be achieved through a strategy for development of a secure high-speed infrastructure, together with a Web foundation, which will contain an eHealth Portal and which will serve as the basis of several eHealth applications.

The eHealth Portal, the first version of which was launched in February 2006, serves as the main communication interface between the citizens, health professionals and the Health Service. The Portal provides a range of services from the purely informational to the fully transactional. It allows the user to find information on certain diseases through an electronic medical library. It also provides the facility to download application forms and also register for certain health promotion programmes offered by the Government, such as smoking cessation clinics and weight reduction clinics. The Portal also provides all information regarding the health care services provided by the Government in terms of what services are available and what one has to do to receive them.

[6] The Draft Strategy had been made issued to the public on the then Ministry for Health and Elderly Care's website. The document dated April 2006, has been withdrawn from the public domain, and it is assumed that it is undergoing further revision.

Email communication between patients and health professionals is one possible means of enquiring on certain diseases or conditions, asking professional advice or enquiring about issues concerning medication. The kingpin of Malta's eHealth system is undoubtedly the new Integrated Health Information System (IHIS) that is being developed in stages primarily for Malta's new acute general hospital, Mater Dei Hospital (MDH), as well as for other public hospitals and health centres. The IHIS should facilitate and improve the interaction between healthcare processes, healthcare delivery units, and different healthcare providers. The main applications, the first phase of which was completed on 18th April 2008 includes the six IHIS applications: the Laboratory Information System (LIS)[7], Radiology Information System (RIS), Picture Archiving and Communication System (PACS), Patient Master Index (PMI), Electronic Medical Records (EMR) and Order Management and Fulfilment (OMF).

By the end of 2008 Malta aims to have a new, fully functioning, acute general hospital with state of the art health information systems that are in full communication with all public hospitals and health centres in Malta, as well as with private healthcare providers. There is also the intention of having these operational systems interfaced directly with patients and the general public through the eHealth Portal. In May 2008, the Maltese Communications Minister Austin Gatt told Parliament that new identity cards to be introduced in 2009 will contain an electronic chip carrying the individual's health record. The information will be linked to Mater Dei Hospital, health clinics and, in time, to general practitioners' clinics.

3.4 Regulatory framework for patients' summaries

Malta doesn't have legal provisions in the area of patients' summaries. However, close contact is kept by the stakeholders responsible for the drafting of the eHealth Strategy with the Office of the Attorney General (which is responsible for the development of any new legislation required for the strategy) to ensure that the eHealth Strategy is congruent with existing legislation and Directives and any draft legislation envisaged in related matters. Moreover, strategic objective 4 of the draft eHealth Strategy speaks of ***Facilitating electronic monitoring of patients' health*** and the long-term aim of providing online access for patients to personal health records and ensuring a high level of security for access to personal health information.

[7] As from June 2008, doctors and other clinical staff at Malta's new Mater Dei Hospital can order laboratory tests and x-rays online and view results and reports using iSoft's order communication software. The systems were recently installed at the hospital under a contract renewal for iSoft's patient management system.

3.5 Regulatory framework for telemedicine

There are no specific provisions in Malta with regards to telemedicine. On the other hand, there does not seem to be any barrier to its practice as long as it respects the provisions of data protection. Towards this purpose, various data protection officers have been appointed to various departments within the health sector, throughout Malta and Gozo.

Strategic Objective 2 of the draft eHealth Strategy speaks of ***Integrating health processes using a holistic approach*** stating that one of the focuses of the strategy is that of setting up a partnership to develop expertise in telemedicine. **Online pharmacies** do not yet exist in Malta, however this subject is currently under discussion as an extension to the eHealth strategy tabled by the Ministry for Investment, Industry and IT. **Online interaction with family doctors** is not a recognised practice in Malta, neither are **telephone-based consultations**. Telephone-based interactions are not encouraged and there is no arrangement for payment in place. However, online consultation with a doctor other than one's family doctor has been tabled within the eHealth Strategy.

3.6 Regulatory framework for electronic prescriptions

No specific legal framework exists for electronic prescriptions. However, whereas the eHealth Strategy speaks of the objective of replacing at least 50 percent of paper communications taking place and 25 percent of paper communications leaving the public healthcare sector by electronic communications, there is no indication that this also includes electronic prescriptions.

3.7 Overview of relevant legislation

There have been limited legislative changes in support of the health service reforms that have taken place since the early 90's. This section describes both enacted and pending legislation. In 1995 legislation governing the ***licensing of private medical clinics*** was enacted. This legislation paved the way for the opening of private hospitals. This legislation hailed a change in policy regarding the involvement of the private sector in hospital care. It deals with aspects such as facilities, human resources required and types of procedures that may be carried out. In 1997 administrative measures were taken to ***introduce a flat-rate co-payment for medicines provided free of charge*** by Government. This was mostly intended to curb abuse rather than to provide significant revenue. This measure only lasted for nine months as the co-payment system was abolished following a

change of government. These circumstances make it seem unlikely that similar co-payments within the Government Health Service will be introduced in the near future.

There is also a ***Draft Health Services Act*** which aims to establish a reformed administrative set up of the Health Division with a clear demarcation between the regulator and provider roles.

4 Regulatory framework for the healthcare profession

4.1 Legal conditions for the practice of healthcare

Malta's size and geographical isolation present a unique set of challenges for policy-makers seeking to ensure the provision of comprehensive health services of a high standard compatible with legislation. One of the greatest of these challenges is the recruitment, training and retention of highly skilled health care professionals.

Between 1800 and 1964, Malta was a colony of the British Empire. During this period, human resource policies and the training and regulation of health professionals were organized in the same manner as in the United Kingdom. Doctors pursuing a specialization spent a number of years training in the United Kingdom. Those returning to Malta practiced in the one and only tertiary hospital. Even after independence, the links between Malta and the United Kingdom remain strong and many health professionals undertake some time of their training there.

Malta boasts one of the oldest universities and medical schools in Europe. The University of Malta traces its origins to the founding of the Collegium Melitense in 1592, while medical undergraduate training was established in 1676. Today, medical studies consist of five years of formal training at university, plus at least one year of supervised practice. The first two years of studies are pre-clinical, the last three clinical. In the late 1980s and early 1990s, the University of Malta opened its doors to all students with the qualification for admission to university. The *numerus clausus* for medical studies was formally lifted in 1998. The Ministry of Health does not formally regulate the number of students enrolled or the quality and content of the teaching programmes. However, an expert group appointed by the European Commission which examined course outlines and modules in 2002 found them in conformity with EU requirements.

Health care professions are regulated through the statutory bodies established by the Health Care Professions Act of 2003 (updated in 2008), one of the main aims of which was to bring Maltese legislation into line with the EU *acquis* on mutual recognition of professional qualifications. Four statutory bodies regulate the health care professions: the Medical Council (comprising doctors and dentists), the Pharmacy Council (responsible for pharmacists and pharmacy technicians), the Council for Midwives and Nurses, and the Council for Professions Complementary to Medicine. Unlike in the past, the statutory regulatory bodies have the same roles and responsibilities and the same degree of professional autonomy. The Act also provides for Specialist Accreditation Committees that have the tasks, inter alia, of issuing certificates of completion of specialist training in the various specialities enshrined in the law; to advise the Minister and the relevant Council on issues concerning specialist training and registration, and any other matter

that may be referred to it; to act as the advisory body for training in any of the special areas of practice; to accredit post-graduate training programmes;

According to the Health Care Professions Act of 2003, no person shall practice a health care profession unless he fulfils the conditions for the taking up and pursuit of that health care profession in Malta. A person shall only be entitled to use a professional title if he fulfils the conditions set by the relevant Council. The titles include those of: medical practitioner, dental surgeon, midwife, nurse, pharmacy technician and that of pharmacist. Malta recognizes qualifications issued by other EU member states as long as the conditions enshrined in Part VIII of the Act are met.

4.2 Control over the practice of medicine

The primary role of the bodies mentioned above is to maintain registers of health care professionals. They are additionally responsible for monitoring the education and training of health care professionals, in conjunction with the University of Malta and the specialist accreditation committees. The councils also have a role in establishing criteria for continuing medical education. Other main tasks of the councils are to establish professional guidelines and codes of ethics and to investigate cases of professional misconduct or negligence, including the proactive investigation of complaints. As in other European countries, actions by health professionals in Malta are coming under increasing scrutiny and litigation is becoming more common. The Government nominates lay people to the councils. Specialist accreditation committees will have the role of regulating the standards for postgraduate training and education. An area requiring more attention in the future will be to strengthen the cooperation between the different regulatory bodies.

In addition to the statutory bodies, health professionals are organized in professional associations on a voluntary basis. The Medical Association of Malta (representing doctors) and the Malta Union of Midwives and Nurses also play the role of trade unions. The Medical Association of Malta has acted as a coordinating body for the medical specialist associations that have emerged in recent years.

All health care professionals are accountable to their respective statutory regulatory bodies for their professional actions. Health professionals employed in the public sector are subject to the rules and regulations of the Public Service Management Code, covering the conditions of recruitment, employment and disciplinary mechanisms for civil servants. All promotions and calls for job applications are controlled by a central body, the Public Service Commission, in line with the Maltese constitution.

4.3 Professional liability

The Health Care Professions Act also regulates the issue of professional liability. The relevant Councils identified above have the power, either on the complaint of any person or of its own motion to investigate an allegation of professional misconduct or breach of ethics by a health care professional falling under its supervision. Any inquiry into the misconduct or other failure shall be barred by the lapse of two years which shall run from the day from which the complainant should have become aware of the facts or incidents that give rise to the complaint and in any case by the lapse of ten years from the date on which the alleged fact or incident was committed.

Proceedings by a relevant Council under this Act do not prejudice the taking of criminal or civil action on the same facts against the party liable, and criminal and/or civil action on such facts shall not be an obstacle to the taking of disciplinary action by the relevant Council.

In Malta, various codes regulate patient rights, responsibilities, entitlements and liabilities not in a specific manner but by applying general legal principles contained in:

- the Civil Code (Cap. 16);
- the Criminal Code (Cap. 9);
- the Constitution of Malta.

These general principles are interpreted by the Court as they apply to patient rights, responsibilities, entitlements and liability issues. A specific Patient Charter in Maltese and English is available for patients making use of the main acute hospital in Malta. A number of quality service charters apply to several parts of the Maltese health sector. The Social Security Act (Cap. 318) covers certain aspects of entitlement to free medicines for persons suffering from chronic diseases and for persons in low income groups. The Healthcare (Fees) Regulations (LN 201/04) stipulates who should pay for medical care received in Malta.

4.4 Professional secrecy

Among patients as well as doctors it is commonly held that confidentiality has been the foundation of the therapeutic relationship since the introduction of the Hippocratic oath. Nevertheless, medical confidentiality is a controversial issue. In Malta, professional secrecy between doctor and patient is protected by Chapter 377 of the Laws of Malta or the Professional Secrecy Act. This legislation confers upon a member of the medical profession a legal obligation not to disclose confidential information concerning a patient, which he learns during the course of his professional practice.

The Act also identifies the exceptions to the general rule of non-divulgence. These include instances where

(*a*) a person discloses in good faith, secret information in the course of and for the purpose of obtaining advice or directions from the body regulating his profession;
(*b*) a person disclosing in good faith secret information to a public authority or before a court or tribunal to the extent that is proportionate and reasonably required for the specific purpose of:
(i) defending himself against any claim with regard to professional work in connection with which the secret information has been obtained by him; or
(ii) initiating and maintaining judicial proceedings seeking the recovery of fees or other sums due to him or the enforcement of other lawful claims or interests;

Another exception is the case where disclosure is compelled by law, that is, a person is required to divulge information otherwise covered by professional secrecy by a competent law enforcement or regulatory authority, by a magistrate in the cause and for the purposes of *in genere* proceedings and by a court of criminal jurisdiction in the course of prosecution for a criminal offence.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

The legislation relating to data protection is contained in the following legislations:
- the Constitution of Malta;
- Chapter 440 of the Laws of Malta, the Data Protection Act, 2002;
- L.N 16 of 2003 – Data Protection Act (Cap 440) Processing of Personal Data (Telecommunications
- Sector) Regulations 2003;
- Chapter 422 of the Laws of Malta, the Malta Statistics Authority Act;
- Chapter 377 of the Laws of Malta, the Professional Secrecy Act, 1994;
- Chapter 418 of the Laws of Malta, the Malta Communications Authority Act, 2000;
- Chapter 399 of the Laws of Malta, the Telecommunications (Regulations) Act, 1997;
- L.N 19 of 2003 – Telecommunications (Regulations) Act (CAP 339) (Personal Data and Protection of Privacy) Regulations, 2003;
- Chapter 350 of the Laws of Malta, the Broadcasting Act, 1991; and
- the Medical Council Regulations.

In May 2004, Malta joined the European Union. In order to comply with the EU Data Protection Directive 2002/58/EC, the Republic of Malta enacted the Data Protection Act in 2001, which entered into force on July 15, 2003. Pursuant to the Act, the Republic named a Data Protection Commissioner and a Data Protection Appeals Tribunal in March 2002. The Act outlines nine principles to ensure the protection of personal information. Data collectors must state to individuals the specific purpose for the collection of information, and the data may not be used for other purposes. The Act also contains accuracy requirements, mandating that "reasonable measures" be taken to "complete, correct, block or erase data to the extent that such data is incomplete or incorrect." Regarding consent, an individual's "unambiguous" consent is required in order to process personal information and "explicit" consent it necessary in order to process "sensitive personal data."

Most of laws relating to Health Care were drafted prior to the Data Protection Act (DPA) and are hence, not prescriptive in relation to Data Protection. However, they outline the need for confidentiality. Recent laws make reference to the DPA which is to be observed in conjunction with medical laws and regulations.

The processing of health-related data is allowed for health and hospital care services if necessary for:
- preventive medicine and protection of public health;

- medical diagnoses;
- health care treatment;
- management of health and hospital care services;
- by a health professional subject to professional secrecy

The Malta Statistics Authority Act (Chapter 422, 2000) defines “confidential data” as “data obtained by the National Statistics Office for the production of official statistics when such data allow statistical units to be identified directly or indirectly, thereby disclosing individual information.

Further protection to confidentiality is provided by the Professional Secrecy Act (1994). This Act interprets Section 257 of the Criminal Code (Chapter 9) and defines persons covered by this Act, namely, persons who, by reason of their calling, profession or office, fall within the scope of section 257 of the Criminal Code. These include members of a profession regulated by the Medical and Kindred Professions Ordinance. In this context it is to be noted that scientists as such are not mentioned, although medical scientists are included in the Medical and Kindred professions Ordinance.

Further regulation of data transmission is available in the Malta Communications Authority Act (Chap 418, 2000), which defines “communications” to include telecommunications, postal services, data protection, electronic commerce, internet services, and such other matters as the Minister may by Order from time to time prescribe.

Chapter 399 of the Telecommunication (Regulation) Act (1997) prescribes measures to be taken by authorised providers for the purpose of ensuring the inviolability of the telecommunications transmitted and their confidentiality and the protection of privacy in relation to any telecommunications service including data protection measures and matters related to the use of information obtainable in the telecommunications sector for the purpose of direct marketing.

5.2 Transposition of article 8 of Directive 95/46/EC

As far as the processing of special categories of personal data, which the Data Protection Act describes as “Sensitive Personal Data”, is concerned, Art. 12 states that this shall not be processed except in particular cases or as may be prescribed by the Minister having regard to an important public interest. Sensitive personal data may be processed if the data subject:
(*a*) has given his explicit consent to processing; or
(*b*) has made the data public.

Sensitive personal data may be processed if appropriate safeguards are adopted and the processing is necessary in order that:
(*a*) the controller will be able to comply with his duties or exercise his rights under any law regulating the conditions of employment; or
(*b*) the vital interests of the data subject or of some other person will be able to be protected and the data subject is physically or legally incapable of giving his consent; or
(*c*) legal claims will be able to be established, exercised or defended.

Any body of persons or other entity not being a commercial body or entity, with political, philosophical, religious or trade union objects may, in the course of its legitimate activities and with appropriate guarantees, process sensitive personal data concerning the members of the entity and other persons have regular contact therewith, provided that sensitive personal data may be provided to a third party only if the data subject explicitly consents to this.

The Data Protection Act goes on to say that sensitive personal data may be processed for health and hospital care purposes, provided that it is necessary for:
(*a*) preventive medicine and the protection of public health;
(*b*) medical diagnosis;
(*c*) healthcare or treatment; or
(*d*) management of health and hospital care services,
provided that the data is processed by a health professional or other person subject to the obligation of professional secrecy. In this context, "health professional" means a person in possession of a warrant to exercise a profession regulated by the Medical and Kindred Professions Ordinance and any person acting under the personal direction and supervision of such person.

Sensitive personal data may be processed for research and statistics purposes, provided that the processing is necessary for the performance of an activity that is carried out in the public interest or in
the exercise of official authority vested in the controller or in a third party to whom the data is disclosed and as long as the processing referred to above has been approved:
(*a*) in the case of statistics, by the Commissioner himself;
(*b*) in the case of research, by the Commissioner on the advice of a research ethics committee of an institution recognised by the Commissioner

Data relating to offences, criminal convictions or security measures may only be processed under the control of a public authority. A complete register of criminal convictions may only be kept under the control of a public authority.

The identity card number may, in the absence of consent, only be processed when such processing is clearly justified having regard to:
(*a*) the purpose of the processing;
(*b*) the importance of a secure identification;
(*c*) some other valid reason as may be prescribed.

The following comments can be made with regard to art. 12 of the Maltese Data Protection Act:

- Given the lack of a definition of what health data constitutes generally refers to administrative and clinical hospital data including information concerning the past, present and future, physical or mental health of an individual and contained in a patient's file.
- Processing personal data concerning health is only lawful if it is done under the responsibility of a healthcare professional. The term "health professional" is also defined and refers to a broad spectrum of healthcare professions, including scientists and researchers.
- All persons who have access to the health-related data need to be subject to a legal or equivalent contractual duty of confidentiality with regard to the data concerned.

5.3 Information and access rights of data subjects

According to Article 21 of the Data Protection Act, upon a request in writing by the data subject to the data controller, the former has the right to be made aware of what kind of personal data is being processed. Moreover, the data subject has a right to know details relating to actual information about the data subject which is processed and the purpose for the latter; who has access to such information, where it is being collected, how it is being updated and what safeguards are in place to ensure its safe keeping with a view to prevent undue access to such data to third parties. This applies to both manual and electronic data.

The same applies to patients rights to information and to see their medical histories as will be seen later on in this report.

5.4 Other relevant rules regarding personal data protection

In Malta, the Data Protection Commissioner has drafted guidelines regarding the processing of personal data, particularly sensitive personal data. These guidelines have

been disseminated to all the relevant Maltese Government entities and other public bodies with a view to ensure that Data Protection principles are fully respected. Moreover, the data protection officers within each Government Department meet in a forum once a month with a view to discuss best practice, controversial or difficult data protection issues, etc. These principles will be regarded in further detail in section 6 of this report.

6 Rights and duties of healthcare providers and patients

The rights and duties of healthcare providers and patients are regulated in the array of health acts, namely,

- The Medical and Kindred Professions Ordinance, Chapter 31 of the Laws of Malta;
- The Health Care Professions Act, Chapter 464 of the Laws of Malta
- The Prevention of Disease Ordinance, Chapter 36 of the Laws of Malta
- The Notification of Cancer Act, Chapter 154 of the Laws of Malta
- The Medicines Act, Chapter 458 of the Laws of Malta
- Dept. of Health (Constitution) Ordinance, Chapter 94 of the Laws of Malta
- Etc, etc (including subsidiary legislation).

6.1 Scope of the law

The Maltese Acts identified above do not give a definition of "healthcare" or "patient" or "healthcare services" which gives the Maltese court very wide discretion as to what constitutes any of the three terms identified above and whether, for example, medical experiments are covered by the law's domain of application. On the contrary, the Health Care Professions Act describes a "health care professional" as a person who is authorised to practise a health care profession in accordance with the provisions of this Act. This includes professions complementary to medicine.

6.2 Duty of the patient to co-operate

The duty of the patient to co-operate is not specified by the law.

6.3 Right to quality care

The Health Care Professions Act states that the health care professional must act in accordance with "professional and ethical standards". These standards relate to the general conduct of a member of a health care profession, including the behaviour of such member towards his client or the patient under his care or being attended by him, during or consequential to the exercise of his profession, and the behaviour of such member towards other members of his profession and towards members of other health care professions and towards society.

6.4 Right to a free choice

The right to freely choose one's health professional and to change that choice, is not enshrined in Maltese legislation. Having said this, the "Patients' Charter of Rights and Responsibilities" issued by the Malta College of Family Doctors/St. Luke's Hospital refers to the right of a patient to "give or withhold consent to medical or other care and treatment". It also advises patients that they can "choose whether or not they wish to take part in research or student training."

6.5 Rights related to information about the state of health

One of the dilemmas that any practitioner attending a seriously sick/ terminally ill patient experiences is whether he should tell the patient all the truth about the seriousness of his illness or not. The doctor, as an expert, is expected to provide thorough information by explaining to the patient the diagnosis, the prognosis and the treatment options and this goes beyond giving out simple information. In this manner, the doctor is creating the basis of autonomy for the patient; the ability to make informed choices as finally the patient has a right to actively participate in the management of his health.

However, it appears that there are no **official** guidelines on the subject of truth telling. Having said this, the Patients' Charter of Rights and Responsibilities, which is provided to patients at all levels of care in both the public and private sectors states that the Patient has the right:

- To be fully and clearly informed of the services available at the Health Care centre/hospital/private clinic. This information is easily accessible to and presented in a way that is comprehensive, yet easy to understand;
- To a clear explanation on any proposed treatment, including any risks involved and any alternative forms of treatment to help make an informed decision;
- To have all records and information about oneself stored in a confidential manner;
- To have all questions about one's medical condition answered.

In exceptional cases, the health professional may withhold information about the patient's state of health if disclosure would cause grave harm to the patient.

6.6 Right to give consent

In accordance with the Patients' Charter of Rights and Responsibilities, identified above, the patient has the right to be asked to give **explicit** consent (in line with the DPA) prior to any form of treatment. The patient's consent should be given voluntarily following a clear explanation of the document that one is asked to sign. The patient also has a right to

know if the treatment being offered is experimental in nature or being used in research, and if so, the patient may refuse to participate in the medical research or experiment. The patient may also change his/her mind or refuse treatment at any time and be given an explanation of the possible consequences of not taking the advice of the health care professional. The patient also has a right to be given information about diagnostic tests and to have the results and implications explained prior to the decision-making.

In the case of young adults, the latter have a right to be consulted and to make decisions on their own behalf (once 16). In the case of minor, the persons holding parental authority have a right to decide. In the case of emergency, medical procedures are allowed to be carried out when one is unable to give consent if such treatment is of a life-saving nature.

6.7 Rights related to the patient’s medical record

Medical records are primarily kept so that a patient's condition can be documented and care planned accordingly. Accurate and complete information is vital to ensure that patients receive appropriate treatment. The proper retention of records is becoming increasingly important in view of the shift towards a multidisciplinary health care system where different health professionals might be involved in the treatment of a single patient. Within such a system, it is evident that a complete set of records must be available to be handed over to each successive professional to ensure a seamless treatment plan.

Although it would seem that records are to be kept solely for patients' benefit, this is not really the case. They may constitute evidence that is essential for a physician's defence in the course of a malpractice suit. Records will show that a physician has in fact carried out requisite examinations and prescribed medicinals on specific dates - all details that may prove to be pertinent in the course of litigation.

In the light of the above, it would be in order to see what the situation obtaining in Malta is when it comes to the drawing up of medical records, and whether a patient's right of access to his/her medical records is adequately safeguarded. It would seem that there are no statutory guidelines as to the type or extent of information, which a physician is to keep about the patients under his care. This is left to his discretion.

While the taking of copious notes is obviously impractical for those practitioners who examine a large number of patients suffering from minor ailments daily, very scant notes or a failure to record any details of the symptoms described by patients might lead to a

situation where vital details are missed by successive doctors, with disastrous results for the patient. Statutory guidelines soon to be issued by the relevant professional body - the Medical Council - lay down the minimum amount of information that should be taken down by physicians, ensuring a safer scenario for all.

The patient has a recognized right to a medical file, which is carefully updated and safely stored by the health professional. A file is opened for each patient and very health professional should keep a medical record about every patient to whom he provides healthcare services. This file should contain the medical history of the patient to date. What is interesting to note is that up to relatively recent times, the file featured the words "***Not to be handled by the patient".*** This is no longer the practice as the patient now has the recognized right to access what information is actually held about him/her and to see his/her medical history. Indeed, while the actual medical chart is the property of the physician who compiled it, the information contained in the chart is the property of the patient. So a patient has every right to request his medical records

The **standardized** forms to be catalogued in the medical record are given a form number which also includes information about the data controller, the name of the Hospital and the Department within the hospital. There is a DP statement on each form and a DP policy is illustrated in a short information sheet.

The movement of files has been reorganized in Maltese healthcare units to ensure it is carried out in a more secure manner. Indeed, all the movement of forms takes place in sealed envelopes. Forms are only handled by appropriate professional officers and are to be inserted in patient's file as early as possible to avoid misplacement. The public health file storage storage facilities have also been recently revamped to enhance security.

Patients' records are also kept in soft format in a patients' administration system which records appointments and other brief medical records. A retention policy has also been established with regards to public health. Once a person dies, his/her clinical records are moved to an off-site archive immediately after death. These records are destroyed 10 years after death. Indeed the policy relating to the storage and handling of medical records is in line with the guidelines of storing and handling sensitive data under the DPA. The patient has been empowered with rights and responsibilities. His/her right to respect to human dignity is recognized. Moreover, the patient also has a right to receive spiritual and moral assistance in accordance with his/her religious beliefs.

Malta's eHealth Strategy has as one of its objectives the setting up of an electronic archive of a patients' records and/or references to their nature and location. This is called the Electronic Medical Record (EMR). The system is envisaged to make will make all clinical information related to a patient available electronically at every point of care

through intranet or secure Internet access and will enable public health care providers to share patient medical information.

The EMR should contain only patient health care information, which needs to be shared internally or externally throughout the hospital (Health Centres, GPs) and between different medical staff. This shared information should help to promote inter-disciplinary and outcome-focused care and also enable medical staff to make better-informed clinical decisions. The EMR should enable easier tracking of a patient's medical history. It should provide a more holistic view of the patient's data, thereby making the record a more meaningful and complete resource. Data sharing is fundamental to the concept of EMR but this should be in line with a number of formally established security and confidentiality policies.

The EMR will be accessed by multiple users and at various physical locations within and outside the public health care network boundary (e.g. GPs outside the hospital should be able to access EMR to provide continuity of care once the patient is discharged from hospital; a patient should be able to access his medical record up to authorised levels; researchers should be able to access population data to contribute to medical knowledge). Having said this, the strategy does not give a reference target date for when this objective will materialise.

6.8 Right to protection of privacy and intimacy

In Malta, patients have the right to the protection of their privacy in any medical service, particularly in relation to the information about their health. They have also a right to the protection of their intimacy. All personal data is kept confidential. The patients' privacy is protected when discussing medical conditions. No other persons than those whose presence is required for the delivery of medical services shall be allowed to assist in the provision of care, without the patient's consent. Moreover, the patient is entitled to expect that all personal details and records pertaining to the patients' care are treated as confidential.

There are exceptions to this right of privacy in the case where the disclosure to the police procedure is an obligation by law. The health care professional is obliged to inform the police of any patient admitted to emergency units following an accident or a criminal act. The information relating to the patient's condition is exclusively given to the identified Police Inspectors or authorised police officers and only minimum information of the patient's condition and the incident are given. This can only take place upon a request in writing. A record is also kept of the information given to the police and by whom. The police have a right to investigate further if so required.

Moreover, the health professional also has a right to use the information regarding a patient in his/her care if this is required in the interest of public health, in cases of:

- Cancer (Notification of Cancer Act – 1957);
- Mortality;
- Congenital Anomalies;
- Obstetrics;
- Organ transplants.

6.9 Right to representation in case of incompetence

The law contains rules to protect the rights of patients who are legally or factually not capable of exercising their rights as a patient. In the case of minor patients, the patient rights are exercised by the parents who have parental authority over the minor or by the patient's guardians. The minor patient will be involved in exercising his rights, bearing in mind his age and level of maturity, as identified above. Minor patients who are deemed capable of understanding their medical situation may exercise their own rights. A similar case arises in relation to mentally disabled patients and the same conditions apply in this case.

7 Identity management in the health sector

7.1 Overview - The Identity Card as the patient identifier

When patients present themselves to health care units, they are obliged to take with them any documents they may need for the purpose of identification. For example, one's ID card or passport. Other documents such as the Pink or Schedule V Cards would be required if he/she would like to collect free medicines. One should also present prescriptions, referral tickets, etc. Moreover, the presentation of special ID cards may entitle one to certain privileges (such as Kartanzjan +75; Care Workers; People with Special Needs).

With regards to personal identification, Malta has been one of the forerunners of personal identity management, having taken a very important step when Government introduced the Identity Card in 1975. The importance of this step is mostly because it brought about the creation of what is known as the ID Card number, a unique reference for each individual permanently residing in Malta. Since then, this unique reference has been responsibly but extensively used in all Government business processes and even in the private sector.

In 2004, the then Ministry for Investment, Industry and Information Technology (MIIIT) started issuing the electronic identity (e-ID), based on the internationally recognised four-tier security model. It has so far implemented and launched up to the second level consisting of a soft PKI digital certificate, and is in the process of completing the implementation of the third level which will consist of a Smart ID Card. Strategic target 4.24 of the National ICT Strategy (2008-2010)[8] states that:

> *Through the investment we are making in our integrated health information systems and the Smart ID Card, we will partner with private health care providers and general practitioners to provide patients with the benefit of a portable clinical health record offering access to patient data from multiple points.*

Malta's propitious situation, where every permanent resident has a unique ID Card number, offers the required opportunity to move in the direction of a harmonised electronic register as described in the Strategic target 5.9 of the National ICT Strategy (2008-2010):

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[8] The National ICT Strategy (2008-2010) website is at http://www.thesmartisland.gov.mt

> *All the current identity handling databases will be drawn together into a single **national identity management system** serving all public and private sector requirements for physical and virtual identity registration, authentication and verification.*

From a ***health perspective,*** it will enable Government to deliver on its promise of electronic health records which, with the patient's consent, may be used across hospitals and clinics without borders; it will also set the right environment for the collection of prescriptions from local pharmacies (a project known as Pharmacy of Your Choice, launched in 2008, and which is currently in a pilot stage).

The electronic components of the e-ID Card, in fact, may absorb the function of other health-related identity documents currently being issued. These include but may not be limited to the *Kartanzjan* (the elderly person's card) and the European Health Insurance Card (EHIC).

7.2 Special Identity Cards for Persons with Disability and the EHIC

Irrespective of gender and age, any person with a disability, as defined by the Social Security Act 1987, may be entitled to the Special Identity Card, which offers a myriad of privileges including free transport service to hospital and back, priority service in hospitals and health and community care clinics,

The European Health Insurance Card is another essential tool for people from other Member States requiring health care treatment during their sojourn in Malta. Furthermore, it guarantees a quick and simplified reimbursement of expenses incurred locally or shortly after return to the place of residence. Since 1 January 2006, the European Health Insurance Card is issued and recognised by all concerned countries and replaces the previously used paper forms, such as the well-known E 111.

While the main purpose of the European Health Insurance Card is to ensure easy access to health services during a temporary stay in another country, it also provides a series of additional benefits, for healthcare providers, patients and insurers alike. The main advantages of the EHIC may be summarised as follows:

- facilitated access to foreigners from other EU Member States to healthcare in Malta;
- quick and easy reimbursement of expenses;
- security of data;
- improved reliability;

- less administration;
- simplicity: simpler and faster procedures for obtaining healthcare.

Generally speaking, the ‘smart card’ used contains only basic information such as the card holder’s personal identification number, name and surname and date of birth, but no medical details. It is simple to use and easily recognisable. Further, the information is presented in a standardised way, so that it could be read regardless of the language.

7.3 Authentication of healthcare professionals

Medical practitioners are the fulcrum of every medical activity. They are tools by which Government can provide proper care for its citizens. For this reason, it is important that only duly qualified and competent health care professionals be given the right to exercise their profession. Health care professionals are registered.

Four statutory bodies regulate the health care professions in accordance with the Health Care Professions Act, and are responsible to maintain ***registers of health care professionals***. These are:

- the Medical Council (comprising doctors and dentists);
- the Pharmacy Council (responsible for pharmacists and pharmacy technicians);
- the Council for Midwives and Nurses; and
- the Council for Professions Complementary to Medicine.

The Act also provides for Specialist Accreditation Committees that have the tasks, inter alia, of issuing certificates of completion of specialist training in the various specialities enshrined in the law; to advise the Minister and the relevant Council on issues concerning specialist training and registration, and any other matter that may be referred to it; to act

as the advisory body for training in any of the special areas of practice; to accredit post-graduate training programmes;

According to the Health Care Professions Act of 2003, no person shall practice a health care profession unless he fulfils the conditions for the taking up and pursuit of that health care profession in Malta. A person shall only be entitled to use a ***professional title*** if he fulfils the conditions set by the relevant Council. The titles include those of: medical practitioner, dental surgeon, midwife, nurse, pharmacy technician and that of pharmacist. Malta recognizes qualifications issued by other EU member states as long as the conditions enshrined in Part VIII of the Act are met.

In addition to the statutory bodies, health professionals are organized in professional associations on a voluntary basis. The Medical Association of Malta (representing doctors) and the Malta Union of Midwives and Nurses also play the role of trade unions. The Medical Association of Malta has acted as a coordinating body for the medical specialist associations that have emerged in recent years.

All health care professionals are accountable to their respective statutory regulatory bodies for their professional actions. Health professionals employed in the public sector are subject to the rules and regulations of the Public Service Management Code, covering the conditions of recruitment, employment and disciplinary mechanisms for civil servants. All promotions and calls for job applications are controlled by a central body, the Public Service Commission, in line with the Maltese constitution.

Government offers a number of ***online services, through the eHealth Portal***, which are only accessible by Medical Practitioners. Users are authorised on the basis of whether or not they are on the appropriate register of healthcare professionals. Access to these restricted sections is then available to the Medical Practitioner through his/her e-ID.

8 Electronic prescription

No specific legal framework exists for electronic prescriptions. Moreover, whereas the eHealth Strategy speaks of the objective of replacing at least 50 percent of paper communications taking place and 25 percent of paper communications leaving the public healthcare sector by electronic communications, there is no indication that this also includes electronic prescriptions. The eHealth Strategy does not even make mention of any barriers in relation to electronic prescriptions. It omits the subject completely in relation to the Maltese context. Therefore, no further information can be given in this regard.

9 General assessment

During the course of drafting this report, one could clearly recognise that the Government of Malta is committed to developing eHealth systems and services. In various respects, Malta could be considered as having front-runner status in the quality of healthcare delivery, which has been repeatedly recognised by the WHO. Consequently, it is pursuing its commitments to continue enhancing its Health Service through the new opportunities being created by ICT. Malta also seems to be cognizant of the rapid development of the eHealth sector taking place within the European Union in the wider context of the implementation of the Lisbon strategy, and wants to be a full participant in this development.

Having said this, the regulatory framework is not yet ready for a full implementation of eHealth projects such as electronic prescriptions, telemedicine etc. This is primarily because most of the legislation drafted in connection with the Health Care Professions was drafted before the Data Protection Act, the eCommunications and eCommerce Acts and hence, one has to rely on guidance documents rather than a concrete legal framework with a view to modernise and introduce technological development in health care processes.

One important step towards modernisation has been the setting up of the eHealth Portal, which serves as the main communication interface between the citizens, health professionals and the Health Service and provides a range of services from the purely informational to the fully transactional. Moreover, the IHIS should facilitate and improve the interaction between healthcare processes, healthcare delivery units, and different healthcare providers. The main applications, the first phase of which was completed on 18th April 2008 includes the six IHIS applications: the Laboratory Information System (LIS), Radiology Information System (RIS), Picture Archiving and Communication System (PACS), Patient Master Index (PMI), Electronic Medical Records (EMR) and Order Management and Fulfilment (OMF).

The completion of the eHealth strategy and its gradual implementation, based on the vision of improved communication between citizens and healthcare providers, will lead to better governance and improved health and quality of life for the citizens of Malta.

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