Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services

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Overview of the national laws on electronic health records in the EU Member States

National Report for Portugal

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Executive Summary

1. Stage of development of EHRs in Portugal

One of the objectives in the area of public health included in the Programme of the XVIII Constitutional Government was to ensure that, by the end of 2012, all Portuguese would have an electronic health record (EHR). In May 2012, as the result of the work carried out by a series of specialised working bodies specifically created for this purpose, the National Platform for Health Data was finally launched in Portugal.

This platform consists of two different portals connected to the National Health Service – one for health professionals and other for the patients. The Health Professionals' Portal provides access to three different types of information, including to the RCU2, the Portuguese Single Clinical Summary, which compiles the most relevant data from other electronic health records (EHRs) which is identified by the patient's physician as essential information to be provided to health professionals for the provision of health services. The Patient's Portal allows these to register their health data (including e.g. height, weight, blood glucose, blood pressure, cholesterol). The user needs to authorize the access to his data and has the possibility to consult the historic of accesses. Since July 2013, users of this portal have also access to some of the information included in their own RCU2.

It should be noted that the information included in this report on the functioning of the Platform for Health Data and in particular of the RCU2 is based solely on desk research, especially on the decision of the National Commission for Data Protection which authorized the establishment of the Platform for Health Data and the creation of the RCU2 in 2012. Despite several attempts, it was not possible to contact the Shared Services of the Ministry of Health in order to confirm whether this is information still reflects accurately how the Platform for Health Data and the RCU2 currently operate.

2. Summary of legal requirements applying to EHRs

There are no specific laws governing EHRs in Portugal and as result the general legislation on data protection, and in particular on health data, is applicable. The Portuguese Data Protection Law dates from 1998 and results from the transposition of Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. In 2005, the Portuguese Parliament adopted the Personal Genetics and Health Data Law. This law, which focuses mainly in personal genetics data as a particular sensitive part of health data, defines some important concept and sets the general principles for the processing of health data.

There is no express definition of EHR in Portuguese legislation, however, the definition of health record contained in the Personal Genetics and Health Information Law covers also records in "electronic format" i.e. health records are defined independently of their format. There are also no legal provisions defining exactly what the content of an EHR should be i.e. what must and must not be covered, in particular there are no legal rules defining the scope of information covered by the RCU2. Notwithstanding, an Order of the Cabinet of the Secretary of State of Health sets the minimum requirements to be included in the (internal) health records of the institutions part of the National Health Service.

There is no specific authorisation or license to host and process data from EHRs, but in accordance with the Data Protection Law, the processing of health data must be notified to the National Commission for Data Protection. By decision of 30 April 2012, the National Commission for Data Protection authorized the establishment of the Platform for Health Data and the creation of the RCU2.

The RCU2 is created independently of the consent of the patient. According to the National Commission of Data Protection, this situation falls under the scope of Article 7(4) of the Data

Protection Law which allows for the processing of data when necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services. There are no specific rules on consent from the patient to share EHRs but under the general data protection rules applicable, the patient would have the right to oppose to the processing of the data in certain circumstances. In practice, the patient has to authorise the sharing of data from his RCU2 - the RCU2 is by default accessible to health professionals unless the patient expresses his opposition through the options available in the Patient's Portal.

Even though, there are no specific national rules on consent from the patient to EHRs being accessed by a health practitioner or health institution outside of the Member State, one of the options available in the Patient's Portal concerns the authorisation for the sharing of data from the RCU2 with "foreigner professionals (adherent to the epSOS project)".

In accordance with the Personal Genetics and Health Information Law, data must be registered in the health record by the physician who has provided care to the data subject or, under his supervision, by other professional also subject to professional secret. Also according to the same law, health records can only be accessed by the physician in charge of providing medical care to the data subject or, under his supervision, by other health professionals obliged to professional secret.

Pursuant to the Data Protection Law, the data subject has the right to the rectification, erasure or blockage of the data which were not processed in accordance with the law. In general, however, patients cannot update, modify or erase the content of the RCU2. On the contrary, they can update, modify and erase the information available in the Patient's Portal that the patients themselves have registered.

The national legislation does not set specific medical liability rules related to the use of EHRs and therefore the general medical liability rules would apply. These are based on the relevant provisions of the Medical Deontological Code and the provisions on general civil liability set out in the Civil Code. The rules set out in the Criminal Code on medical-surgical procedures and treatments are also relevant.

The general rule on the secondary use of health data allows access to health data for research purposes as long as this information is anonymized. The National Commission on Data Protection authorized the archiving of the data included in the Platform for Health Data for a period of six months after the death of the data subject

The only requirement on interoperability of EHRs identified comes from an order of the Cabinet of the Secretary of State of Health, which prescribes that certain medical notes (within the National Health Service) must be recorded in electronic format in order to be available to health professionals through the Platform of Health Data. These are then used to feed the RCU2.

The EHR system and the e-Prescription are independent from each other and at different stages of development. If on one hand, the existence of EHRs is not a precondition for the ePrescription system, on the other hand access to ePrescriptions does not imply access to EHRs.

3. Good practices and legal barriers

Despite several attempts, it was not possible to contact the Shared Services of the Ministry of Health, the National Commission for Data Protection or the Portuguese Medical Association in order to include their views on the current state of affairs and identify potential good practices and legal barriers for the development of the EHR system in Portugal. In any case, among the positive aspects, the fact that the transmission of data within the Platform for Health Data is encrypted and made though a closed network should be highlighted. One of the negative aspects identified is the lack of specific legislation, in particular in what relates to liability.

Contents

List of abbreviations

EHRs	Electronic Health Records
GP	General Practitioner (*Medico de Família*)
SPMS	Shared Services of the Ministry of Health
RCU2	Portuguese Single Clinical Summary

1. General context

1.1. EHR systems in place

One of the objectives in the area of public health included in the Programme of the XVIII Constitutional Government was "*to ensure that, by the end of 2012, all Portuguese have an electronic health record"*.[1] Therefore, in April 2009, the Ministry of Health created a Working Group for Electronic Health Records to define goals and policies in this field, in line with the initiatives at EU level, and present a report which should be the base for the implementation of a Portuguese EHR.[2] Drawing on the conclusions of the report presented by the Working Group for Electronic Health Records, the Central Administration of the National Health System (*Administração do Sistema de Saúde*) presented in February 2010 an operational plan for the implementation of EHRs in Portugal.[3] This plan identified the actions to be implemented in 2010-2012, the objectives to achieve, and the governance model adopted, suggesting in addition the establishment of a National Commission for Electronic Health Records (*Comissão Nacional para o Registo de Saúde Electrónico*).

The National Commission for Electronic Health Records was created in early 2011,[4] but replaced little after by the Commission on Clinical Information Technology (*Comissão para a Informatização Clinica*),[5] functioning under the direct supervision of the Secretary of State for Health. The Commission on Clinical Information Technology was assigned with the specific goal of implementing a Platform for Health Data (*Plataforma de Dados de Saúde*)[6] and creating a Single Clinical Summary for the beneficiaries of the National Health System – RCU2 (*Resumo Clinico Único do Utente - RCU2*).[7] Once the Platform for Health Data and the RCU2 were launched the Commission on Clinical Information Technology was replaced by the Monitoring Commission on Clinical Information Technology (*CAIC – Comissão de Acompanhamento da Informatização Clinica*).[8] It should be noted that the information included in this report on the functioning of the Platform for Health Data and in particular of the RCU2 is based solely on desk research, especially on the decision of the National Commission for Data Protection which authorized the establishment of the Platform for Health Data and the creation of the RCU2 (for more details please see below). Despite several attempts, it was not possible to contact the Shared Services of the Ministry of Health in order to confirm whether this is information still reflects accurately how the Platform for Health Data and the RCU2 currently operate.

The National Platform for Health Data was launched in May 2012 and consists of two different portals – one for health professionals working in the National Health Service (*Portal do Profissional de Saúde*, here and after referred to as Health Professionals' Portal) and other for the beneficiaries of the National Health System (*Portal do Utente*, here an after referred to as Patient's Portal). The idea is that, progressively, the Platform is also connected to health providers not part of the National Health Service.

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[1] Programa do XVIII Governo Constitucional (2009), p. 78, available in Portuguese at http://www.portugal.gov.pt/media/468569/gc18.pdf

[2] Despacho n. 10864/2009 do Gabinete do Secretário de Estado de Saúde, de 28 de Abril, available in Portuguese at http://www.acss.min-saude.pt/Portals/0/Despacho_10864.2009_Grupo_RCE.pdf

[3] RSE – Registo de Saúde Electrónico - Plano de Operacionalização, Administração Central do Sistema de Saúde, 19 February 2010, available in Portuguese at http://www.portaldasaude.pt/NR/rdonlyres/7C590A0B-1758-4659-A699-73F70100633D/0/RSE_PO.pdf

[4] Despacho n. 381/2011dos Ministérios das Finanças e da Administração Pública e da Saúde, de 15 Dezembro 2010, available in Portuguese at http://dre.pt/pdf2sdip/2011/01/005000000/0087100872.pdf

[5] Despacho n. 16519/2011 do Gabinete do Secretário de Estado de Saúde, de 25 de Novembro, available in Portuguese at http://www.portaldasaude.pt/NR/rdonlyres/F65AC9F5-501D-479D-BD09-61E2D3A716E0/0/4766947669.pdf

[6] More information available at https://servicos.min-saude.pt/utente/portal/paginas/default.aspx

[7] Despacho n. 8742/2012 do Gabinete do Secretário de Estado de Saúde, de 22 de Junho, available in Portuguese at http://www.portaldasaude.pt/NR/rdonlyres/F79816D9-0E59-4681-B647-34FDCCA581F1/0/2305423054.pdf

[8] Despacho n. 9725 do Gabinete do Secretário de Estado de Saúde, de 11 de Julho, available in Portuguese at http://spms.min-saude.pt/wp-content/uploads/2013/10/Despacho-9725_2013-cria%C3%A7%C3%A3o-da-CIAC-no-%C3%A2mbito-da-SPMS.pdf

The Health Professionals' Portal provides access to three different types of information. It provides access to some of the health data recorded in the "internal" EHR of a particular health institution (*Processo Clinico Electrónico – PCE*) – this information is not editable and summarizes the clinical episodes that a patient had in that institution. It also provides access to the Information Notes on Health (*Notas de Informação de Saúde*), which consist of a timeline with the clinical episodes of the patient, mostly administrative information. Finally, the Health Professionals' Portal provides access to the RCU2, which compiles the most relevant data from the other EHRs which is identified by the patient's GP as essential information to be provided to health professionals for the provision of health services. The RCU2 is updated automatically for "very relevant episodes" like clinical alerts, allergies, chronic medication and vaccines, and by the patient's GP, under proposal of any physician that has provided healthcare to the patient, for all other information deemed "relevant".

The Patient's Portal allows these beneficiaries to register their health data (including e.g. height, weight, blood glucose, blood pressure, cholesterol). It is also possible to schedule medical appointments with the providers of primary health care in the National Health Service or consult the waiting lists for surgery. In order to register in the platform, the authentication of the user is required, namely through his electronic ID. By January 2014, more than 1 million users had already registered in the Patient's Portal.[9] The user needs to authorize the access to his data and has the possibility to consult the historic of accesses; it is also possible to access, rectify, update or erase the data registered by the user at any time. Since July 2013, users of this portal have also access to some of the information included in their own RCU2.

A wide range of EHRs are held in Portugal by health professionals and institutions, they are however not designed for a shared access and are therefore not detailed in this study. It was considered that the RCU2, as the first step towards a single EHR, should be the main focus of analysis.

1.2. Institutional setting

The main institutions involved in the development and deployment of EHRs in Portugal are the following:

- The Ministry of Health (*Ministério da Saúde*)[10]

The Ministry of Health ensures the development, execution, monitoring and evaluation of the national health policies. In particular, with regards to the National Health System, it is competent for regulation, planning, financing, direction, monitoring, evaluation, auditory and inspection. The Ministry of Health is thus responsible for the supervision of the implementation of the Platform for Health Data and the RCU2, in particular through the Shared Services of the Ministry of Health (SPMS).

- The Shared Services of the Ministry of Health (*SPMS - Serviços Partilhados do Ministério da Saúde, EPE*)[11]

The Shared Services of the Ministry of Health (SPMS) are the public corporation with the competence to ensure the provision of shared services to the entities integrates in the National Health System with regards to acquisitions, logistics, financial management, human resources and IT. The creation of the SPMS was decided by the Council of Ministers of 17 December 2009 and its bylaws are set out in Decree-Law 19/2010. By Order of the Cabinet of the Secretary of State for Health of 11 July 2013[12], the Monitoring Commission on Clinical Information Technology (*CAIC – Comissão de*

[9] Jornal Saúde Noticias n. 17 (January 2014), p. 2, available in Portuguese at http://www.saudenoticias.pt/pdf/jornal_jan2014.pdf
[10] More information available at http://www.min-saude.pt/portal
[11] More information available at http://spms.min-saude.pt/english-version/
[12] See above note 8.

Acompanhamento da Informatização Clinica) was created within the SPMS with the purpose to collaborate in the presentation of proposal for the strategy of clinical informatization of the National Health Service and to monitor their implementation.

- The National Commission for Data Protection (*Comissão Nacional de Proteção de Dados*)[13]

The National Commission for Data Protection is the Portuguese independent administrative authority in charge of monitoring and controlling the processing of personal data, ensuring the compliance with the human rights, the freedoms and guarantees established in the Portuguese Constitution and the law. The National Commission for Data Protection issues prior opinions on legislation in the field of data protection. It also exercises powers of investigation and inquiry and can order the blocking, erasure and destruction of data as well as prohibit temporary or ban definitively the processing of personal data. By decision of 30 April 2012 (Authorization 3742/2012)[14], the National Commission for Data Protection authorized the establishment of the Platform for Health Data and the creation of the RCU2.

1.3. Legal setting and future legal developments

There are no specific laws governing EHRs in Portugal and as result the general legislation on data protection, and in particular on health data, is applicable. The Portuguese Data Protection Law dates from 1998 and results from the transposition of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. This law, like Directive 95/46/EC, provides explicitly for the possibility of processing health data if certain circumstances are met. Its provisions on consent, right to information, right to access and others are also relevant for the scope of this study.

In 2005, the Portuguese Parliament adopted the Personal Genetics and Health Data Law.[15] This law, which focuses mainly in personal genetics data as a particular sensitive part of health data, defines some important concept and sets the general principles for the processing of health data. Although it does not contain a definition of EHR, it defines in general terms "health data" and, more important, "health record" which in accordance to its Article 5(2) can have an electronic format. Also relevant are the provisions on the creation and/or update of health records, as well on access and the use of health data for research purposes. Pursuant to Article 22 of the Personal Genetics and Health Data Law, this law should have been developed by the Government within 180 days of its publication, but this is yet to happen (it should be noted however that under paragraph 2 of the same provision, the developing legislation should focus mainly on personal genetics data).

Only very recently eHealth and EHRs became a priority in the field of public health policies in Portugal. While the previous Government set in its programme the objective for each Portuguese to have an EHR by 2012, the current Government set the goal to have a single EHR by 2016 in the National Health Plan 2012-2016.[16] According to this document, the single EHR record should be *"shared by public and private providers and offers information for citizens about their medical condition, including urgency episodes."* In addition, it should be integrated in an *"interface with the citizen, being an instrument of communication, literacy, self-management support and empowerment"*. It should also motivate health professional to *"feel the need to maintain properly documented and updated their records, since these are shared with the citizen himself, for adequacy and performance statistics of the professional and the institution, to and support clinical research."*.

[13] More information available at http://www.cnpd.pt/english/index_en.htm

[14] Autorização n. 3742/2012 da Comissão Nacional de Protecção de Dados de 30 Abril, available in Portuguese at http://www.cnpd.pt/bin/decisoes/Aut/10_3742_2012.pdf

[15] Lei n. 12/2005 de 26 de Janeiro, Informação genética pessoal e informação de saúde, available in Portuguese at http://www.cnpd.pt/bin/legis/nacional/Lei12-2005.pdf

[16] Plano Nacional de Saúde 2012-2016, Direcção-Geral da Saúde (January 2012), available in English at http://pns.dgs.pt/nhp-in-english/

In order to achieve these ambitious objective and benefiting also from the experience gained with the Portuguese participation in epSOS-Smart Open Services for European Patients[17], a large scale pilot project funded by the EU, the Ministry of Health launched the Platform for Health Data and created the RCU2. Up to this date, the only legal basis for these (pilot) projects is the Authorization 3742/2012 given by the National Commission for Data Protection pursuant to Articles 27(1), 28 and 30(2) of the Data Protection Law.[18]

With the purpose of "*ensuring the increasing of the quality and quantity of the information related to health records, available in electronic format in the National Health Service"*, an Order of the Cabinet of the Secretary of State for Health from 2013,[19] obliged the institutions integrated in the National Health Service to keep electronic records (internally) of the medical discharge notes and laboratory exams, in order for these to be accessible to health professionals through the Platform for Heath Data. Although, the list of requirements to include in these notes is quite extensive, only some of them are used to feed the RCU2.

List of relevant national legislation:

- Personal Genetics and Health Data Law (*Informação genética pessoal e informação de saúde*)[20]
  Law 12/2005 of 26 January, defining the concepts of health data and genetics data, the flow of information and the intervention on the human genome in the health system, as well as rules for harvest and conservation of biological products for the purpose of genetic testing or research.
- Data Protection Law (*Lei de Proteção de Dados Pessoais*)[21]
  Law 67/98 of 26 October, rectified by Declaration 22/98 of 28 November, on the protection of individuals in relation to the processing of personal data and the free movement of those data, transposing into Portuguese law Directive 95/46/EC.
- Order 2784/2013 of the Cabinet of the Secretary of State of Health *(Despacho n. 2784/2013 do Gabinete do Secretario de Estado da Saúde)*[22]
  Order 2784/2013 of the Cabinet of the Secretary of State of Health of 11 February lays down the minimum requirements to be included in the health records, available in electronic format in the National Health Service relating to the notes of medical discharge as well as the notes relating to the transfer from intensive care units.
- Medical Deontological Code *(Código Deontológico da Ordem dos Médicos)*[23]
  The current version of the Medical Deontological Code was adopted on 26 September 2008 by the Medical Association. The Medical Deontological Code sets out the ethical rules that the physician should observe and which should guide his professional practice.
- Civil Code (*Código Civil*)[24]
  Decree-Law 47344/66 of 25 November, last amended by Law 23/2013 of 5 of March. The Civil Code includes provisions on the general rules on civil liability which are applicable to EHRs.

[17] More information available at http://www.epsos.eu/
[18] Lei n. 67/98 de 26 de Outubro, Lei da Protecção de Dados Pessoais (transpõe para a ordem jurídica portuguesa a Directiva n. 95/46/CE, do Parlamento Europeu e do Conselho, de 24 de Outubro de 1995, relativa à protecção
das pessoas singulares no que diz respeito ao tratamento dos dados pessoais e à livre circulação desses dados), available in Portuguese at http://dre.pt/pdf1sdip/1998/10/247A00/55365546.pdf
[19] Despacho n. 2784/2013 do Gabinete do Secretário de Estado de Saúde, de 11 de Fevereiro, available in Portuguese http://dre.pt/pdf2sdip/2013/02/036000000/0690806909.pdf
[20] See above note 15.
[21] See above note 18.
[22] See above note 19.
[23] Código Deontológico da Ordem dos Médicos, Ordem dos Médicos (26 Setembro 2008), available in English https://www.ordemdosmedicos.pt/?lop=conteudo&op=9c838d2e45b2ad1094d42f4ef36764f6&id=84c6494d30851c63a55cdb8cb047fadd
[24] Código Civil (1966) available in Portuguese at http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=775&tabela=leis&ficha=1&pagina=1

- Criminal Code (Código Penal)[25]
  Decree-Law 48/95 of 15 March, last amended by Law 60/2013 of 23 August. The Criminal Code set rules on medical-surgical procedures and treatments which are relevant for the purpose of this study.
- Authorization 3742/2012[26]
  This authorization by the National Commission for Data Protection allowed for the sharing of information between the institutions providing healthcare in the National Health System through the Platform for Health Data.

[25] Código Penal (1995) available in Portuguese at http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=109&tabela=leis
[26] See above note 14.

2. Legal requirements applying to EHRs in Portugal

2.1. Health data to be included in EHRs

2.1.1. Main findings

There is no express definition of EHR in Portuguese legislation, however, the definition of health record contained in Articles 5(2) and (3) of the Personal Genetics and Health Information Law covers also records in "electronic format" i.e. health records are defined independently of their format.

There are also no legal provisions defining exactly what the content of an EHR should be i.e. what must and must not be covered, in particular there are no legal rules defining the scope of information covered by the RCU2. Notwithstanding, by Order of the Cabinet of the Secretary of State of Health, since 1 July 2013, the notes of medical discharge as well as the notes relating to the transfer from intensive care units in the National Health Service need to be recorded in electronic format in order to be available to health professionals through the Platform of Health Data. This order also lays down the minimum requirements to be included in the (internal) health records of the institutions part of the National Health Service. These include diagnostic, reason for hospitalization, indication of the therapeutic used, description of care needed after discharge record of known allergies, etc. Some of this information is then used to feed the RCU2.

2.1.2. Table on health data

Questions	Legal reference	Detailed description
Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)	Data Protection Law, Art. 5(1)(c)	Article 5(1)(c) of the Data Protection Law, which transposed Article 6(1)(c) of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995, set the general principle governing the content of personal data stating that the personal data must be adequate, pertinent and not excessive in relation to the purposes for which they are collected and further processed.
	Order 2784/2013, Art. 1	Within this context, Order 2784/2013 of the Cabinet of the Secretary of State of Health lays down the minimum requirements to be included in (internal) health records, available in electronic format in the National Health Service relating to the notes of medical discharge as well as the notes relating to the transfer from intensive care units. The Order also prescribes that from 1 July 2013 onwards these notes must be recorded in electronic format in order to be available to health professionals through the Platform of Health Data. The minimum requirements cover: - name, birthdate, gender, nationality and habitual residence - date of admission, date of medical discharge - number of beneficiary of the National Health Service - name of the physician in charge, number of his professional license and professional email - destination (death, other hospital, home, etc.) - diagnostic from the catalogue ICD10 (International Classification of Diseases) in use in the Information System of Death Certificates, in case of death - reason for hospitalization - summarized description of the hospitalization - indication of the therapeutic used - description of the care needed after discharge, including the medicines prescribed - indication of whether mechanical ventilation or any other invasive techniques were used

Questions	Legal reference	Detailed description
		- record of know allergies - focus of attention, diagnoses and nursing interventions in ICPN (International Classification for Nursing Practice) language - list of medical diagnoses described in a way which is understandable for the patient followed by the relevant ICD9 (International Classification of Diseases) code or by the relevant code from the Diagnostic and Statistical Manual of Mental Disorders of the World Health Organisation - list of medical or surgical procedure described in a way which is understandable for the patient followed by the relevant ICD9 (International Classification of Diseases) code - mention of the existence of one or more implantable devices with reference to the code of the National Authority of Medicines and Health Products (INFARMED – Autoridade Nacional do Medicamento e Produtos de Saude) - mention of any support products which were prescribed during the hospitalization in accordance with the list of the National Institute of Rehabilitation (INR – Instituto Nacional de Reabilitacao) - indication of the gravity and risk for admission and transfer to and from Intensive Care Units
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?	Order 2784/2013, Art. 1	The information to be included in the "health records, available in electronic format in the National Health Service" pursuant to Order 2784/2013 of the Cabinet of the Secretary of Health is restricted to general information about the identity of the patient and medical information.
Is there a definition of EHR or patient's summary provided in the national legislation?	Personal Genetics and Health Information Law, Art. 5(2) and (3)	There is no definition of EHR in national legislation. However, Articles 5(2) and (3) of the Personal Genetics and Health Information Law define "health record". Health record means any record, in electronic format or not, which contains health data on patients and their relatives; each health record should contain all the medical data available, with the exception of genetic data that has no immediate implications for the current state of health of the patient.
Are there any requirements on the content of EHRs (e.g. detailed	Order 2784/2013, Art. 1	As explained above Order 2784/2013 of the Cabinet of the Secretary of Health sets out the minimum requirements to be included in the "health

Questions	Legal reference	Detailed description
requirements on specific health data or general reference to health data)?		records, available in electronic format in the National Health Service".
Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?	Order 2784/2013, Art. 1	Order 2784/2013 of the Cabinet of the Secretary of Health, which lays down the minimum requirements to be included in the records available to health professions through the Platform of Health Data refers to the following coding systems/standards: - International Classification for Nursing Practice - International Classification of Diseases - National list of medicines and health products of the National Authority of Medicines and Health Products - National list of support products of the National Institute of Rehabilitation
Are EHRs divided into separate categories of health data with different levels of confidentiality (e.g. data related to blood type is less confidential than data related to sexual diseases)?	Personal Genetics and Health Information Law, Art. 4(5)	There are no specific national rules prescribing different categories of health data with different levels of confidentiality, however, Article 3(5) of the Personal Genetics and Health Information Law states that *"the management of the organization systems of health data must ensure the separation between health and genetics data and the remaining personal data, namely through the establishment of different levels of access."*
Are there any specific rules on identification of patients in EHRs?	Order 2784/2013, Art. 1	In accordance with Order 2784/2013 of the Cabinet of the Secretary of State of Health, in the records available to health professions through the Platform of Health Data the patient is identified through his name, birthdate, gender, nationality and habitual residence, as well as by his number of beneficiary of the National Health System.
Is there is a specific identification number for eHealth purposes?		There is no specific identification number for eHealth purposes; the patients are identified by their number of beneficiary of the National Health System.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

As there are no specific legal rules about the hosting and management of data from EHRs, the more general provisions of the Personal Genetics and Health Information Law and the Data Protection Law are applicable.

There is no specific authorisation or license to host and process data from EHRs, however, under Article 7(4) of the Data Protection Law, the processing of health data must be notified to the National Commission for Data Protection. By decision of 30 April 2012 (Authorization 3742/2012), the National Commission for Data Protection authorized the establishment of the Platform for Health Data and the creation of the RCU2.

There is also no express obligation to have the information included in EHRs encrypted, but in accordance with Article 15(4) of the Data Protection Law, under certain circumstances the National Commission for Data Protection may decide that the transmission of sensitive data (such as health data) is encrypted. The transmission of data within the Platform for Health Data is encrypted and made though a closed network.

2.2.2. Table on requirements on the institutions hosting EHRs data

Questions	Legal reference	Detailed description
Are there specific national rules about the hosting and management of data from EHRs?	Personal Genetics and Health Information Law	Provisions of the Personal Genetics and Health Information Law do not refer explicitly to the hosting and management of data from EHRs; however, they do apply to health records in general (including those in electronic format) and therefore are relevant for this study.
Is there a need for a specific authorisation or licence to host and process data from EHRs?	Data Protection Law, Art. 7(4) and Art. 27(3)	Although there is no specific authorisation or license to host and process data from EHRs, the general rules on the processing of sensible data which are set out in the Data Protection Law are applicable. Under Article 7(4) of the Data Protection Law, the processing of health data must be notified to the National Commission for Data Protection. Pursuant to Article 27(3), the authorisation by National Commission for Data Protection must be published in the Official Journal and specify: - The purpose of the processing of data; - The data or categories of data to be processed; - The category or categories of data subjects; - The addressees or categories of addressees to who the data is made available; and - The archiving duration of the data. By decision of 30 April 2012 (Authorization 3742/2012), the National Commission for Data Protection authorized the establishment of the Platform for Health Data and the creation of the RCU2.
Are there specific obligations that apply to institutions hosting and managing data from EHRs (e.g. capacity, qualified staff, or technical tools/policies on security confidentiality)?	Personal Genetics and Health Information Law, Art. 4(2)	Although there are no specific obligations that apply to institutions hosting and managing data from EHRs, Article 4(2) of the Personal Genetics and Health Information Law sets the general obligations for institutions holding health records (including those in electronic format). Accordingly, the institutions providing services to the National Health System should *"prevent unauthorized third party access to medical records and computerized systems that contain health data, including security backups, ensuring appropriate levels of security and the compliance with the requirements established by data protection legislation, in particular to prevent their destruction, accidental or*

Questions	Legal reference	Detailed description
		unlawful, alteration, disclosure or unauthorized access or any other unlawful form of processing information".
In particular, is there any obligation to have the information included in EHRs encrypted?	Data Protection Law, Art. 15(4)	There is no express obligation to have the information included in EHRs encrypted, however, in accordance with Article 15(4) of the Data Protection Law, when sensitive data (including health data) circulates in a network and where this may put in risk the rights, freedoms and guarantees of the data subjects, the National Commission for Data Protection may decide that the transmission of data is encrypted. The transmission of data within the Platform for Health Data is encrypted through a mechanism of "private keys", which encrypts the data in the source which is then unencrypted in the receptor. In addition, it should be noted that access to the Professionals' Portal is only possible through a closed network - Internal Network of Health (*RIS – Rede Interna de Saude*).
Are there any specific auditing requirements for institutions hosting and processing EHRs?	Personal Genetics and Health Information Law, Art. 4(6)	Article 4(6) of the Personal Genetics and Health Information Law sets general auditing requirements which although not specific to EHRs apply to EHRs. Pursuant to this provision, the management of IT systems must ensure the regular and frequent processing of backup copies of health data, but always in compliance with the confidentiality rules established by law.

2.3. Patient consent

2.3.1. Main findings

There are no specific national rules on consent from the patient to set-up EHRs and therefore the general rules of the Data Protection Law are applicable.

The RCU2 is created independently of the consent of the patient. According to the National Commission of Data Protection, this situation falls under the scope of Article 7(4) of the Data Protection Law which allows for the processing of data when necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, if the data processed by a health professional or by another person also subject to an obligation of secrecy, and as long as this is communicated to the National Commission of Data Protection and the adequate measures for the security of the data are ensured.

There are no specific national rules on consent from the patient to share EHRs but under Article 12(a) of the Data Protection Law, the patient would have the right to oppose to the processing of the data in certain circumstances. In practice, the patient has to authorise the sharing of data from his RCU2 - the RCU2 is by default accessible to health professionals unless the patient expresses his opposition through the options available in the Patient's Portal

Even though, there are no specific national rules on consent from the patient to EHRs being accessed by a health practitioner or health institution outside of the Member State, one of the options available in the Patient's Portal concerns the authorisation for the sharing of data from the RCU2 with "foreigner professionals (adherent to the epSOS project)".

2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
Are there specific national rules on consent from the patient to set-up EHRs?		There are no specific national rules on consent from the patient to set-up EHRs and therefore the general rules of the Data Protection Law are applicable. The RCU2 is created independently of the consent of the patient. This was authorised by the National Commission of Data Protection as long as the data is stored in the Health Centres. According to the National Commission of Data Protection (Authorization 3742/2012, of 30 April 2012), this situation falls under the scope of Article 7(4) of the Data Protection Law which allows for the processing of data when necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, if the data processed by a health professional or by another person also subject to an obligation of secrecy, and as long as this is communicated to the National Commission of Data Protection and the adequate measures for the security of the data are ensured.
Is a materialised consent needed?		There are no specific national rules on consent from the patient to set-up EHRs and therefore the general rules of the Data Protection Law are applicable (see above comments on Article 7(4)). The RCU2 is created independently of the consent of the patient.
Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?	Data Protection Law, Art. 10	There are no specific national rules on consent from the patient to set-up EHRs and therefore the general rules of the Data Protection Law are applicable. Under Article 10 of the Data Protection Law, the patient would have the right to be informed, *inter alia*, about the purposes of the processing of the data The RCU2 is created independently of the consent of the patient and therefore there are no requirements to inform the patient about the consequences of the consent or withholding consent to create EHRs. Some information is available on the website of the Platform of Health Data.

Questions	Legal reference	Detailed description
Are there specific national rules on consent from the patient to share data?	Data Protection Law, Art. 12(a)	There are no specific national rules on consent from the patient to share EHRs and therefore the general rules of the Data Protection Law are applicable. Under Article 12(a) of the Data Protection Law, the patient would have the right to oppose to the processing of the data if there are serious and legitimate reasons relating to his particular situation that justify such opposition. The access to the RCU2 is dependent on the consent of the patient. This consent is expressed through the options available in the Patient's Portal.
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?		There are no opt-in/opt-out rules for patient consent with regard to processing of EHRs (but see above on the right of opposition of the patient under Article 12(a) of the Data Protection Law). The RCU2 is processed independently of the consent of the patient.
Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?		There are no opt-in/opt-out rules for patient consent with regard to sharing of EHRs (but see above on the right of opposition of the patient under Article 12(a) of the Data Protection Law). In practice, however, it seems that the RCU2 is by default accessible to health professionals unless the patient expresses his opposition through the options available in the Patient's Portal.
Are there requirements to inform the patient about the purpose of EHRs and the consequences of consent or withholding consent on the sharing of EHRs?	Data Protection Law, Art. 10	There are no specific national rules on consent from the patient to set-up EHRs and therefore the general rules of the Data Protection Law are applicable. Under Article 10 of the Data Protection Law, the patient would have the right to be informed, *inter alia*, about the purposes of the processing of the data Some information on the purposes and advantages of sharing data is available on the website of the Platform of Health Data.
Can the patient consent to his/her EHRs being accessed by a health practitioner or health institution outside of the Member State (cross-border situations)?		There are no specific national rules on consent from the patient to EHRs being accessed by a health practitioner or health institution outside of the Member State. It should be noted, however, that one of the options available in the

Questions	Legal reference	Detailed description
		Patient's Portal concerns the authorisation for the sharing of data from the RCU2 with "foreigner professionals (adherent to the epSOS project)".
Are there specific rules on patient consent to share data on a cross-border situation?		There are no specific national rules on consent from the patient to EHRs being accessed by a health practitioner or health institution outside of the Member State.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

There are no specific national legal rules regarding creation, access to and update of EHRs. Therefore the more general provisions of the Personal Genetics and Health Information Law and the Data Protection Law are applicable.

In accordance with Article 5(4) of the Personal Genetics and Health Information Law, data must be registered in the health record by the physician who has provided care to the data subject or, under his supervision, by other professional also subject to professional secret. On the other hand, pursuant to Article 5(5) of the same law, health records can only be accessed by the physician in charge of providing medical care to the data subject or, under his supervision, by other health professionals obliged to professional secret. Therefore, it seems that although non-health professionals can register data in EHRs, only health professionals have access to the information registered in EHRs. In practice, the RCU2 can only be accessed and updated by health professionals either from the Health Centre where the patient is registered or from other Health institutions.

In accordance with the Personal Genetics and Health Information Law the data subject has the right to access to the entirety of his health record, without prejudice of this access being refused in duly justified exceptional circumstances and if it is evident that granting access to the all the content of the health record could be damaging to the data subject. Thus, the patient has access to the data included in the RCU2, but only to that data that his physician allows, taken into account the possible damages that a full knowledge can bring to the patient.

Pursuant to Article 11(1)(d) of the Data Protection Law, in line with the provisions of Directive 95/46/EC, the data subject has the right to the rectification, erasure or blockage of the data which were not processed in accordance with the law. In general, however, patients cannot update, modify or erase the content of the RCU2. On the contrary, they can update, modify and erase the information available in the Patient's Portal that the patients themselves have registered.

There are no specific rules on identification and authentication for health professionals but it should be noted that access to the Health Professional's Portal is not made in an open network; it is not available to the general public but only to the users of the Internal Network of Health.

Information on who had access to a patient's health data through the Platform of Health Data is available to patient through an application in the Patient's Portal.

2.4.2. Table on creation, access to and update of EHRs

Questions	Legal reference	Detailed description
Are there any specific national rules regarding who can create and where can EHRs be created?	Personal Genetics and Health Information Law, Art. 5(4)	There are no specific national rules regarding who can create EHRs and where can these be created. Therefore the general rules on health records laid down in the Personal Genetics and Health Information Law would apply. In accordance with Article 5(4) of the Personal Genetics and Health Information Law, *"medical data is registered in the health record by the physician who has provided care to the data subject or, under his supervision, by other professional also subject to professional secret, within the scope of the specific competence of each professional and following the deontological rules applicable."* The RCU2 can only be created by health professionals from the Health Centre where the patient is registered.
Are there specific national rules on access and update to EHRs?	Personal Genetics and Health Information Law, Art. 5(5) and 5(4)	There are no specific national rules regarding who can access and update EHRs. Therefore the general rules on health records laid down in the Personal Genetics and Health Information Law would apply. Under Article 5(5) of the Personal Genetics and Health Information Law "*health records can only be accessed by the physician in charge of providing medical care to the data subject or, under his supervision, by other health professionals obliged to professional secret."* As already explained above, in accordance with Article 5(4) of the Personal Genetics and Health Information Law, medical data is registered in the health record by the physician who has provided care to the data subject or by other professional also subject to professional secret, as long as supervised by that physician. The RCU2 can only be accessed and updated by health professionals either from the Health Centre where the patient is registered or from other Health institutions.
Are there different categories of access for different health professionals?	Personal Genetics and Health Information Law, Art. 4(5)	There are no specific national rules prescribing different categories of access for different health professionals, however, Article 4(5) of the Personal Genetics and Health Information Law states that *"the management of the organization systems of health data must ensure the*

Questions	Legal reference	Detailed description
		separation between health and genetics data and the remaining personal data, namely through the establishment of different levels of access." It is not completely clear whether all the information available in the RCU2 can be accessed by different categories of health professionals.
Are patients entitled to access their EHRs?	Personal Genetics and Health Information Law, Art. 3(1-3) Medical Deontological Code, Art. 100(4)	There are no specific national rules regarding the patient's access to EHRs. Therefore the general rules on patient's access to health records laid down in the Personal Genetics and Health Information Law would apply. Article 3(1) of the Personal Genetics and Health Information Law states explicitly that health data is property of the data subject. Article 3(2) stipulates that the data subject has, in general, the right to access to the entirety of his health record. Article 3(3) clarifies that the patient's right to access to his health record is made through a physician, duly qualified, and chosen by the patient. In addition, Article 100(4) of the Medical Deontological Code prescribes that the patient has the right to know the information recorded in his health record which can be made available to him by his physician or by other physician chosen by the patient. The patient has access to the data included in the RCU2, but only to that data that his physician allows, taken into account the possible damages that a full knowledge can bring to the patient.
Can patients have access to all of EHR content?	Personal Genetics and Health Information Law, Art. 3(2)	There are no specific national rules regarding the extent of the patient's access to EHRs. However, as mentioned above, Article 3(2) stipulates that the data subject has the right to access to the entirety of his health record, without prejudice of this access being refused in duly justified exceptional circumstances and if it is evident that granting access to the all the content of the health record could be damaging to the data subject. The patient has access to the data included in the RCU2, but only to that data that his physician allows, taken into account the possible

Questions	Legal reference	Detailed description
		damages that a full knowledge can bring to the patient.
Can patients download all or some of EHR content?		No legal rules were identified on the possibility for patients to download all or some of EHRs content. It is not clear whether the information available in the RCU2 which is accessible to the patients can be downloaded.
Can patients update their record, modify and erase EHR content?	Data Protection Law, Art. 11(1)(d)	Not directly. The national legislation does not provide for specific rights for patients to update, modify and erase the content of their EHRs. Nonetheless, in accordance with Article 11(1)(d) of the Data Protection Law, the data subject has the right to the rectification, erasure or blockage of the data which were not processed in accordance with the law. In general, patients cannot update, modify or erase the content of the RCU2; however, they can, at any time, update, modify and erase the information available in the Patient's Portal that the patients themselves have registered (including e.g. height, weight, blood glucose, blood pressure, cholesterol).
Do different types of health professionals have the same rights to update EHRs?	Personal Genetics and Health Information Law, Art. 5(4)	There are no specific national rules regarding different rights for different types of professionals to update EHRs, however, Article 4(4) of the Personal Genetics and Health Information Law stipulates that *"medical data is registered in the health record by the physician who has provided care to the data subject or, under his supervision, by other professional also subject to professional secret, within the scope of the specific competence of each professional and following the deontological rules applicable."* No distinction is made for different health professionals and it in fact it seems that it is even possible for non-health professionals to register data in EHRs. The RCU2 is updated automatically for "very relevant episodes" like clinical alerts, allergies, chronic medication and vaccines, and by the patient's GP, under proposal of any physician that has provided healthcare to the patient, for all other information deemed "relevant".

Questions	Legal reference	Detailed description
Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians…)	Personal Genetics and Health Information Law, Art. 3(1) and 5(5)	The national legislation does not provide for explicit prohibitions for some professionals to access EHRs, however, Article 3(1) of the Personal Genetics and Health Information Law states that health data cannot be used for purposes other than provision of health services, health research and other stipulated by law. In addition, with regards specifically to health records (although not referring explicitly to EHRS), Article 5(5) of Personal Genetics and Health Information Law prescribes that *" health records can only be accessed by the physician in charge of providing medical care to the data subject, or under his supervision, by other health professionals obliged to professional secret."* The RCU2 is only accessible for health professionals; their access is made through the local applications existing in the Health Centres.
Are there exceptions to the access requirements (e.g. in case of emergency)?		No legal rules were identified on exceptions to the general access requirements.
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*		No specific rules on identification and authentication for health professionals were identified. The access to the Health Professional's Portal is not made in an open network; it is not available to the general public but only to the users of the Internal Network of Health. The access is made through the local applications existing in the Health Centres, where health professionals are already authenticated.
Does the patient have the right to know who has accessed to his/her EHRs?	Data Protection Law, Art. 11(1)(c)	There are no specific rules on the patient's right to know who has accessed to his EHRs. Therefore, the general rules on the right to access set out in the Data Protection Law would apply. Under Article 11(1)(c), the data subject has the right to be informed about the addressees or the categories of addressees to who the data is provided. Information on who had access to a patient's health data through the Platform of Health Data is available to patient through an application in

Questions	Legal reference	Detailed description
		the Patient's Portal. This information include the identification of the health professional, the institution from where the information was accessed, date, hour and context of the access.
Is there an obligation on health professionals to update EHRs?	Medical Deontological Code, Art. 100(1-2)	The general obligation for physicians to update health records results from Article 100 of the Medical Deontological Code, which prescribes that physicians should carefully record the conclusions of the clinical observations of their patients and that the records should be sufficient clear and detailed in order to allow their use by other physicians who may in the future provide healthcare to their patients.
	Order 2784/2013, Art. 1 and 2	Order 2784/2013 of the Cabinet of the Secretary of State of Health, with the purpose of *"ensuring the increasing of the quality and quantity of the information related to health records, available in electronic format in the National Health Service"*, lays down the minimum requirements to be included in these records relating to the notes of medical discharge as well as the notes relating to the transfer from intensive care units. The Order also prescribes that from 1 July 2013 onwards these notes must be recorded in electronic format and be available to health professionals through the Platform of Health Data.
Are there any provisions for accessing data on 'behalf of' and for request for second opinion?	Personal Genetics and Health Information Law, Art. 5(5)	There are no specific national rules regarding access to EHRs on 'behalf of' and for request for second opinion, however, Article 5(5) of the Personal Genetics and Health Information Law prescribes that *"health records can only be accessed by the physician in charge of providing medical care to the data subject or, under his supervision, by other health professionals obliged to professional secret."*
Is there in place an identification code system for cross-border healthcare purpose?		None identified. The national identity number is used for this purpose.
Are there any measures that consider access to EHRs from health professionals in another Member State?		One of the options available in the Patient's Portal concerns the authorisation for the sharing of data from the RCU2 with "foreigner professionals (adherent to the epSOS project)".

2.5. Liability

2.5.1. Main findings

The national legislation does not set specific medical liability rules related to the use of EHRs and therefore the general medical liability rules would apply. These are based on the relevant provisions of the Medical Deontological Code and the provisions on general civil liability set out in the Civil Code. The rules set out in the Criminal Code on medical-surgical procedures and treatments are also relevant.

Some provisions of the Data Protection Law are also relevant in this context - Article 43 sets the sanctions for persons who intentionally divert or use personal data in a way which not compatible with the purpose of the collection of data or the requirements of the legal basis; Article 44 sets the sanctions for persons who, without the required authorisation, access personal data which access is denied to them.

2.5.2. Table on liability

Questions	Legal reference	Detailed description
Does the national legislation set specific medical liability requirements related to the use of EHRs?	Civil Code, Art. 483 and Art. 798	The national legislation does not set specific medical liability rules related to the use of EHRs and therefore the general medical liability rules would apply. These are based on the provisions on general civil liability set out in the Civil Code and the relevant provisions of the Medical Deontological Code. The rules set out in the Criminal Code on medical-surgical procedures and treatments are also relevant. The jurisprudence of the Supreme Court of Justice shows that both the rules on non-contractual (Art. 483 onwards) and contractual (Art. 798 onwards) civil liability have been applied in cases where medical liability is triggered.[27]
	Medical Deontological Code, Art. 34	Article 34 of the Medical Deontological Code states that *"the physician is responsible for his acts and for the acts carried out by the professionals under his supervision, as long as they do not disrespect his instructions, or go beyond the limits of their competence".*
	Criminal Code, Art. 150(2)	Article 150(2) of the Criminal Code provides that health professionals are criminally liable when they do not follow the "legis artis" in the performance of their duties, creating risk for the life of their patients or to their health. The penalties are of imprisonment up to 2 years or fine up to 240 days (unless more serious penalties are applicable under other legal provisions).
Can patients be held liable for erasing key medical information in EHRs?		Patients cannot update, modify or erase the content of the RCU2. They can however, at any time, update, modify and erase the information available in the Patient's Portal that the patients themselves have registered (including e.g. height, weight, blood glucose, blood pressure, cholesterol).
Can physicians be held liable because of input errors?		Inputting information in an erroneous way (whether this input was negligent, reckless, or intentional) could be considered a professional

[27] For more info, please see http://www.stj.pt/ficheiros/jurisp-tematica/responsabcivilactomedico2001-2012.pdf

Questions	Legal reference	Detailed description
		fault triggering medical liability as explained above.
Can physicians be held liable because they have erased data from the EHRs?		Withholding information necessary for an adequate provision of health services could be considered a professional fault triggering medical liability as explained above.
Are hosting institutions liable in case of defect of their security/software systems?	Civil Code, Art. 483 and Art. 798	There are no specific rules on liability in case of defect of security/software systems for the hosting and processing of EHRs and therefore the general liability rules set out in the Civil Code would apply.
Are there measures in place to limit the liability risks for health professionals (e.g guidelines, awareness-raising)?		None identified.
Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?	Data Protection Law, Art. 44(1)	There are no specific rules related to breach of access to EHRs, however, the general rules on unlawful access to personal data set out in the Data Protection Law would apply. Pursuant to Article 44(1) of the Data Protection Law a person who, without the required authorisation, accesses personal data which access is denied to him is punished with imprisonment up to one year or fine up to 120 days (the maximum limit of the sanction is doubled under certain circumstances).
Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?		There is no legal obligation, however, in cases where an EHR exists and the health professional does have access to it, not consulting the EHR prior to take a decision involving the patient (whether this lack of action is negligent, reckless, or intentional) could be considered a professional fault triggering medical liability as explained above.
Are there liability rules related to the misuse of secondary use of health data?	Data Protection Law, Art. 43(1)(c)	There are no specific rules related to the misuse of secondary use of health data included in EHRs, however, the general rules on non-compliance of obligations related to data protection set out in the Data Protection Law would apply. Pursuant to Article 43(1)(c) read in conjunction with Article 43(2) of the Data Protection Law, a person who intentionally diverts or uses personal data in a way which not compatible with the purpose of the collection of data or the requirements of the appropriate legal basis is punished with imprisonment up to two years or fine up to 240 days.

2.6. Secondary uses and archiving durations

2.6.1. Main findings

There are no specific legal rules on secondary uses and archiving durations of EHRs. Therefore the more general provisions of the Personal Genetics and Health Information Law and the Data Protection Law are applicable.

The National Commission on Data Protection authorized the archiving of the data included in the Platform for Health Data for a period of six months after the death of the data subject, without prejudice of allowing the archiving for a longer period in cases there are on-going court proceedings.

The general rule on the secondary use of health data is set under Article 4(4) of the Personal Genetics and Health Information Law, which allows access to health data for research purposes as long as this information is anonymized.

No opt-in/opt-out rules were identified for the secondary uses of eHealth data included in EHRs.

2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
Are there specific national rules on the archiving durations of EHRs?	Data Protection Law, Art. 5(1)(e)	In accordance with the general rules of the Data Protection Law, personal data must be *"kept in a way to allow the identification of their subject only during the period necessary for the purposes of the collection or further processing"*. The National Commission on Data Protection authorized the archiving of the data included in the Platform for Health Data for a period of six months after the death of the data subject, without prejudice of allowing the archiving for a longer period in cases there are on-going court proceedings (Authorization 3742/2012, of 30 April 2012).
Are there different archiving rules for different providers and institutions?		None identified.
Is there an obligation to destroy data at the end of the archiving duration or in case of closure of the EHR?		There are no specific rules about an obligation to destroy data at the end of the archiving duration or in case of closure of the EHR.
Are there any other rules about the use of data at the end of the archiving duration or in case of closure of the EHR?		No specific rules about the use of data at the end of the archiving duration or in case of closure of the EHR were identified.
Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?	Personal Genetics and Health Information Law, Art. 4(4)	There are no specific rules on the secondary use of health data included in EHRs. The general rule on the secondary use of health data is set under Article 4(4) of the Personal Genetics and Health Information Law, which allows access to health data for research.
Are there health data that cannot be used for secondary use?		There are no express exceptions to the general rule allowing using health data for research purposes.
Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?	Personal Genetics and Health Information Law, Art. 4(4)	The general rule on the secondary use of health data is set under Article 4(4) of the Personal Genetics and Health Information Law, which allows access to health data for research purposes as long as this information is anonymized.
Does the law say who will be		The law states that health data can be used for research purposes but

Questions	Legal reference	Detailed description
entitled to use and access this data?		does not specify who is entitled to use and access this data.
Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?		No opt-in/opt-out rules were identified for the secondary uses of eHealth data included in EHRs, however it should be noted that this information must be anonymized (please see above).

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

The only requirement on interoperability of EHRs identified comes from Order 2784/2013 of the Cabinet of the Secretary of State of Health, which prescribes that certain medical notes (within the National Health Service) must be recorded in electronic format in order to be available to health professionals through the Platform of Health Data. These are then used to feed the RCU2.

2.7.2. Table on interoperability of data requirements

Questions	Legal reference	Detailed description
Are there obligations in the law to develop interoperability of EHRs?		None identified.
Are there any specific rules/standards on the interoperability of EHR?	Order 2784/2013, Art. 1	Order 2784/2013 of the Cabinet of the Secretary of State of Health prescribes that from 1 July 2013 onwards the notes of medical discharge as well as the notes relating to the transfer from intensive care units in the National Health Service must be recorded in electronic format in order to be available to health professionals through the Platform of Health Data.
Does the law consider or refer to interoperability issues with other Member States systems?		None identified.

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

The two systems are independent and at different stages of development. If on one hand, the existence of EHRs is not a precondition for the ePrescription system, on the other hand access to ePrescriptions does not imply access to EHRs.

2.8.2. Table on the links between EHRs and ePrescriptions

- ***Infrastructure***

Questions	Legal reference	Detailed description
Is the existence of EHR a precondition for the ePrescription system?		The existence of EHRs is not a precondition for the ePrescription system. The two systems appear to be independent and at different stages of development. The promotion of the use of ePrescriptions was one of the objectives set out in the programme of the XVIII Constitutional Government in the area of public health and their use is currently widespread. In this context, Decree-Law 106-A/2010 of 1 October introduced a series of measures to foster the implementation of ePrescriptions, e.g. from 1 March 2011 only medicines prescribed electronically are reimbursed by the State. This Decree-Law also set out that the rules for ePrescriptions were to be defined by Ordinance by the Ministry of Health taking into account the *"generalization of prescriptions made through electronic means"*.
Can an ePrescription be prescribed to a patient who does not have an EHR?		There are no rules indicating that an ePrescription cannot be prescribed to a patient who does not have an EHR. The two systems are independent (please see above).

- ***Access***

Questions	Legal reference	Detailed description
Do the doctors, hospital doctors, dentists and pharmacists writing the ePrescription have access to the EHR of the patient?	Personal Genetics and Health Information Law, Art. 5(5)	The two systems appear to be independent (please see above) and therefore access to ePrescriptions does not imply access to EHRs. Consequently, pharmacists do not have access to EHRs - as it was explained above, under Article 5(5) of the Personal Genetics and Health Information Law *"health records can only be accessed by the physician in charge of providing medical care to the data subject or, under his supervision, by other health professionals obliged to professional secret"*. The RCU2 can only be accessed and updated by health professionals

Questions	Legal reference	Detailed description
		either from the Health Centre where the patient is registered or from other Health institutions.
Can those health professionals write ePrescriptions without having access to EHRs?		No rules were identified indicating that a health professional has to access the patient's EHR in order to prescribe an ePrescription. The two systems are independent (please see above).

3. Legal barriers and good practices for the deployment of EHRs in Portugal and for their cross-border transfer in the EU.

Despite several attempts, it was not possible to contact the Shared Services of the Ministry of Health, the National Commission for Data Protection or the Portuguese Medical Association in order to include their views on the current state of affairs and identify potential good practices and legal barriers for the development of the EHR system in Portugal. In any case, among the positive aspects, the fact that the transmission of data within the Platform for Health Data is encrypted and made though a closed network should be highlighted. One of the negative aspects identified is the lack of specific legislation, in particular in what relates to liability.