

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

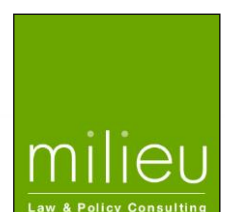
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Overview of the national laws on electronic health records in the EU Member States

National Report for Latvia



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Executive Summary

1. Stage of development of EHRs in Latvia

Electronic Health Records (**EHR**) are at a development stage in Latvia and initial pilot phase is ought to be launched on the first of April 2014. EHRs are covered by the strategy document “Guidelines for eHealth in Latvia” prepared already in August 2005 and ratified by Cabinet of Ministers. However after nearly a decade of development of eHealth system the first regulation with regards to initial stage of EHR will hopefully be adopted this year.

The aim of eHealth and Health Information System (**HIS**) is to create a single data centre, which will electronically store medical records of each resident of the State and would also integrate all internal information systems of health care institutions as a unified one. Such integration should allow creation, storage and transfer of EHRs according to the principle “one resident – one EHR”.

National Health Service (**NHS**) is the primary institution responsible for development and implementation of HIS that will include also EHR. The Data State Inspectorate (**DSI**) will remain the principal supervisor for personal data protection, supervising the use and access to EHRs.

The legal ground for development of HIS was set in place by Chapter 14 of the Law on Medical Treatment, which introduced the concept of Health information system and eHealth. Cabinet of Ministers Regulations on United Health Sector Information Systems (**RUHSIS**) as secondary legislative act is being drafted at the moment. The legal basis is provided in Section 78 of Law on Medical Treatment that requires the creation of HIS. However general requirements related to data protection, creation of information systems, archiving and other matter are also applicable.

2. Summary of legal requirements applying to EHRs

As the implementation of EHR and the whole eHealth has just started, the specificities of these projects are still unclear. RUHSIS is being in the stage of development and will have to be ratified by Cabinet of Ministers, therefore some changes and amendments to the current version of the draft RUHSIS referred to in this report are likely to be made.

The general law regulating medical documentation states that medical records shall have full and truthful information about diagnoses, treatment and the results of treatment. Moreover, the draft RUHSIS provides a detailed list of all the information that has to be included in EHRs, providing different levels of access for such information based on its type.

In order to access HIS health institutions have to conclude a written agreement with NHS according to the provisions of the draft RUHSIS. These institutions have to undertake the obligation to guarantee that their information system is secure and sophisticated to ensure that the rules on EHRs are fulfilled and that health data is well protected.

The national legislation does not require patient consent in order to create EHR or access and process the medical data stored in EHRs.

The national legislation does not set specific medical liability requirement related to the use of the EHR. As a result, the general rules on medical liability apply.

An EHR must be kept for a period of one to 75 years after its closure. There are no specific rules on the secondary use of EHR health data (e.g. scientific research). The general rules on the secondary use of health data therefore apply.

The draft RUHSIS allows health practitioners to create, access, use and modify EHRs. The patient will have the right to access his own data on national e-governance internet portal and to restrict access levels to all or some of his medical records to certain health professionals. State institutions will have the full access to information that they are entitled to receive by law.

Interoperability of EHRs is a technical issue and has not been regulated in Latvia. According to the information provided by NHS, their main focus at this moment is to create HIS that would be functioning in Latvia and develop it further at later stages.

3. Good practices

The Latvian authorities are very optimistic about launching pilot phase of EHRs on 1 April 2014. However it has been nearly a decade since “Guidelines for eHealth in Latvia” has been ratified and the launching date moved further away.

Therefore it is too early to tell the good practices for the development of EHRs in Latvia, because the system has not been launched yet.

Furthermore the effectiveness and universality of EHRs system would be ensured due to the fact that the patients consent would not be required for the set-up of his/her EHR as it will be established as a legal obligation of the data controller to process such data under the applicable personal data protection laws.

4. Legal barriers

At the moment it is not yet clear how the interoperability in cross-border cases would be ensured as it was indicated by the stakeholders that the system is created mainly for medical data transfer in Latvia. The main issue raised by the related subjects is the unification of the language and classifiers used in the national systems of the Member States. Furthermore it is not clear what will be required from the health practitioners to ensure the use of EHR as each of them had a very different understanding of the situation and the requirements.

The national legislation does not set specific medical liability requirement related to the use of the EHR. Therefore the liability of health practitioner with regard to the use of EHR is unclear.

As regards to the effective accessibility and usage of EHRs, the current regulation provides that users of HIS could access the databases with the qualified digital certificate or other equivalent means of identification. In practice e-signature issued with ID authorisation card or authorization through banking system would be used. However such requirements would demand a considerable amount of time from the health professional in order to access each patient’s EHR. As alternative it is proposed that health practitioners purchase their own information system that would connect to the HIS; however that requires further expenses that are not covered by the State. This might be an obstacle to general practitioners that are practicing individually.

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List of abbreviations

| | |
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| DSI | Data State Inspectorate |
| EHRs | Electronic Health Records |
| HIS | Health Information System |
| NHS | National Health Service |
| RUHSIS | Regulations on United Health Sector Information System |

1. General context

1.1. EHR systems in Latvia

Electronic Health Record is under development stage in Latvia and initial pilot phase is ought to be launched on the first of April 2014. EHRs are covered by the strategy document “Guidelines for eHealth in Latvia” prepared already in August 2005 and ratified by Cabinet of Ministers. However after nearly a decade of development of eHealth system the first regulation with regarding EHRs will be adopted this year.

The Health Information System in which EHRs would be stored is a system of organisational, technical and software measures aimed to develop centralized database of health care information and to ensure the exchange of such information among patients, health care professionals and institutions. It is expected that implementation of HSI would improve society’s health, promote individual control of their health; reduce wasted time spend on patients contacts with medical institutions; increase the effectiveness of the health care, providing health care specialists with a quick access to necessary patient health data; reduce the amount of information that health care specialists need to enter into the documents; increase the amount and usability of a structured information; increase effectiveness of medical institutions; increase health care data reliability and security.

Currently in Latvia there are 4 projects of eHealth related to HSI that are being implemented in order to launch the pilot phase (1st stage of eHealth Development). The development and implementation of those projects are supervised by National Health Service.

The aim of eHealth and HIS is to create a single data centre, which will electronically store medical records of each resident of the state and would also integrate all internal information systems of health care institutions as a unified one. Such integration should allow creation, storage and transfer of EHRs according to the principle “one resident – one EHR”. Currently in Latvia majority of the largest health care institutions have their own internal systems for the storage of patient data which is done for administrative or medical purposes. Electronic patient data transfer is almost non-existent among Latvian general practitioners.

It is intended that data to HIS will be transferred either directly by using special eHealth portal or through internal information systems that will be integrated and will connect to HIS transferring data to central server.

It is planned that the data stored in HIS would be accessible by the patients who will have the right to opt out of eHealth services and restrict access to their data. The possibility to register and access the database would be allowed via special national internet portal www.latvija.lv, which is currently already used for multiple e-governance services in Latvia. Any person can access the services provided to this internet portal by registering using secure electronic signature or by registering with person’s bank account data (username, password).

1.2. Institutional setting

The main institutions involved in the development and implementation and responsible for supervision of the HIS in the Republic of Latvia are:

- **The Government of the Republic of Latvia**

The Government of the Republic of Latvia (Cabinet of Ministers) is the competent authority responsible for approval of regulations and appointment of controller of HIS at a general level.

- **The Ministry of Health**

The Ministry of Health is the leading institution responsible for coordination and supervision of the implementation of eHealth in Latvia. The general goals regarding EHRs that shall be implemented are expressed in the strategy document “Guidelines for eHealth in Latvia” of 2005 that are ratified by Cabinet of Ministers.

- **The National Health Service**

NHS is the primary institution responsible for development and implementation of HIS. NHS is the controller of HIS and is the principal institution that coordinates eHealth projects and participates in creation of draft RUHSIS.

- **The Data State Inspectorate**

DSI is the institution responsible for the supervision and control of enforcement of the Personal Data Protection Law. Therefore it also supervises compliance of subjects of health services with requirements of data protection. However, DSI was not invited to participate in eHealth projects and they have very limited information about EHR.

1.3. Legal setting and future legal development

The legal ground for development of HIS was set in place by Chapter 14 of the Law on Medical Treatment, which introduced the concept of Health information system and eHealth. Currently more detailed regulation is in the stage of being drafted. The draft of Cabinet of Ministers Regulations on United Health Sector Information System (RUHSIS) has been provided by NHS; however, it may be subject to further changes and amendments before it is seen and ratified by Cabinet of Ministers. RUHSIS would have a status of a secondary legislative act that is created in accordance with Section 78 of Law on Medical treatment.

Furthermore general regulatory enactments related to data protection, creation of information systems, archiving and other matters will also applicable.

Documentation of medical records is regulated by the Law On the Rights of Patients and by the Cabinet of Ministers Regulations No 265 of 4 April 2006 on "The Procedures for the record-keeping of medical documentation". The regulation mainly concerns health records with different types of content e.g. health card, ambulance card, dental care card. There is no regulation concerning EHRs specifically in either of those legal acts.

The Personal Data Protection Law applies as a general law to all personal data protection issues related to EHRs insofar as there is no more specific regulation in other legal acts. DSI supervises the compliance with the Personal Data Protection Law.

The Law on State Information Systems establishes security classes for information systems. The security class of HIS is also established on the basis of this law.

The legal principles for the civil liability of the providers of medical services are provided in the Civil Law. Latvian laws do not provide more specific legal regime for the liability related to the use of EHR systems. Therefore, the general principles for negligence/malpractice apply having also provisions in the Administrative Violations Code and the Criminal Law.

The general regulation of the Civil Law is applicable to the health services agreement because there is no specific regulation on health services agreements. In practice the agreement contains the confidentiality obligation of the healthcare service provider and healthcare professionals, the obligation to document the provision of healthcare services and the liability of healthcare service providers.

Prescriptions are currently being regulated by the Cabinet of Ministers Regulations No 175 of 8 March 2005 "Regulations for Manufacture and Storage of Prescription Forms, as well as Writing out and Storage Prescriptions". This regulation will be applicable to digital prescriptions unless specific regulation for ePrescription is adopted at a later stage.

Below is the summary of the legal framework related to the implementation and the use of EHRs:

- **Legal framework related to the implementation of eHealth policies:**

- Draft project for Cabinet of Ministers Regulations on Health Sector Information Systems.
- Guidelines eHealth in Latvia, 2005.

- **General legal framework related to medical data records:**

- Archives Law.
- The Civil Law.
- The Criminal Law.
- The Administrative Violations Code.
- The Electronic Documents Law.
- Law on the Rights of Patients.
- Medical Treatment Law.
- The Personal Data Protection Law.
- Law on State Information Systems.
- Cabinet of Ministers Regulations No 473 of 28 June 2005 on "Procedures for the Preparation, Drawing Up, Storage and Circulation of Electronic Documents in State and Local Government Institutions, and the Procedures by which Electronic Documents are Circulated between State and Local Government Institutions, or Between These Institutions and Natural Persons and Legal Persons".
- Cabinet of Ministers Regulations No 175 of 8 March 2005 "Regulations for Manufacture and Storage of Prescription Forms, as well as Writing out and Storage Prescriptions".
- Cabinet of Ministers Regulations No 265 of 4 April 2006 on "The Procedures for the record-keeping of medical documentation".
- Cabinet of Ministers Regulations No 746 of 15 September 2008 on "Creation of the registers for the patients with particular diseases".
- Cabinet of Ministers Regulations No 152 of 3 April 2001 on "Procedures for Issuance of Sick-Leave Certificates".

2. Legal requirements applying to EHRs in Latvia

2.1. Health data to be included in EHRs

2.1.1. Main findings

At the moment Latvia has only general legal framework applicable to all medical data in paper files or electronic files that regulates the scope of information that has to be included in personal health records. The draft RUHSIS lists the information to be included in EHR. However, as RUHSIS is still in the drafting stage, it can only be used as indicator of possible outcome but not as a binding regulation.

Cabinet of Ministers Regulations No 265 of 4 April 2006 on “The Procedures for the record-keeping of medical documentation” provides the general requirement that all health records should contain information that identifies the patient, attests the diagnosis, substantiates the examinations made and the methods used as well as truthfully reflects the results of provided medical treatment. The draft RUHSIS further specifies that the data that will be included in HIS will have to be categorised according to their type and accessibility – publicly accessible data and restricted data which then will be divided in basic data and additional data, each having different level of authorised access.

In practice given the broad definitions of requirements health care institutions choose the scope of the content of patients’ health records themselves taking account that the records have to reflect the necessity of treatment and treatment provided. In addition, following a patient’s stay in a health institution, health professionals have to bring summaries of the key elements of the stay to the health records. Usually dispatch summaries include data related to:

- inpatient discharge summary;
- outpatient visit prescription;
- referral to consultations, laboratory tests, treatments;
- answer to referral;
- picture;
- vaccination summary;
- order for laboratory;
- laboratory results;
- various relevant test results;
- performed surgeries, surgical procedures;
- prescribed medications.

2.1.2. Table on health data

| Questions | Legal reference | Detailed description |
|---|---|---|
| <p><i>Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)</i></p> | <p>Cabinet of Ministers Regulations No 265 of 4 April 2006 on “The Procedures for the record-keeping of medical documentation”, Section 10</p> <p>Draft Cabinet of Ministers Regulations on United Health Sector Information System, Sections 5 to 10</p> | <p>Latvian legislation does not provide specific rules on the content of EHRs yet, however draft RUHSIS is in the process of development and it can be used as indication that there will be specific rules on the content of EHRs.</p> <p>As regards to the regulation of EHR content, Section 5 to Section 10 of the RUHSIS provides broad list of information that could be processed in EHR database of HSI:</p> <p>As basic data to be included in EHRs, following information should be included:</p> <ul style="list-style-type: none"> - Patients name and surname - Personal ID code - Citizenship - Sex - Date of Birth - Address - Information about legal capacity - Date of death - Information related to the coming of age - Information regarding the residency permit in Latvia - Information about received out-of-family (nursing) care; - Contact information; - Data about person(s) that are entitled to process patient’s data in HIS in the name of patient. - Information about parents, authorised persons or legal guardians (name, surname, personal ID code, contact information); - Information about general practitioner (name, surname, contact information) - Information about documents (the type of document, the issuing institution, the date document is valid till) that are issued in accordance with European Parliament and Council Regulation No 883/2004 (EC) of 29 April 2004 and European Parliament and Council Regulation No 987/2009 of 16 September 2009. - Health data: information about allergies and the date of their diagnose, the |

| Questions | Legal reference | Detailed description |
|--|---|---|
| | | <p>diagnosed illnesses and chronic health conditions in accordance to international classification system ICD-10, information regarding implants, prosthetic appliances, disability, past surgeries, and information about illnesses diagnosed during the past 12 months and prescribed medicines as well as other warnings regarding the health of the patient.</p> <p>As restricted accessibility data, following information must be included:</p> <ul style="list-style-type: none"> - Full information about received medical treatment and ordered treatment - Patient summary, discharge information; - Sick-leave certificate; - ePrescription; - Data about identifiable person that is processing the patients data in the name of health institutions or pharmacies (name, surname, Personal ID code, ID number in the health professionals' register, profession and speciality); - The date and time of data input, access and processing of patient's data. |
| <i>Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?</i> | <p>Cabinet of Ministers Regulations No 265 of 4 April 2006 on "The Procedures for the record-keeping of medical documentation", Section 10</p> <p>Draft Cabinet of Ministers Regulations on United Health Sector Information System, Sections 5 to 10</p> | <p>Currently applicable legislation restricts the input to only purely medical information. Cabinet of Ministers Regulations No 265 of 4 April 2006 on "The Procedures for the record-keeping of medical documentation" states that information in medical records should truthfully reflect received medical treatment, description of the diagnosis and discharge summary.</p> <p>However, the draft RUHSIS includes additional, not purely medical information that may be included in HIS for example, information regarding authorised persons, legal guardians, citizenship, etc.</p> |
| <i>Is there a definition of EHR or patient's summary provided in the national legislation?</i> | | <p>Neither Cabinet of Ministers Regulations No 265 of 4 April 2006 on "The Procedures for the record-keeping of medical documentation" nor Draft RUHSIS provide a definition of EHR. The sole requirement is that the information must be 'necessary for the coordination of health-related care given to the care recipient' or be 'key elements of the stay' in a health institution.</p> |
| <i>Are there any requirements on the content</i> | Cabinet of Ministers | Currently applicable legislation Cabinet of Ministers Regulations No 265 of 4 |

| Questions | Legal reference | Detailed description |
|---|--|---|
| <i>of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?</i> | <p>Regulations No 265 of 4 April 2006 on “The Procedures for the record-keeping of medical documentation”, Section 10</p> <p>Draft Cabinet of Ministers Regulations on United Health Sector Information System, Sections 5 to 10</p> | <p>April 2006 on “The Procedures for the record-keeping of medical documentation” provides only general requirement that information that has to be included in medical records should truthfully reflect received medical treatment.</p> <p>However, the draft RUHSIS includes additional requirements and further specifies the information that has to be included in EHR should be divided into publicly accessible information, basic information and restricted information. This distinction is made to make it easier to legally regulate different levels of access to patient’s data.</p> |
| <i>Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?</i> | <p>Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 6(17)2, Section 6(17)4, Section 6(17)5</p> | <p>Currently applicable legal framework does not provide specific rules on the use of common terminology.</p> <p>The draft RUHSIS state that for the entries regarding surgeries Nordic Medico-Statistical Committee classification (NOMESCO) should be used and for Surgical Procedures Classification NCSP+ should be used. For diseases, disorders and disability ICD-10 International Classification of Diseases Latvian adapted version (SSK-10) should be used.</p> |
| <i>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)?</i> | <p>Draft Cabinet of Ministers Regulations on United Health Sector Information System, Sections 5 to 10</p> | <p>Currently applicable legislation - the Cabinet of Ministers Regulations No 265 of 4 April 2006 on “The Procedures for the record-keeping of medical documentation” does not divide data into categories with different level of access.</p> <p>However, the draft RUHSIS access levels by the type of the information stored - publicly accessible information, basic information and restricted information. The regulation further specifies which information can be accessed by general practitioners, pharmacists, health professionals and state institutions.</p> |
| <i>Are there any specific rules on identification of patients in EHRs?</i> | | <p>Legal regulation provides no specific rules on the identification of patients in EHRs.</p> |
| <i>Is there is a specific identification number for eHealth purposes?</i> | | <p>The current legal framework does not provide any specific requirements on the content of EHRs.</p> <p>The personal ID code is sufficient in that respect. It is unique to each individual throughout Latvia, and serves many purposes.</p> |

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

The legislation currently in force in Latvia does not provide particular requirements applicable to the institutions hosting EHRs data, data safety regulations, including technical and organizational requirements, requirements for the employees of hosting institution, etc.

The draft RUHSIS will provide a little more regulation stating requirement to conclude the agreement in writing between NHS and health institution in order to use HIS.

In this agreement health institutions and pharmacies will undertake the obligation to secure their systems according to the general data safety requirements and make sure that multiple data copying will not be possible. In order to conclude the contract health institutions and pharmacies will have to provide extensive information demonstrating that their hosting system is secure and sophisticated to ensure that the rules on RUHSIS are fulfilled and that health data is well protected.

Health Institutions and pharmacies will also be responsible for compliance and integration of their systems with HIS while making sure their systems are protected with secure firewalls, anti-virus programmes, and encryption when necessary. NHS will survey whether those requirements are fulfilled.¹

¹ Interview No. 4

2.2.2. Table on requirements on the institutions hosting EHRs data

| Questions | Legal reference | Detailed description |
|---|---|---|
| <i>Are there specific national rules about the hosting and management of data from EHRs?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 14 | The draft RUHSIS provides data safety regulations, including technical and organizational requirements, requirements for the employees of hosting institution, etc. that are applicable to NHS as the central institution and to the health practitioners as the data processors. In addition internal information systems of health care institutions must be compliant with the national HSI. |
| <i>Is there a need for a specific authorisation or licence to host and process data from EHRs?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 13 | The current legislation does not provide any requirements for specific authorisation or licence to host and process data from EHRs. However, the draft RUHSIS requires to obtain prior authorisation to access data in HIS. The authorisation is obtained by concluding a written agreement with NHS and showing the compliance with security, connectivity and confidentiality requirements of the internal systems. |
| <i>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)?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 14 | Currently there are no specific obligations that apply to institutions hosting and managing data from EHRs, therefore general requirements under Personal Data Protection Law apply. In addition to the general regulation the draft RUHSIS specifies the list of required technical and organisational safety measures; requirements for safe processing of electronic information; control procedures for safe data reporting to users of HSI. |
| <i>In particular, is there any obligation to have the information included in EHRs encrypted?</i> | | It is not explicitly required by the law that the information included in EHRs must be encrypted. |
| <i>Are there any specific auditing requirements for institutions hosting and processing EHRs?</i> | | The current legislation does not provide any specific auditing requirements for institutions hosting and processing EHRs. |

2.3. Patient consent

2.3.1. Main findings

The general principle under Latvian law is that processing (including sharing) of health data for the purposes of medical treatment, provision of health care services or administration thereof, the distribution of means of medical treatment or for collection of statistical information by the state does not require consent from the patient. The data processor also is not obliged to inform the patient about health data processing unless the patient has required it. In other situations processing of health data would require a written consent or would be subject to other conditions as described in Section 11 of the Personal Data Protection Law.

The same regulation will apply to HIS (and EHRs accordingly) after the draft RUHSIS comes into force. In addition to that RUHSIS foresees opt-out solutions, where the patient is entitled to prohibit access of certain EHRs in HIS to practitioners and medical institutions. Such health data would still be accessed by certain governmental institutions for health purposes as described in Section 10 of the Law on Patients' Rights. There are no legal regulations requiring the health professional to warn the patient about possible consequences of hiding the EHR data moreover the draft RUHSIS does not foresee that.

The HIS is a national initiative. Cross-border issues are not specifically regulated by the current legal framework or draft RUHSIS. Cross-border exchange of health data may be carried out according to the general regulation described in the Personal Data Protection Law.

2.3.2. Table on patient consent

| Questions | Legal reference | Detailed description |
|--|---|--|
| <i>Are there specific national rules on consent from the patient to set-up EHRs?</i> | <p>Personal Data Protection Law, Section 11</p> <p>Medical Treatment Law, Section 79, Section 80</p> <p>Law on Patients' Rights, Section 10 (2), (5¹), (5²)</p> <p>Draft Cabinet of Ministers Regulations on United Health Sector Information System,</p> | <p>The current legislation does not provide any specific rules on consent from the patient to set-up EHRs.</p> <p>According to the Personal Data Protection Law health data are considered as sensitive data. Section 11(5), (9) foresees that processing of sensitive data (without consent) is prohibited except where processing of personal data is necessary for the purposes of medical treatment, the provision of health care services or the administration thereof, the distribution of means of medical treatment or for collection of statistical information by the state. According to Section 80 of the Medical Treatment Law the patient does not have to be informed about such processing of sensitive data unless the patient has required to be informed about processing of the sensitive data for the above mentioned purposes.</p> <p>Section 10(5¹), (5²) Law on Patients' Rights, Section 79(2) of the Medical Treatment Law and RUHSIS foresee clear circumstances under which EHRs shall be created and processed by health professionals without obtaining patient's consent for the creation and usage of the EHR. For example, there are different access levels to health data depending on the processor of the data and duration of processing is also limited (see Section 2.4.). In any other situation sharing of information regarding the patient is subject to his/her written consent (Section 10 (2) of the Law on Patients' Rights).</p> |
| <i>Is a materialised consent needed?</i> | <p>Law on Patients' Rights, Section 10(2)</p> <p>Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 23</p> | <p>There are no specific rules providing that, as a rule, a consent is needed to set up an EHR. However, according to Section 23 of draft RUHSIS a general practitioner (family doctor) in case of short term (non-registered) patients is obliged to obtain an informed consent (permission in writing) prior to processing patient's health data available in the HIS.</p> |
| <i>Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or</i> | | <p>The current legislation or the draft RUHSIS does not provide requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs.</p> |

| Questions | Legal reference | Detailed description |
|--|--|---|
| <i>withholding consent to create EHRs?</i> | | |
| <i>Are there specific national rules on consent from the patient to share data?</i> | <p>Law On the Rights of Patients, Section 10(2)</p> <p>Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 23</p> | <p>A materialised consent may be needed, if data to be shared is not data to be included in the EHR or if data to be shared relates to a short term (non-registered) patient. Please see the description above for more detailed information.</p> <p>The patient is entitled opt-out solutions in relation to sharing health data to be included in EHRs (see below).</p> |
| <i>Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?</i> | | <p>There are no opt-in/opt-out rules for patient consent with regard to storing EHRs on HIS, because HIS is a governmental data base and individuals are not entitled to require removal of any data from governmental data bases.²</p> |
| <i>Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?</i> | <p>Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 32.1, 32.4</p> | <p>The current legal regulation does not provide any opt-in or opt-out rules in relation to processing the EHRs. However Section 32.4 of draft RUHIS does provides opt-out rules allowing the patient to prohibit medical institutions to access the data stored in HIS as follows:</p> <ul style="list-style-type: none"> - denying all medical institutions to access all data stored in HIS; - denying all medical institutions to access specific data stored in HIS; - denying certain medical institutions to access all or specific data stored in HIS (according to draft RUHSIS this option will be available only from 1 January 2016); - denying certain medical personnel and medical support person all or specific data stored in HIS (according to draft RUHSIS this option will be available only from 1 January 2016). <p>This would not apply to the health data, which is made inaccessible to the patient by the practitioner due to the reasons described in Law On the Rights of Patients as it is provided in Section 32.1 of the draft RUHSIS).</p> |
| <i>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?</i> | | <p>National legislation provides no requirements to inform the patient about the purpose of EHRs and the consequences of consent or withholding consent on the sharing of EHRs. Also, the draft RUHSIS does not foresee such requirement.</p> |

² Interview No. 4

| Questions | Legal reference | Detailed description |
|---|-----------------|---|
| <i>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)?</i> | | <p>Cross-border issues are not specifically regulated by the national legal framework or draft RUHSIS as regards to implementation of EHR.</p> <p>The HIS is a national initiative. Therefore only practitioners and health institutions of Latvia would be allowed to access patient's EHR.</p> <p>However a patient would be allowed to consent to his EHRs being transferred by a health practitioner or health institution outside of the Member State under the general regulation of data protection provide by the Personal Data Protection Law.</p> |
| <i>Are there specific rules on patient consent to share data on a cross-border situation?</i> | | <p>Cross-border issues are not specifically regulated by the current legal framework or draft RUHSIS.</p> |

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

The draft RUHSIS provides the right to access the EHR on the same conditions as to the regular patient health record. Therefore the access is granted only to the patient and to the health professional providing the medical treatment as well as state institutions (e.g. Immigration service, State Health Inspectorate, NHS) in very limited amount within the scope set by law.

In order to access EHR the health professional will have to be registered as a health professional in a registry kept by State Health Inspectorate. If health professional is no longer registered he has no right to continue the access to EHR. The notion of health professionals under the law encompasses multiple professions, including but not limited to, physicians, nurses and physical therapists whether or not they exercise their activities in public or private practice.

In order to retain control over information flow and data access RUHSIS requires that health professionals to be properly authenticated before acceding to EHRs. Health professionals will have the option to authenticate directly on the eHealth portal or in their own internal systems.

The draft RUHSIS provide the rights for health institutions to automatically access patients' data in EHR if that is necessary to provide medical treatment. Patients reserve the right to access e-governance service internet portal via by registering using bank authentication data or by registering using electronic signature.

Once they will have the access the patients will have the right to restrict the access to their private medical data (they will have the option to choose all data or partial data access restriction and also the scope of subjects allowed to access the data), therefore Latvia has opted to choose "opt-out" approach, which is heavily criticized by Patients' Ombud as being contrary to the notion that patient's data is the sole property of the patient and to process it prior consent should be obtained.³

The general law provides that sensitive documents can also be hidden from the patient in some circumstances and therefore excluded from medical record. Usually this decision is made by multiple doctors that all sign it, however, the interviewed stakeholders indicated that so far the draft RUHSIS does not provide this option as RUHSIS provides that only one person may create information entry on EHR and therefore the draft regulation would need to be further amended.

Under emergency procedures, EHR may be accessed without a patient's prior consent.

³ Interview No. 5

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

| Questions | Legal reference | Detailed description |
|--|---|--|
| <i>Are there any specific national rules regarding who can create and where can EHRs be created?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 21 | <p>Currently there is no specific legislation in force that would regulate EHRs.</p> <p>However, it is planned that pilot phase of HIS will be launched on 1 April 2014, and by then the RUHSIS would have to be implemented. The draft RUHSIS provide that after the launch of HIS, EHRs will be created by health professionals or health institution personnel who have the authorisation to access HIS.</p> <p>The creation of an EHR can be organised in any place and at any time (the reception, the admissions office, care unit, etc.), as soon as a face-to-face with the patient is possible and provided. The time limits to organise the input of information in HIS is specified in draft RUHSIS (3 days for pharmacists, 5 to 14 days for general practitioners and 14 days for hospitals).</p> |
| <i>Are there specific national rules on access and update to EHRs?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 21 to Section 31 | <p>Currently there is no specific legislation in force that would regulate EHRs.</p> <p>However, the draft RUHSIS provide that the access to the EHRs is only allowed to the patient and to the treating health professional. Such access is allowed only if it is necessary to provide medical treatment.</p> |
| <i>Are there different categories of access for different health professionals?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 21 to Section 31 | <p>Currently there is no specific legislation in force that would regulate EHRs and therefore consultation of the patients' health records is possible to the patient and to health professionals within the scope that is necessary to provide medical treatment.</p> <p>Draft RUHSIS provide different data categories to which different level of access is granted to different health professionals. Once access has been granted, the health professional can access all information within the scope defined in RUHSIS (except if it has been restricted by the patient).</p> <p>The patient may exercise his/her right to hide information against several physicians or health institutions. However, in any case, a document is always visible to:</p> <ul style="list-style-type: none"> - the patient him/herself (see below for further information on |

| Questions | Legal reference | Detailed description |
|---|---|---|
| | | <p>exceptions), and</p> <ul style="list-style-type: none"> – the author of the document. |
| <i>Are patients entitled to access their EHRs?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 31 | <p>Currently there is no specific legislation in force that would regulate EHRs and therefore consultation of the patients' health records is possible to the patient as set by general law provisions – allowed unless in special circumstances where it may cause harm to the patient.</p> <p>The draft RUHSIS states that the patient that has authenticated via e-governance service internet portal may access all his medical data in HIS. Moreover, the patient if he is unable to access HIS through national internet portal may upon prior request, access his EHR with the help and in the presence of his general practitioner (family doctor).</p> |
| <i>Can patient have access to all of EHR content?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 31 | <p>Currently there is no specific legislation in force that would regulate EHRs and therefore consultation of the patients' health records is possible to the patient as set by general law provisions – allowed unless in special circumstances where it may cause harm to the patient.</p> <p>The draft RUHSIS states that in certain situations when the health professional has forbidden the access to certain medical data, the patient will not be able to access it on HIS.</p> <p>Apart from this very specific situation, a patient retains access to all documents on his/her EHR.</p> |
| <i>Can patient download all or some of EHR content?</i> | | <p>Currently there is no specific legislation in force that would regulate EHRs and therefore consultation of the patients' health records is possible to the patient as set by general law provisions. According to those the patient has the right to access its medical information and make copies.</p> <p>This question is not detailed in the draft RUHSIS.</p> |
| <i>Can patient update their record, modify and erase EHR content?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 31 Law On the Rights of Patients, | <p>Currently there is no specific legislation in force that would regulate EHRs and therefore consultation of the patients' health records is possible to the patient as set by general law provisions.</p> <p>The draft RUHSIS states that the patient may access his EHR and modify contact information. However, under Section 9 of the Law On the Rights of</p> |

| Questions | Legal reference | Detailed description |
|--|--|---|
| | Section 9(3) | <p>Patients, if patient finds that his personal data is incorrect or inaccurate, patient has the right to immediately contact the healthcare institution that has processed the data. Healthcare institution must immediately check the indicated data and decide on the patient's request (in writing or personally by submitting identification document) whether to correct false or inaccurate data and (or) to stop processing of such data.</p> <p>The patient may not erase any EHR content.</p> |
| <i>Do different types of health professionals have the same rights to update EHRs?</i> | Regulations on United Health Sector Information System, Section 21 to Section 30 | <p>Currently there is no specific legislation in force that would regulate EHRs and therefore consultation of the patients' health records is possible only as set by general law provisions. The current regulation does not specifically establish whether different types of health professionals have the same rights to update patients' health records.</p> <p>However, the draft RUHSIS does not include provisions that would regulate in detail the right to update EHRs. As RUHSIS regulates the right to access and process the data it may be understood as the right to update according to same conditions as access levels. The draft RUHSIS grants access in the amount necessary to provide medical treatment. As opposed, the pharmacists have very limited access to EHRs, therefore the system is created by the principle "need to know".</p> <p>Users of HSI have the access rights only to the data in the extent necessary for their direct activities and in the course of their direct functions.</p> |
| <i>Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians...)</i> | | <p>Currently there is no specific legislation in force that would regulate EHRs and therefore consultation of the patients' health records is possible only as set by general law provisions.</p> <p>Also, the draft RUHSIS does not provide any explicit occupational prohibitions as regards to data of EHRs.</p> |
| <i>Are there exceptions to the access requirements (e.g. in case of emergency)?</i> | | There are no exceptions provided in the currently applicable legislation or in the draft RUHSIS. |
| <i>Are there any specific rules on identification and authentication for</i> | | The draft RUHSIS provide only aggregated rules on identification and authentication for healthcare professionals. |

| Questions | Legal reference | Detailed description |
|---|-----------------|---|
| <i>health professionals? Or are they aggregated?</i> | | |
| <i>Does the patient have the right to know who has accessed to his/her EHRs?</i> | | Every access to the EHR is traced and the patient can obtain this information from the EHR interface without the need to fill in a specific request. ⁴ |
| <i>Is there an obligation on health professionals to update EHRs?</i> | | Currently there is no general obligation to use HIS in Latvia. According to the draft RUHSIS when the agreement with NHS will be concluded, health practitioners will have the obligation to submit relevant information to HIS within certain time limits after the consultation (immediately but no later than 5 days after the consultation or 14 days if in hospital). |
| <i>Are there any provisions for accessing data on 'behalf of' and for request for second opinion?</i> | | Current legislation does not regulate whether accessing data on "behalf of" and for request for second opinion is allowed or subject to specific requirements. This is also not regulated in the draft RUHSIS. |
| <i>Is there in place an identification code system for cross-border healthcare purpose?</i> | | Cross-border issues are not regulated by the current legal framework as the main focus was to create the system that would be used in Latvia. ⁵ |
| <i>Are there any measures that consider access to EHRs from health professionals in another Member State?</i> | | This has not been a consideration during the deployment of the EHR scheme, the main objective being a generalised deployment and use of the scheme in Latvia. |

⁴ Interview No. 5

⁵ Interview No. 4

2.5. Liability

2.5.1. Main findings

The national legislation does not set specific liability requirements related to the use of EHR. Therefore, the general rules on liability are applicable.⁶

Input of information necessary for the coordination of healthcare provided to the patient in an erroneous way (whether this input was negligent, reckless, or intentional) could be considered as professional fault and thus be subject to civil, administrative or criminal liability depending on the seriousness of the infringement.

Currently patients are not entitled to erase health data. After the draft RUHSIS comes into force patients will be entitled to modify, update or erase information on such data that would not impose such risk to result in liability of the patients.

EHR system hosting institutions could be held liable for defect in their security/software systems, if it resulted in damage to any party and if it incurred due to non-compliance with technical and organisational measures required by legal framework in order to protect personal data and to prevent their illegal processing.

⁶ Interview No. 4

2.5.2. Table on liability

| Questions | Legal reference | Detailed description |
|--|--|--|
| <i>Does the national legislation set specific medical liability requirements related to the use of EHRs?</i> | | The national legislation does not set specific medical liability requirements related to the use of EHR. Therefore, the general rules on liability would be applicable. |
| <i>Can patients be held liable for erasing key medical information in EHRs?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 32.2 Criminal Law, Section 244. ¹ | The current legal regulation does not provide patients with the right to erase any health data (only to require the relevant institution to erase them upon certain occasions as prescribed in the Personal Data Protection Law). After the draft RUHSIS comes into force the patient according to Section 32.2 shall be entitled to erase only data provided by the patient him/her-self, which according to draft RUHSIS basically is various contact information. Patient will not be able to erase data in EHR therefore there is no possibility the patient might be held liable. However, if the patient uses unauthorised means to access and modify the content of HSI, then it is a criminal offence under Latvian Criminal Law for unauthorised access to data information systems. |
| <i>Can physicians be held liable because of input errors?</i> | Civil Law, Section 1635, 1775 Latvian Administrative Violations Code, Section 45 ¹ Criminal law, Section 138 | According to Sections 10(1)4) and 29(4)3) of the Personal Data Protection Law the physicians are required to correct the input errors or the Data State Inspectorate will forcefully correct them. However mandatory laws do not foresee any liability for input errors unless these errors have caused any damage. Input of information necessary for the coordination of healthcare provided to the patient in an erroneous way (whether this input was negligent, reckless, or intentional) could be considered a professional fault subject to liability. Depending on the seriousness of the consequences of the infringement the practitioner may be subject to civil, administrative or criminal liability. |
| <i>Can physicians be held liable because they have erased data from the EHRs?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 3.3 Civil law, Sections 1635, 1775 Latvian Administrative | Under the current legal regulation practitioners could be held liable because they have erased data from health records. Erase of the data (whether it was negligent, reckless, or intentional) could be considered a professional fault subject to liability. However after the draft RUHSIS comes into force situation may change, because according to Section 3.3 the NHS must ensure archiving of all the erased data from the EHRs. Therefore the data erased from the EHRs will still be available in HIS. |

| Questions | Legal reference | Detailed description |
|---|---|---|
| | Violations Code, Section 45 ¹ Criminal law, Section 138 | In any case the practitioner shall be held liable, if such erase has been unauthorised and has caused any damage to patients. |
| <i>Are hosting institutions liable in case of defect of their security/software systems?</i> | Personal Data Protection Law, Section 25(1) Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 3.1.4 | Section 25(1) of the foresees that a data controller and data processor have the duty to use the necessary technical and organisational measures in order to protect personal data and to prevent their illegal processing. According Section 3.1.4 of the draft RUSHIS the NHS determines the safety and technical standards, which shall be foreseen in the agreement between NHS and the practitioner or medical institution. Practitioners may access HIS either directly online or through their local EHR systems in place ⁷ therefore requirements for security and software systems may differ. In any case the NHS and the practitioners or medical institutions could be held liable for a defect of their security/software systems, only if it resulted in some damage and it was caused due to the noncompliance with the necessary technical and organisational measures as foreseen by Section 3.1.4 of the draft RUSHIS or other legal requirement regulating technical and organisational measures of the security or software systems used for EHRs. |
| <i>Are there measures in place to limit the liability risks for health professionals (e.g guidelines, awareness-raising)?</i> | | Current national legislation does not provide specific measures limiting the liability risks for health professionals. However it would be advisable to create guidelines on health data protection for health professionals. ⁸ |
| <i>Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?</i> | Latvian Administrative Violations Code, Section 204 ⁸ | Current national legislation does not provide liability rules related to the breach of access to EHRs. Only general requirements of data protection are applicable in such case. If a person is denied access to its personal data, the data processor or controller may be held liable for withholding information from the data subject, which the data subject has the right to receive. |
| <i>Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?</i> | | Current national legislation does not provide an obligation on health professionals to access EHRs prior to take a decision involving the patient. |
| <i>Are there liability rules related to the</i> | Civil Law Sections 1635, | Under Latvian legislation there are no specific rules in regard with misuse of |

⁷ Interview No. 3

⁸ Interview No. 5

| Questions | Legal reference | Detailed description |
|--|---|---|
| <i>misuse of secondary use of health data?</i> | 1775 Administrative Violations Code, Section 204 ⁷ Criminal law, Section 145 | secondary use of health data. General rules on misuse of health data in such situation would apply. Misuse of health data may be subject to civil, administrative and criminal liability. |

2.6. Secondary uses and archiving durations

2.6.1. Main findings

The Latvian legislation provides requirement that patient's personal medical data should be kept up to 75 years.⁹ There are no other provisions that would be applicable only to EHR.

The draft RUHSIS ensures that health data kept in HIS might be used for secondary purpose (eg scientific research or statistics) under particular conditions. More detailed list regarding allowed secondary use of the patient's medical data is included in the Law on the Rights of Patients. It provides obligation to disclose such information to state institutions and courts when it is necessary to protect other interests protected by law, it might also be disclosed for scientific research, state health surveys and statistical data collection.

⁹ Cabinet of Ministers Regulations No 265 of 4 April 2006 on "The Procedures for the record-keeping of medical documentation"

2.6.2. Table on secondary uses and archiving durations

| Questions | Legal reference | Detailed description |
|---|--|--|
| <i>Are there specific national rules on the archiving durations of EHRs?</i> | Cabinet of Ministers Regulations No 265 of 4 April 2006 on “The Procedures for the record-keeping of medical documentation”, Chapter V | Latvian legislation does not provide specific rules on the content of EHRs yet therefore there are no specific regulations on the archiving durations of EHRs. Moreover the draft RUHSIS is in the process of development and its current version provides an indication that there will not be specific rules on the content of EHRs. Therefore the general requirement to keep medical records up to 75 will be applicable. |
| <i>Are there different archiving rules for different providers and institutions?</i> | Cabinet of Ministers Regulations No 265 of 4 April 2006 on “The Procedures for the record-keeping of medical documentation”, Chapter V | The rules related to the archiving durations of EHR data are general and applicable to all providers and institutions similarly. |
| <i>Is there an obligation to destroy (...) data at the end of the archiving duration or in case of closure of the EHR?</i> | | Legal regulation provides obligation to destroy data at the end of the archiving duration under the particular conditions. However it does not provide obligation to destroy data in case of closure of the EHR. According to stakeholder, the same obligation applies to paper files and EHR, therefore if there is closure of EHR the medical records should be printed out and kept in paper files. |
| <i>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?</i> | Archives Law, Section 7 | Section 7 of the Archives Law provides that the documents kept in institutions that are subject to liquidation and to which the retention period has not expired have to be transferred to the legal successor. If there is no legal successor then the documents must be transferred to the State Archives. This would apply in case there is closure of EHR. |
| <i>Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?</i> | Personal Data Protection Law, Section 11 Law on the Rights of the Patients, Section 10(7) | The general rules on the secondary use of health data are set under Personal Data Protection Law which allows disclosure of personal data for scientific purposes. The Law on the Rights of the Patients provides more detailed list of exceptions when medical data may be used for secondary purposes, for example, there is obligation to disclose such information to state institutions and courts when it is necessary to protect other interests protected by law, it might also be disclosed for scientific research, state health surveys, statistical data. The data may be used in scientific research only if the patient cannot be directly or indirectly identified according to the information to be analysed; or the patient has consented in |

| Questions | Legal reference | Detailed description |
|---|--|---|
| | | writing that the information regarding him or her may be used in a specific trial. |
| <i>Are there health data that cannot be used for secondary use?</i> | | All personal health data can be used for secondary use subject to requirements set under the law. |
| <i>Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?</i> | Personal Data Protection Law, Section 11 Law on the Rights of the Patients, Section 10(7) | Non-anonymised data cannot be used for secondary purpose apart under very specific circumstances. Furthermore the result of the use of these data must be presented in such a way (e.g. aggregated data) that individuals concerned cannot be identified. |
| <i>Does the law say who will be entitled to use and access this data?</i> | | As regards to use and access of the health data legal regulation does not say who will be entitled to use and access this data. For scientific research in some cases a permit or authorization may be needed. |
| <i>Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?</i> | | Without the data subject's consent, personal data may be processed for the purposes of scientific research only. There is no "opt-out" option with regards to medical data and its secondary use under the existing regulation. |

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

EHR system in Latvia is planned to be centralised and all medical data shall be found in the HIS. The HIS shall consist of aggregation of several other systems such as EHRs, ePrescriptions and e-booking. However the interface of HIS shall look like a one centralised system.¹⁰ HIS shall gather data from other state data bases and eventually become the only one being used in the field of health. Medical institutions and practitioners shall be able to connect to HIS in two ways: either directly, or by adapting their own local EHRs system. Most of the practitioners shall use the second method, because the list of information to be entered into HIS is limited (see Section 2.1) and connection directly to HIS would be lengthier.¹¹

The development of HIS is at its 1st phase and the work on interoperability of national EHRs with other Member States EHRs systems shall begin only in the 2nd phase. Therefore there is no legal framework on interoperability of national EHRs with other Member States EHRs systems yet.

¹⁰ Interview No. 4

¹¹ Interview No. 1, 2, 3

2.7.2. Table on interoperability of data requirements

| Questions | Legal reference | Detailed description |
|--|---|--|
| <i>Are there obligations in the law to develop interoperability of EHRs?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 38 | Current legal regulation does not provide any obligations to develop interoperability of EHRs. However Section 38 of the draft RUHSIS foresees an obligation for medical institutions and pharmacies to conclude the agreement with NHS on usage of HIS no later than till 31 December 2015. Furthermore the draft RUHSIS regulates, which information and when must be added to HIS by the health institutions and pharmacies. |
| <i>Are there any specific rules/standards on the interoperability of EHR?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 6.17.2 | Health institutions and practitioners upon filing in information in EHRs are obliged to use such classifiers as SSK-10, NOMESCO un NCSP+ in order to provide interoperability of EHRs. |
| <i>Does the law consider or refer to interoperability issues with other Member States systems?</i> | | Cross-border issues are not regulated by the current legal framework or the draft RUHSIS. However the first thing, which needs to be done, is harmonisation of classifiers with other Member States. ¹² |

¹² Interview No. 4

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

EHR and ePrescription are designed as separate databases of HIS. However at the same time these data bases shall be inter-connected and introduced in HIS. HIS will show both – information provided in EHRs and information provided in ePrescriptions depending on the level of authorisation of the user.

Practitioners and health institutions in HIS shall have access both to EHRs and ePrescriptions, whereas pharmacists shall only have access to ePrescriptions.

2.8.2. Table on the links between EHRs and ePrescriptions

- *Infrastructure*

| Questions | Legal reference | Detailed description |
|--|--|--|
| <i>Is the existence of EHR a precondition for the ePrescription system?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 7 | EHR and ePrescription shall be designed as separate databases, however these data bases shall be interconnected in HIS. When using HIS these data bases shall appear with one interface. ¹³ Thus the existence of EHR is not a precondition for the ePrescription system. |
| <i>Can an ePrescription be prescribed to a patient who does not have an EHR?</i> | | This is not regulated by the current legal framework or the draft RUHSIS. |

- *Access*

| Questions | Legal reference | Detailed description |
|--|---|--|
| <i>Do the doctors, hospital doctors, dentists and pharmacists writing the ePrescription have access to the EHR of the patient?</i> | Draft Cabinet of Ministers Regulations on United Health Sector Information System, Section 11.6, Annex No 5 | Pharmacists will not have access to EHRs on HIS. They will have access to ePrescriptions. Pharmacists and their assistants will be able to review information on the ePrescription regarding the patients name, information on the issuer of ePrescription, main ePrescription data, diagnose, special conditions, the prescribed medicine and usage indications. The pharmacist and their assistants will be obliged provide information regarding the provided medicine to the patient. The pharmacists and their assistants shall be able to view only valid and open prescriptions, not any past ones. |
| <i>Can those health professionals write ePrescriptions without having access to EHRs?</i> | | Health professionals will be working also in their local EHR system, which shall synchronise with HIS. Therefore it is not obligatory for them to have direct access to HIS in order to write an ePrescription. Whereas pharmacists shall have no access to EHRs at all. |

¹³ Interview No 4

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

The feedback of Latvian stakeholders on the current development of ERHs differed. The general consensus was that the eHealth as a concept is necessary in Latvia, because it would ease work with patients and retention of their health data and the patients would more conveniently access their health information. However the stakeholders, who provide health care and who would be using the EHRs, were not satisfied with the current development of EHRs and the system through which the EHRs would be accessed - HIS.¹⁴ And the Patients' Ombud Office expressed their concern about the opt-out approach for setting up EHRs.¹⁵

- **Good practices for the development of EHRs in Latvia**

The Latvian authorities are very optimistic about launching pilot phase of EHRs on 1 April 2014 and HIS actually will be more user friendly than expected.¹⁶ However it has been nearly a decade since “Guidelines for eHealth in Latvia” has been ratified and the launching date moved further away. Therefore it is too early to tell what are the good practices for the development of EHRs in Latvia, because the system has not been launched yet.

The effectiveness and universality of EHRs system would be ensured due to the fact that that the patients consent would not be required for the set-up of his/her EHR as it will be established as a legal obligation of the data controller to process such data under the laws. The patients shall have opt-out option in order to hide health data from health institutions or practitioners, if they wished.¹⁷

- **Potential legal barriers for the development of EHRs in Latvia**

The list of information to be provided in HIS is exhaustive. But different doctors need access to different information, therefore the information to be included in HIS should be broader.¹⁸ Otherwise this is one of the reasons why practitioners and health institutions will be forced to use a local EHRs system and connect it to HIS.¹⁹ An additional reason to implement local EHRs will be the fact that working online in HIS is more time consuming than in a local EHRs system and the authorisation procedure to access HIS is rather complex (for example, during the same visit a practitioner must repeatedly authorise to HIS, if the practitioner needs to issue a prescription for the patient). And also, this is one of the major concerns of the stakeholders, that the time frame to access to patients EHRs is too short and situations may incur where the authorisation must be carried out again. The state covers the costs of implementing HIS, however the state will not cover the costs on acquiring local EHRs systems or connecting the existing local EHRs systems to HIS.²⁰

The usage of a local EHRs system and HIS also creates a problem that the health data, which does not need to be transferred to HIS must be retained by the practitioners and health institutions, which do not have as much memory space in their computers as HIS does in its server. Therefore the retention period of data not transferred to HIS should also be revised.²¹

According to provisions in the draft RUHSIS the patient will have access to all information in his/her EHR, however the practitioner is entitled to hide certain information, if it believes that such

¹⁴ Interview No. 1, 2, 3

¹⁵ Interview No. 5

¹⁶ Interview No. 4

¹⁷ Interview No. 4

¹⁸ Interview No. 2

¹⁹ Interview No. 3

²⁰ Interview No. 3

²¹ Interview No. 3

information imposes a serious risk on the patient's or other person's life or health. At the same time the legal framework does not provide a mechanism in HIS to be used for hiding patient's health data, which imposes a threat on patients' rights to receive health data.²² Also Patients' Ombud Office considered the opt-out approach in implementing EHRs to be unsafe because it imposes a greater risk on patients confidentiality than the opt-in option.²³

At the moment it is not yet clear how the interoperability in cross-border cases would be ensured. HIS is created mainly for medical data transfer in Latvia.²⁴ The main issue raised by the related subjects is the unification of the language and classifiers used in the national systems of the Member States.²⁵ Furthermore it is not clear what will be required from the health practitioners to ensure the use of EHR as each of them had a very different understanding of the situation and the requirements.²⁶

One of the main issues regarding local and cross border interoperability of EHRs are classifiers. The SSK-10 diagnostic classifiers, which are used locally, are not absolute.²⁷ In case of cross border interoperability the SSK-10 diagnostic classifiers are not consistent with the SNOMED diagnostic classifiers used abroad, therefore interoperability of health data is not yet possible, while diagnostic classifiers for cross border interoperability are established.

And finally the lack of consensus on various practical, technical, operational and financial issues between the practitioners and institutions responsible for implementing eHealth, although not legal, is also a barrier.

²² Interview No. 5

²³ Interview No. 5

²⁴ Interview No. 4

²⁵ Interview No. 3, 5

²⁶ Interview No. 1, 2, 3

²⁷ Interview No. 3, 5