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 SLOVAKIA

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Milieu Ltd. (Belgium), rue Blanche 15, B-1050 Brussels, tel: +32 2 506 1000; fax: +32 2 514 3603; florent.pelsy@milieu.be; web address: www.milieu.be

Executive Summary

1. Stage of development of EHRs in Slovakia

Slovakia only recently started preparing an Electronic Health Records (EHRs) system providing for a single database operated by the competent administrative body.

In 2013, new legislation was adopted giving legal base for the development and deployment of an eHealth Programme in the Slovak Republic. Act No 153/2013 Coll. on the National Health Information System (NHIS) amended all the key legal regulations in the health care area in order to enable the execution of the National eHealth Implementation Programme. The Act on the NHIS has also given the legal definitions of Electronic Health Book (i.e. EHRs) and Patient's Summary.

From 1 January 2017 all health care providers (i.e. individuals in private practice and institutions) will be obliged to record the patient's health data into his file in the Electronic Health Book on the provided health care.

The main competent authorities responsible for implementation of the National eHealth Implementation Programme in the Slovak Republic are the Ministry of Health and the National Health Information Centre.

2. Summary of legal requirements applying to EHRs

The Slovak national legislation provides an exhaustive list of the health data to be included in the Electronic Health Book, including the data to be contained in the Patient' Summary. These data are not limited only to medical information but also contain other information related to the patient and his well-being.

There are also detailed legal rules on the institutions hosting EHRs in terms of how they operate and the security requirements they need to comply with. The information system of the health care provider will have to be certified by the National Health Information Centre to ensure that it complies with the informatics standards in health care.

The consent of the patient to process his personal data is not required by law. There is a legal obligation to set up an Electronic Health Book and therefore the patient's file is created and processed independently of his consent.

Every time the patient receives health care services his EHR will be obligatory updated by the health care provider via his own information system. The access to the patient's Electronic Health Book is only possible once the patient inserts his insurance card with an electronic chip into the electronic devise of the health care provider.

There are no specific liability rules enacted in the national legislation relating to malpractice with EHRs. The general liability rules of the Civil Code are therefore applicable.

All the data gathered in the NHIS are given to the Ministry of Health, Ministry of Finance and to the Statistical Office for statistical purposes, but they must be sent in an anonymous form.

All the data are stored in a central database operated by the National Health Information Centre. For that purpose, health care providers will have to use information systems that have been certified by the National Health Information Centre, and that comply with the legal regulations with regards to connectivity standards, security standards and identification and authentication of health professionals.

It should be noted that national legislation does not foresee the interoperability among EU Member States yet.

ePrescriptions are part of the EHRs contained in the Electronic Health Book of the patient. They form integral part of the EHRs and cannot be used independently.

3. Good practices

No good practices have been identified as there is no EHR system already in place in the Slovak Republic.

4. Legal barriers

The main legal barrier identified relates to the interoperability of the EHRs with other EU Member States, as the Slovak national legislation does not foresee the possible data sharing with health professionals from other EU Member States.

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List of abbreviations

EHRs	Electronic Health Records
NHIS	National Health Information System

1. General context

1.1. EHR systems in place

The delay of the Slovak Republic in comparison with other developed countries concerning eHealth activities is estimated to be 7-10 years.[1] Slovakia's answer to tackle this problem was the adoption of the National eHealth Implementation Programme. In 2008, the Ministry of Health started the preparation of the National eHealth Implementation Programme with the government's approval of the eHealth Strategic Goals.

The National eHealth Implementation Programme was finally adopted in 2009 and updated in February 2011 and is a strategy aimed at the digitalisation of health services and comprises several implementation stages. Each stage has one fundamental project and several support projects.

The fundamental project for stage 1 is the national project "Electronic Health Services" financed from the European Structural Funds through the Operational Programme "Information Society". The project is to be completed by the end of September 2015.

This project includes:

- the launch of a National Health Portal with basic information related to health, illnesses and medical and health care;
- the development and launch of the following applications (within pilot operation): Electronic Health Book, Electronic prescription, Electronic medication, eAllocation – Management of laboratory examination and vaccination;
- the creation of conditions for the integration of health care providers information systems (IS HCP) in a national system .

The fundamental project planned for stage 2 is the national project "National Health Information System" (NHIS) also financed from European Structural Funds through the Operational Programme "Information Society". This project should start by the end of 2015.

This project includes:

- the integration of all health care providers in the NHIS;
- the extension of functionality and full utilisation of: National Health Portal, Electronic Health Books, ePrescription, eMedication, eAllocation for the benefit of citizens and health professionals;
- the preparation of new eHealth domains (PACS, telemedicine, genomics and others).[2]

On 17 May 2013 Slovakia adopted Act No 153/2013 Coll. on the NHIS that gives legal grounds for the implementation of eHealth services in Slovakia, including Electronic Health Books and ePrescriptions. The purpose of this Act is to create a legislative framework for the digitalisation of health care enabling the creation and operation of the NHIS.

The Act on the NHIS has also amended all the key laws relating to the provision of the health care (the list is provided below). The system is still in a preparatory phase but it should be effective and obligatory from 1 January 2017. In the transition period the use of the system will be optional.

[1] This information was gathered from the official web page on eHealth in Slovakia http://www.ezdravotnictvo.sk/en/eHealth_Programme/Pages/default.aspx

[2] This information was gathered from the official web page on eHealth in Slovakia http://www.ezdravotnictvo.sk/en/eHealth_Programme/Pages/default.aspx

The Electronic Health Book is defined as an ensemble of data from the medical documentation of the person which is kept in the national registry of Electronic Health Books in accordance with the Act on the NHIS. General physicians must record medical documentation of the patient and specialized physician records only medical documentation in the scope of provided health care. This obligation is enacted in the Act No 576/2004 Coll. on health care. The patient will also be entitled to insert or erase data in the Electronic Health Book only within the section "Personal records of the patient". Otherwise the patient will have only read access to Electronic Health Book through the National Health Portal.

1.2. Institutional setting

The main institutions involved in the development and deployment of the EHR scheme in Slovakia are:

A. Ministry of Health

The Ministry of Health is the central state administrative body in the area of, *inter alia*, health care, health protection, public health insurance and continuous training of health professionals. As such, it is responsible for overseeing the execution of the National eHealth Implementation Programme in the Slovak Republic.

B. National Health Information Centre

The National Health Information Centre is a state contributory organization, which was established by the Ministry of Health. It has competences in the area of health service informatics, standardization of information systems on health services and its tasks include the collection, processing and provision of health statistical data. It is also the operator of the NHIS.

C. The Office of Personal Data Protection

The Office of Personal Data Protection was established on 1 September 2002 under Act No. 428/2002 Coll. on Protection of Personal Data, later repealed and replaced by Act No. 122/2013 Coll. on Personal Data Protection, transposing 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. The Office is the supervisory body overseeing the compliance with the laws of the Slovak republic and legally binding acts of international law on the protection of personal data of individuals. It contributes to the protection of fundamental rights and freedoms of individuals with regard to the processing of their personal data as guaranteed by the Constitution of the Slovak republic.

According to the Act on the NHIS the data processed pursuant to this Act, i.e. data covered by the Electronic Health Books, shall be governed by the Act on Personal data Protection, therefore the Office of Personal Data protection of the Slovak Republic is the competent supervisory body.

1.3. Legal setting and future legal developments

EHRs are regulated by the Act on the NHIS, which provided the legal base for the development and deployment of the eHealth Programme in the Slovak Republic and defined some of its key elements such as Electronic Health Book, Patients Summary and Electronic Health Record.

This Act defines the NHIS as a set of health information systems for the collection, processing and dissemination of information in health care; the National Health Portal is also part of the NHIS. The Act on the NHIS also stipulates how the data from the NHIS should be available to individual stakeholders, as well as the standardisation of the medical information and the requirements on data hosting institutions and their integration with the database of the NHIS.

The Act on the NHIS amended Act No 580/2004 Coll. on health insurance. Effective from 1 July 2014, the amended Act on health insurance defines key elements of the new insurance card with electronic chip and provides that until 31 December 2016 each health insurance company must send to its public health policyholders a new insurance card with electronic chip. From 1 January 2017 each public health policyholder must carry the insurance card with electronic chip and insert it in the technical device of the provider of health care in each medical appointment.

The Act on the NHIS also amended Act 578/2004 Coll. on health care providers From 1 January 2017 all health care providers must use information systems that have been certified by the National Health Information Centre. After each medical appointment the health professional must update the patient's Electronic Health Book. Each health professional has its own electronic identification card issued by the National Health Information Centre which should be used to access the NHIS, therefore all the changes in the Electronic Health Book are traceable.

Furthermore the Act on the NHIS amended Act No 362/2011 Coll. on medicine and medical devices. Pursuant to this act, from 1 January 2017, pharmacists must also use an information system that has been certified by the National Health Information Centre.

It should be noted that although legal framework for the eHealth system is set already by the Act on the NHIS, the implementing decrees and ordinances of the Ministry of Health are still in the preparatory phase and have not yet been published.

List of relevant national legislation:

- **Act No 153/2013 Coll. on the NHIS**

The Act on the NHIS is the basic legislative pillar for the development and deployment of EHRs in Slovakia. It also provides the requirements for data hosting institutions and the procedure for the certification of the information systems of the health care providers. Furthermore, it provides the legal base for the creation of national health registries, *inter alia*, the National Register of Electronic Health Books.

- **Act No 576/2004 Coll. on health care, services related to provision of health care and on changes and amendments of certain acts as amended**

The Act on health care, services related to provision of health care and on changes and amendments of certain acts regulates medical documentation in general (both in paper and electronic format) and gives the Ministry of Health supervisory powers over the National Health Information Centre.

- **Act No 578/2004 Coll. on health care providers, health professionals, professional organization in health care and on changes and amendments of certain acts as amended**

This Act regulates the obligations of the health care providers related to EHRs.

- **Act No 579/2004 Coll. on emergency medical service and on changes and amendments of certain acts as amended**

This Act requires operators of the emergency medical services to use information systems that have been certified by National Health Information Centre and to use technical devices enabling their authentication in the NHIS

- **Act No 580/2004 Coll. on medical insurance and on changes and amending Act No 95/2002 Coll. on insurance and on changes and amendments of certain act as amended**

This Act creates the insurance card with the electronic chip, defines the content of the insurance card and regulates the obligations of the insurance health companies in this respect.

- **Act No 581/2004 Coll. on health insurance companies, health care supervision and on changes and amendments**

This Act stipulates the reporting obligations of the health insurance companies relating to data that must be part of the national medical registries.

- **Act No 362/2011 Coll. on medicine and medical devices and on changes and amendments of certain acts.**

According to this Act pharmacist must also use information system that has been certified by the National Health Information Centre and pharmacist must ask the patient to prove his identity with the insurance card with electronic chip otherwise the medicine will not be given to the patient.

- **Act No 122/2013 Coll. on protection of personal data and on changes and amendments certain acts as amended**

The Act on protection of personal data provides the legal framework and sets the requirements on protection of personal data including those gathered during the provision of healthcare. This Act transposes 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.

2. Legal requirements applying to EHRs Slovakia

2.1. Health data to be included in EHRs

2.1.1. Main findings

The definitions of EHR, Electronic Health Book and Patient's Summary are all provided in the Act on the NHIS. The Act on the NHIS also provides a detailed list of the health data to be included in the patient's Electronic Health Book. This list covers information on medical examinations, emergency health care, etc. The information to be included in the Patient's Summary (which is part of the Electronic Health Book) is also defined by law and refers to *inter alia* blood type, allergies or record of vaccines.

The national legislation refers to the terminology and codes of the List of diseases adopted pursuant to the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Geneva, WHO, Vol. 1. 1992 (updated version) and pursuant to the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision - German Modification Version 2011.

Each public health policyholder will have its own unique insurance card with electronic chip issued by the particular health insurance company, based on which the patient will be identified in the NHIS.

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?)	Act on the NHIS, Art. 5	Article 5 of the Act on the NHIS provides an exhaustive list of the data to be included in the Electronic Health Book.
Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?	Act on the NHIS, Art. 5	The information contained in the Electronic Health Book 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?	Act on the NHIS, Art. 2, Para. 6, 7 and 9	The Act on the NHIS contains the legal definitions of Electronic Health Book, Patient's Summary and EHR: - **Electronic Health Book** is a set of personal medical records kept in the National Register of electronic health books. - **Patient's Summary** is the part of the electronic health book containing basic information about the health status of a person for the purposes of providing health care. - **EHR** is a record of the health professional in an electronic health book in the form of an electronic document signed by electronic signature.
Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?	Act on the NHIS, Art. 5	The Act on the NHIS provides a detailed list of the data to be included in the **Electronic Health Book**: a. **identification data of the person** involving name and surname, birth surname, date of birth, unique birth number, gender, permanent residency (address, municipality, zip code), contact details (land line/mobile telephone, contact address), and the code number of health insurance company; b. **patient's summary** (please see below), c. **record on preventive examination** involving date of the examination, code of the medical service, list of examinations and period of preventive examinations, numerical code, name and surname of the physician, the code number, and name and surname or business name of the health care provider, d. **record of the request for examinations of common diagnostic and treatment components** including a description of the sample: date of

Questions	Legal reference	Detailed description
		request issue, the scope of required tests, a description of the sample taken, code number, name and surname of the physician, code and name or business name of health care provider that issued the request, and epicrisis of health status; e. **record on the result of the examinations of common diagnostic and treatment components** including code number, name and surname of the physician and the code number and name and surname or business name of the health care provider who requested the examination, code number of the provider of common diagnostic and treatment components that carried out the examination, code number of the examination, examination results or conclusion of the examination, the date of examination; f. **record on action in provision of emergency health care**; g. **record on the referral for specialized medical care** including code number, name and surname of the physician and code number and name and surname or the business name of the health care provider, a brief description of the current state of health, a preliminary determination of the disease, including its code, the scope and purpose of the examination and a justification for the referral, date of issue of the referral, in case the health care is covered by public health insurance; h. **record on the referral for admission to hospital health care** including code number, name and surname of the physician and the code number and name and surname or business name of the health care provider, a chronological description of the development of health, an overview of current treatment, data necessary for further provision of health care, a preliminary determination of the disease including its code, date of issue of the referral, in case the health care is covered by public health insurance; i. **record on the provided ambulatory health care** including code of the disease with its detailed specification, code of health care service provided, referral for further treatment, code number, name and surname of the physician and the code and name and surname or business name of the healthcare provider, referral from a physician specialist in the specialized field for a general practitioner, if required by the patient's condition and its further treatment, the date provided of ambulatory health

Questions	Legal reference	Detailed description
		care; j. **record on release of a person from institutional health care** including code number, name and surname of the physician and the code number and name and surname or business name of the health care provider, code number of the operation if provided, code number of the disease on the date of admission and code number of the disease on the date of discharge, data about treatment during the provision of institutional health care and referral for further treatment, data on the duration of the institutional health care provided, including the date of admission and release; k. **prescriptive record** pursuant to Annex 2 of the Act on the NHIS; l. **dispensing record** pursuant to Annex 2 of the Act on the NHIS; m. **medication record** pursuant to Annex 2 of the Act on the NHIS; n. **data from the account of the public health policyholder** pursuant to Annex 2 of the Act on the NHIS; o. **own personal records of the person**; p. **record on access and provision of data and any attempt to access or provide data**. In addition, Article 6 of the Act on the NHIS also provides a list of the data to be included in the **Patient's Summary**: a. data on blood group and Rh factor, if the data is known; b. code of active implanted medical devices, if the data is known; c. information on custom made dental medical device, if the data is known; d. information on allergic history, if the data is known; e. record on the vaccinations including vaccination date, type of vaccine, code and name of the immunological medicine provided, and cancelation of vaccination, if the data is known; f. data on general practitioner with whom the person has concluded an agreement for the provision of health care, the name, surname and address of the place of business, health care professional code, name and code of the healthcare provider, telephone number and electronic mail address, g. information on a contact person designated by the person including name, surname, telephone number and electronic mail address, if he data is

Questions	Legal reference	Detailed description
	Act on the NHIS, Article 6	known; h. identification data of the health insurance company, i. date and time of the last update of the Patient's summary; j. information on prescribed, administered and dispensed medicines from prescribing records, dispensing records or medication records for the past six months including drug code, drug name, amount of drug in a single dose, dosage form, frequency of use, route of administration, dosage form, duration of treatment, date of prescription, drug issue date or the date of administration; k. code of disease according to the International Classification of Diseases with its detailed specification for the diseases of the patient in the past six months.
Are there any specific rules on the use of a common terminology or coding system to identify diseases, disorders, symptoms and others?	Act on the NHIS, Art. 6	Pursuant to Art. 6 Para. 1 letter k) of the Act on the NHIS, in the Patient's Summary diseases should be identified according to the codes of diseases defined in the International Classification of Diseases with its detailed specification for the diseases of the patient in the past six months.
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)?	Act on the NHIS, Art. 6 and 7	EHRs are not divided into categories of health data with different levels of confidentiality. Nevertheless, Articles 6 and 7 of the Act on the NHIS provide a categorisation of health professionals with different types of access to the health data contained in the Electronic Health Book.
Are there any specific rules on identification of patients in EHRs?	Act on Health Insurance, Art. 22, Para. 2, letter j)	Each policyholder (i.e. patient) must carry an insurance card with electronic chip and insert it into the technical device of the health care provider in each medical appointment. The patient is then identified in the system and the data from the Electronic Health Book will be available to the health care provider.
Is there is a specific identification number for eHealth purposes?		There is no specific identification number for eHealth purposes. The patient is identified by his unique birth number.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

The Act on the NHIS defines the standards of medical informatics. These must ensure the unity, security and integrity of information and communication technologies in health care.

Standards and norms in the area of health informatics and statistics are within the competency of the Ministry of Health. The Act on the NHIS empowers the Ministry of Health to adopt an implementing generally binding legal regulation on standards of medical informatics. Nevertheless, the general standards on public sector digitalisation are also binding for the digitalisation of medical services. As the coordinator of the public sector digitalisation standards is the Ministry of Finances, the law requires the Ministry of Health to adopt standards in medical informatics in close cooperation with the Ministry of Finance. No proposal for standards in medical informatics has been adopted so far.

Institutions hosting EHRs (i.e. health care providers) must use an information system that has been verified by the National Health Information Centre and which complies with the legal regulations with regards to connectivity standards, security standards and identification and authentication of health professionals. It should be noted that the implementing legal regulation of the Ministry of Health detailing the requirements to be verified has not yet been adopted.

Furthermore there is a legal obligation for each health care professional to have an identification electronic card issued by the National Health Information Centre. This card serves for the identification, authentication and authorisation of the health care professional in the information system of the health care provider and in the NHIS.

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?	Act on the NHIS, Art. 9 and 14	Article 9 of the Act on the NHIS regulates the standards of medical informatics. The standards of medical informatics must ensure unity, security and integrity of information and communication technologies in health care. The data stored in medical information systems must be understandable, clear and conclusive and must provide accurate information about the recorded facts. The data to be included in the NHIS must be provided in electronic form. Article 14, Para. 2 of the Act on the NHIS provides the legal base for an implementing generally binding legal regulation on standards of medical informatics to be adopted by the Ministry of Health based on the agreement with the Ministry of Finances. Such a regulation has not yet been adopted.
Is there a need for a specific authorisation or licence to host and process data from EHRs?	Act on the NHIS, Art. 7 and 11	Article 11 of the Act on the NHIS regulates the verification of the compliance of the information system of the health care provider with the standards for connection with the NHIS by the National Health Information Centre. The legal requirements on the information system of the health care provider are as follows: a. must be clearly identifiable and include the information system business name, version number, and the name or trade name of the manufacturer, b. must provide unambiguous identity of the user, c. must meet the requirements for the design and use of electronic signatures, d. must meet the data processing standards of medical informatics, e. must allow the use of the health professional electronic card, the insurance card with an electronic chip or civic identification card with an electronic chip, f. must ensure that the document that is sent to the NHIS is dated, g. must ensure that data between the NHIS and the information system of the health care provider are transmitted without compromising their integrity. Furthermore pursuant to Article 7 of the Act on the NHIS there is a legal

Questions	Legal reference	Detailed description
		obligation for each health professional to have an identification electronic card issued by the National Health Information Centre. The identification electronic card of the health professional serves for the identification, authentication and authorisation of the health professional in the information system of the health care provider and in the NHIS. According to the Act on the NHIS a generally binding legal regulation issued by the Ministry of Health of the Slovak Republic must set the details on requirements for the verification of compliance of the information system of the health care provider with the NHIS. It should be noted that such a legal regulation has not yet been adopted.
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)?		There are no other obligations than those provided above. The general requirements pursuant to the Act on Protection of Personal Data (transposition of Directive 95/46/EC) are applicable.
In particular, is there any obligation to have the information included in EHRs encrypted?		None identified. Nevertheless, EHRs records transmission is encrypted. Based on the interview with the spokesman of the National Health Information Centre, the technical solution for storing EHRs is based on the separation of the clinical data from the identification data of the patient. These two types of data are also stored in separate databases and even the administrators of the databases will not be able to interconnect them. The data interconnection in these databases is also encrypted.
Are there any specific auditing requirements for institutions hosting and processing EHRs?		Specific auditing requirements might be established by the implementing Decree of the Ministry of Health detailing the requirements on the verification of the information systems of the health care, which has not yet been adopted. Nevertheless, according to its spokesman, the National Health Information Centre, as the operator of the NHIS, would welcome the auditing of the Institutions who host EHRs data or the establishment of a validation period for the certifications awarded.

2.3. Patient consent

2.3.1. Main findings

The national system of EHRs in the Slovak Republic is based on the mandatory creation of the Electronic Health Book for each patient involved in the public health insurance system. From 1 January 2017 each health professional will be obliged to create an EHR (which should be signed electronically) immediately after the provision of health care, independently of the patient's consent. The Act on Personal Data Protection does not require consent of the data subject in case of provision of health care.

Specialised physicians do not have the same access to the EHRs of the patient as the general physician with whom the patient has concluded an agreement for the provision of health care. In case the patient wishes that a specialised physician accesses all the contents of his Electronic Health Book, he must give his consent by providing the health professional with a security code for that purpose. The specialised physician will have full access to the Electronic Health Book during the period of time the insurance card is inserted in the electronic devise of the health provider and as long as the correct security code has been inputted.

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?	Act on the NHIS, Art. 5	The creation of an Electronic Health Books is mandatory for each public health policyholder within the territory of the Slovak Republic
Is a materialised consent needed?		Please see above.
Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?		None identified.
Are there specific national rules on consent from the patient to share data?		None identified.
Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?	Act on the NHIS, Art. 5	There are opt-in rules for patient consent but only in relation to granting access to specialised physicians. If a patient would like a specialised physician to have full access to his Electronic Health Book he must give his consent. The consent is given in the form of a security code which is provided to the patient together with the insurance card with electronic chip. The specialised physician needs this security code to have full access to the patient's Electronic Health Book.
Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?	Act on the NHIS, Art. 5	Please see above.
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?		None identified.
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 is no legal base for the interoperability of EHRs with other EU Member States.
Are there specific rules on patient consent to share data on a cross-border situation?		None identified.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

From 1 January 2017 all the health care providers in the Slovak Republic will have to create an EHR into the Electronic Health Book of the patient immediately after the provision of health care. In addition, the Act on Health Care Providers requires all the general practitioners to create, no later than 30 June 2017, a Patient's Summary for all the patients with whom they have concluded an agreement for the provision of health care. The patient's general ambulatory health care provider must also update the Patient's Summary every time health care is provided.

The data from the Patient's Summary are made available to the relevant health care providers once the patient's insurance card with an electronic chip is inserted in the technical devise of the health care provider.

The Electronic Health Book of the patient contains more health data than Patient's Summary and access to these data depends on the type of health professional trying to access them. The patient's general ambulatory health care provider has access to all the data contained in the Electronic Health Book (with the exception of the own records of the patient and information on who and when accessed the data or tried to access the data). Other health professionals (such as specialised physicians) have access only to the records created by them, records on the referral of the general ambulatory health care provider for specialized health care and results of health examinations.

The patient has full access to the data contained in his Electronic Health Book with the exception of the records on the result of the examinations of common diagnostic and treatment components. However, these can be made available to the patient by the health professional who requested the medical examination or the treatment.

Health professionals access the data contained in the Electronic health Book (including the Patient's Summary) via their information system, duly certified by the National Health Information Centre; patients access the data via the National Health 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?	Act on Health Care, Art. 20 Act on Health Care Providers, Art. 79	According to the Act on Health Care, the medical documentation of the patient must be recorded by the general ambulatory health care provider. Other specialised health care providers create records in the scope of health care effectively provided by them. Currently, the medical documentation may be kept in paper or in electronic format (signed electronically). In case the medical documentation is kept in electronic format, the health care provider must ensure that security copies of data files are created pursuant to the standards of medical informatics (Art. 9 of the Act on the NHIS). It should be noted that no legal regulation on standards of medical informatics has been adopted so far. Regarding the obligation to create an EHR into the Electronic Health Book of the patient, this obligation will be effective from 1 January 2017 for all the health care providers. These must be created immediately after the provision of health care via the information system of the health care provider, which has been certified by the National Health Information Centre.
Are there specific national rules on access and update to EHRs?	Act on Health Care Providers, Art. 79 Act on the NHIS, Art. 5	The patient's general ambulatory health care provider must update the Patient's Summary after the provision of health care. The data updated by the patient's general ambulatory health care provider are: a. data on blood group and Rh factor, if the data is known; b. code of active implanted medical device, if the data is known; c. information on custom made dental medical device, if the data is known; d. information on allergic history if the data is known; e. record on vaccinations including vaccination date, type of vaccine, code and name of the immunological medicine provided, cancelation of vaccination, if the data is known; f. data on general practitioner with whom the person has concluded an agreement for the provision of health care, the name, surname and address of the place of business, health care professional code, name and code of the healthcare provider, telephone number and electronic

Questions	Legal reference	Detailed description
		mail address, Specialised health care providers update the data relevant to the health care which they have effectively provided. Access to the Electronic Health Book of the patient is provided to each health care provider who has inserted the patient's insurance card with electronic chip in the electronic device of the information system of the health care provider.
Are there different categories of access for different health professionals?	Act on the NHIS, Art. 5	With regard to access to the Electronic Health Book, the Act on the NHIS differentiates between the general ambulatory health care providers and specialised health care providers. A general ambulatory health care provider has full access to the Electronic Health Book, while a specialised healthcare provider has only access to the records created by him, records on the referrals of the general ambulatory health care provider for specialised health care and results of health examinations.
Are patients entitled to access their EHRs?	Act on the NHIS, Art. 5	Patients are entitled to access their own Electronic Health Book via the National Health Portal by entering their security code and inserting their insurance card with electronic chip or their citizen identification card with electronic chip.
Can patient have access to all of EHR content?	Act on the NHIS, Art. 5	The patient has full access to the Electronic Health Book with exception of the records on the result of the examinations of common diagnostic and treatment components. However, these can be made available to the patient by the health professional who requested the medical examination or the treatment.
Can patient download all or some of EHR content?	Act on the NHIS, Art. 5	The patient will be able to print out the content of the Electronic Health Book to the extent provided by the Act on the NHIS.
Can patient update their record, modify and erase EHR content?	Act on the NHIS, Art. 5	The patient will be entitled to insert or erase data in the Electronic Health Book only within the section "Personal records of the patient". Otherwise the patient will have only read access.
Do different types of health professionals have the same rights to update EHRs?	Act on the NHIS, Art. 5 and 6	The data included in the Electronic Health Book are updated based on the EHRs created once the health care has been provided. These data are sent to the NHIS via the information system of the health care provider. Only a general ambulatory health care provider is entitled to directly update

Questions	Legal reference	Detailed description
		the data which are part of the Patient's summary.
Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians…)		None identified.
Are there exceptions to the access requirements (e.g. in case of emergency)?		The patient summary is always displayed to the health professional.
Are there any specific rules on identification and authentication for health professionals? *Or are they aggregated?*	Act on the NHIS, Art. 7	According to the Act on the NHIS, each health professional is obliged to file a request for an "electronic card of the health professional" to the National Health Information Centre at the latest by 31 October 2016. Within the 30 days from the delivery of the request, the National Health Information Centre must send him the card. This card will be used to identify the health professional and authorize him to access data from the Electronic Health Book of the patient.
Does the patient have the right to know who has accessed to his/her EHRs?	Act on the NHIS, Art. 5	The patient can know who and when accessed his Electronic Health Book or who tried to access it.
Is there an obligation on health professionals to update EHRs?	Act on Health Care Providers, Art. 79	From 1 January 2017 each health provider must, immediately after the provision of the health care, create an EHR in the Electronic Health Book.
Are there any provisions for accessing data on 'behalf of' and for request for second opinion?	Act on the NHIS, Art. 5	None identified. Nevertheless the patient has the right to provide access to the specialised health professional to his Electronic Health Book in greater extent than regulated by the law.
Is there in place an identification code system for cross-border healthcare purpose?		None identified.
Are there any measures that consider access to EHRs from health professionals in another Member State?		None identified.

2.5. Liability

2.5.1. Main findings

According to the Act on Health Care, the health care provider is obliged to provide health care correctly. Health care is provided correctly provided that all diagnosis medical interventions have been performed in order to ensure timely and effective treatment with a view to restoring or improving the condition of the person while applying the current medical knowledge.

The Act on Health Care Providers refers to the general provisions of the Civil Code on liability for damage. There is no specific legislation on this matter.

The Act on Health Care imposes an obligation on the health care providers to keep the medical documentation. The health care provider is required to store and protect medical records in such a way as to avoid damage, loss, destruction or misuse (including during the archiving period). Also in case of malpractice in relation to medical documentation the general rules set out in the Civil Code would apply.

However it should be noted that pursuant to Art. 13, Para. 2 of the Act on the NHIS the general regulation on personal data protection is applicable to the processing of personal data according to that Act, i.e. Act No 122/2013 Coll. on protection of personal data and on changes and amendments certain acts (transposing Directive 95/46/EC).

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?		The national legislation does not set any specific medical liability requirements related to the use of EHRs. Nevertheless the Act on Health Care Providers refers to the general provisions of the Civil Code on liability for damage. According to Civil Code in order to fulfil the conditions of legal liability, these four elements must be proved: a. violation of a legal requirement – i.e. provision of incorrect health care, b. caused damage – i.e. the health state of the patient has worsen, c. causal link between malpractice of the individual and damage caused – this element is always very hard to prove l, d. culpability of the individual causing the damage - fulfilment of this is element is assumed by the law.
Can patients be held liable for erasing key medical information in EHRs?		The patient has access to the Electronic Health Book in a read-only mode.
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 fault triggering liability in the terms 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 liability in the terms explained above.
Are hosting institutions liable in case of defect of their security/software systems?		No specific liability rules are imposed on the hosting institutions, however general liability pursuant to Civil Code may apply (in the terms explained above).
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)?		None identified pursuant to Act on the NHIS, however the more general liability rules of the Act on Personal Data Protection would apply. The Office of Personal Data Protection is entitled to impose a fine or disciplinary fine for violation of the Act on personal data protection.
Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?		None identified.

Questions	Legal reference	Detailed description
Are there liability rules related to the misuse of secondary use of health data?		None identified pursuant to Act on the NHIS, however the more general liability of the Act on Personal Data Protection would apply. The Office of Personal Data Protection is entitled to impose a fine or disciplinary fine for violation of the Act on personal data protection.

2.6. Secondary uses and archiving durations

2.6.1. Main findings

The national legislation does not provide any specific rules on the archiving duration of the data gathered in EHRs. However, the Act on Health Care requires general ambulatory health care providers to archive the medical documentation (in general) for the period of 20 years after the death of the patient; specialised health care practitioners must to keep the medical documentation for a period of 20 years after the last provision of the health care. This medical documentation would also include EHRs.

With regard to secondary use of the data gathered from the EHRs, the Act on the NHIS entitled the National Health Information Centre to keep medical statistics on the health condition of the population. These data are provided in anonymous form to the Ministry of Health for the purposes of national health policy and to the Ministry of Finance for analytical purposes and in aggregated form to the Statistical Office for state statistics.

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?	Act on Health Care, Art. 22	There are no legal rules on archiving duration of EHRs. Nevertheless, the Act on Health Care requires health care providers to archive the medical documentation of the patient for 20 years (this would cover EHRs).
Are there different archiving rules for different providers and institutions?	Act on Health Care, Art. 22	Even though there are no rules on archiving duration of EHRs, the medical records of health care providers who practise as general ambulatory physicians must be kept for 20 years after the death of the patient. For other health care providers, such as specialised physicians, the law imposes a time period of 20 years after the last provision of health care.
Is there an obligation to destroy (…) data at the end of the archiving duration or in case of closure of the EHR?		None identified.
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?		None identified,
Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?	Act on the NHIS, Art. 4 and 10	The purpose of medical statistics is to assess the health condition of the population. For this purpose the National Health Information Centre keeps the list of reports on: a. Deaths and causes of death, b. notifications of acceptance into the institutional health care, c. Birth givers (mother), d. New-borns, e. Miscarriages and abortions, f. Provision of information on abortion, g. STDs, h. Occupational diseases or threat of occupational diseases, i. Patients in a psychiatric institution, j. Causes and circumstances of deliberate self-harm, k. Completed spa treatment, l. Drug addiction being treated. These data are provided in anonymous form to the Ministry of Health for the

Questions	Legal reference	Detailed description
		purposes of national health policy and to the Ministry of Finance for analytical purposes and in aggregated form to the Statistical Office for state statistics.
Are there health data that cannot be used for secondary use?		None identified.
Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?	Act on the NHIS, Art. 10	All the data are provided to in anonymous form.
Does the law say who will be entitled to use and access this data?	Act on the NHIS, Art. 10	The law states which specific state authorities have access to the data - the Ministry of Health, Ministry of Finance and Statistical Office.
Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?		None identified.

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

The eHealth system currently implemented in the Slovak Republic, including EHRs, is based on the interoperability within the territory of the Slovak Republic. All the data gathered should be stored in the central database that will be operated by the National Health Information Centre.

Pursuant to Article 9 of the Act on the NHIS, standards of medical informatics must ensure unity, security and integrity of information and communication technologies in health care. Each health care provider will have to use information systems that have been certified by the National Health Information Centre, and which comply with the legal regulations with regards to connectivity standards, security standards and identification and authentication of health professionals.

There are no legal provisions providing for the development of interoperability of EHRs with other EU Member States.

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?	Act on the NHIS, Art. 11	Each health care provider will have to use information systems that have been certified by the National Health Information Centre, and which comply with the legal regulations with regards to connectivity standards, security standards and identification and authentication of health professionals.
Are there any specific rules/standards on the interoperability of EHR?	Act on the NHIS, Art. 9 and 11	Please see above.
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

Prescriptions Records are an integral part of the Electronic Health Book of each public health policyholder in the Slovak Republic. A pharmacist may only access a Prescription Record once the patient presents his insurance card with electronic chip but will not be able to see other information included in the Electronic Health Book of the patient.

As the attending healthcare professional has access to the Patient's Summary he will be able to access to information on prescribed, administered and dispensed medicines from prescribing records, dispensing records or medicated records for the past six months in the scope of the drug code, drug name, amount of drug in a single dose, dosage form, frequency of use, route of administration, dosage form, duration of treatment, date of prescribing, drug issue date or the date of administration.

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?	Act on the NHIS, Art. 5	According to national legislation the Prescription Record is part of the Electronic Health Book. This record is available to the pharmacist once the patient presents his insurance card with electronic chip.
Can an ePrescription be prescribed to a patient who does not have an EHR?		As said above the Prescription Record is part of the Electronic Health Book.

- ***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?	Act on the NHIS, Art. 5	Yes, to the extent provided for in the law. As the attending health care professional has access to the Patient's Summary he will be able to access to information on prescribed, administered and dispensed medicines from prescribing records, dispensing records or medication records for the past six months including the drug code, drug name, amount of drug in a single dose, dosage form, frequency of use, route of administration, dosage form, duration of treatment, date of prescribing, drug issue date or the date of administration. Pharmacists have access only to the Prescription Records but will not be able to see other information included in the Electronic Health Book of the patient.
Can those health professionals write ePrescriptions without having access to EHRs?		The Prescription Record is part of the Electronic Health Book.

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

Due to the fact the eHealth Programme has not yet been launched in the Slovak Republic it is not possible to identify any good practices or legal barriers.

In any case, it should be emphasized that national legislation does not foresee any cross-border transfer of the health data of the patients stored in the databases of the National Health Information Centre. Therefore existing legislation will need to be amended in order to develop cross-border transfer of EHRs for other EU Member States.