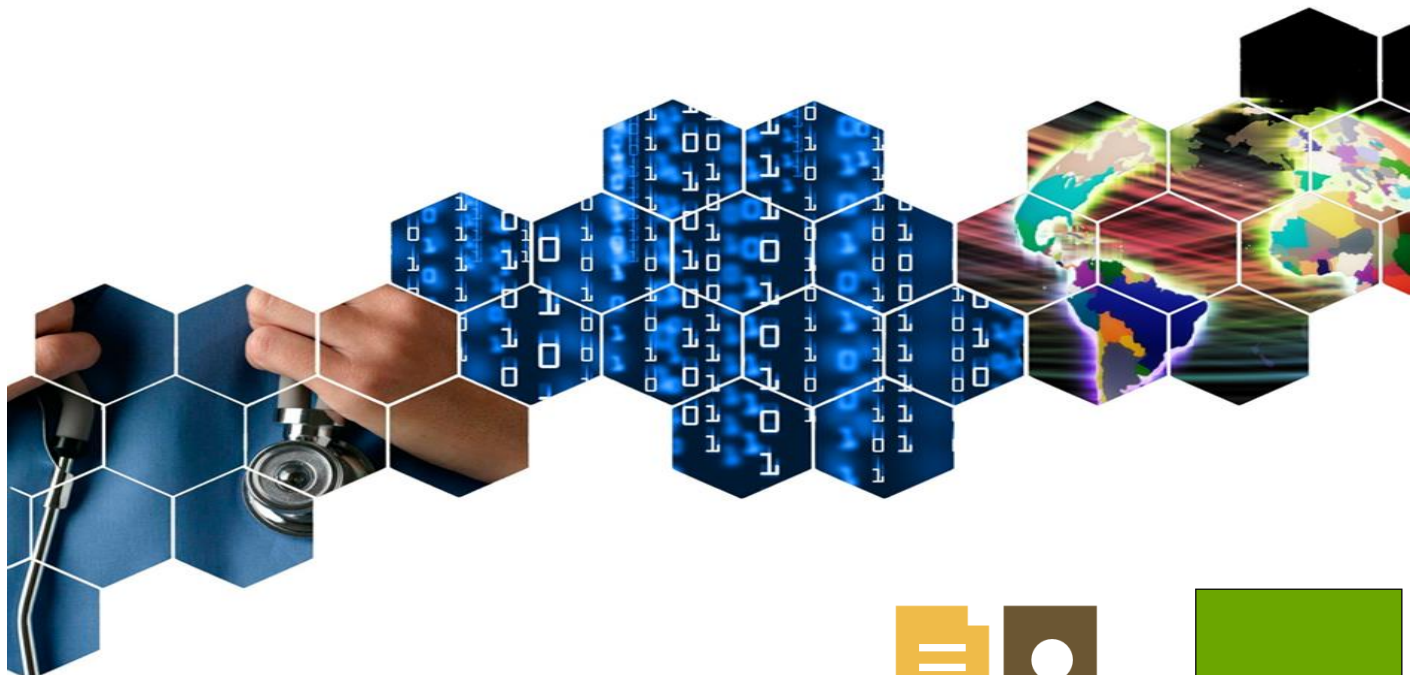


Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services

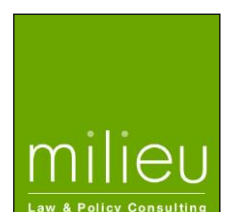
Contract 2013 63 02

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

National Report for Hungary



14/04/2014



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This report was completed by Katalin Adamis-Császár. The views expressed herein are those of the consultants alone and do not necessarily represent the official views of the Executive Agency for Health and Consumers

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Executive Summary

1. Stage of development of EHRs in Hungary

Despite the absence of a nation-wide EHRs system, the collection of patient data through electronic form is common. Some of the patient data, collected by healthcare providers, are submitted to national level registries. Among the national level registries, the one operated by the National Health Insurance Fund Administration (OEP) is considered to be the main one. The OEP registry is the only EHRs system accessible for patients, by using their social insurance ID number as a login. The current system does not allow for full interoperability and IT systems of healthcare professionals are, as a general rule, not interconnected.

The Government has acknowledged the deficiencies of the system, and is currently working on its improvement. The revision of health IT is one of the main healthcare related objectives of the current Government, and is enshrined in various policy documents, including in the National Cooperation Programme 2010-2014 (Government's Programme), the Semmelweis Plan (professional healthcare concept), the Digital Renewal Action Plan of Hungary (2010-2014) and the National Information-Communication Strategy (2014-2020). Project work, financed through public grants under the New Szechenyi Plan (2011-2013) with the aims of developing the necessary IT infrastructure, is on-going.

In parallel with these policy developments, the Government is currently amending the applicable legal framework, comprising mainly Act XLVII of 1997 on the processing and protection of health care data and associated personal data. Once adopted, the amendment will allow for the establishment of the National EHealth Services Platform (*Egészségügyi Elektronikus Szolgáltatási Tér*); an IT system connecting the IT systems of different healthcare professionals.

In Hungary there is no single institution responsible for eHealth. National level organisations responsible for the development of the Hungarian EHRs system include the Ministry of Human Resources and the Ministry of National Development. On the implementation side, project work for developing Hungary's eHealth system is carried out by the National Health Insurance Fund Administration and the National Institute for Quality and Organisational Development in Healthcare and Medicines. The funding of eHealth initiatives is mainly secured through EU Funds, the management of falls under the responsibility of the Prime Minister's Office (until January 2014 the National Development Agency was in charge).

2. Summary of legal requirements applying to EHRs

Health data to be included in EHRs

Hungarian legislation does not contain the definition of EHR. Instead it refers to health data (Article 3(a) of Act XLVII of 1997), which could be both electronic and paper-based. The definition of health data is not restricted to medical information only, but allows for the collection of data on the patient's environment or occupation. In currently operational EHR systems, the patient's health and personal data are, as a general rule, matched (Article 10(1) of Act XLVII of 1997). The level of confidentiality linked to the health data of patients is the same, regardless of the type of health data (i.e. paper or electronic health data).

Hosting the patients' EHRs

Hungarian legislation allows for the collection and processing of health data for the purposes specified in Article 4(1)-(3) of Act XLVII of 1997. The patients' personal and health data are registered by healthcare professionals. The registered data are stored, managed and processed by them to the extent necessary for medical treatment (Article 10(1) of Act XLVII of 1997). The patients' health and personal data are forwarded to central EHRs registries, including to the OEP registry, which is responsible for the management and processing of health data at the central level. While registering, managing and processing health and personal data, the general data protection rules and the provisions

set out in Article 6 of Act XLVII of 1997 should be complied with. Article 6 provides that the personal and health data of patients while being registered, managed and processed must be protected from negligent or intentional destruction, alteration, damage, public disclosure and unauthorised access.

Consent of the patient

Under Hungarian legislation, the patients can explicit consent against the collection, processing and sharing of health data. In some cases the collection, processing and sharing of the patients' health data is mandatory, regardless of whether he/she provides his/her consent. These cases are specified under Article 13 of Act XLVII of 1997.

Creation, access to and update of EHRs

Pursuant to Article 9(1) of Act XLVII of 1997, health data are registered by healthcare professionals as part of the medical treatment. Access to health data (which as described under Section 2.1 encompasses EHRs) is, as a general rule, allowed to the patients and to healthcare professionals, provided that the patient did not oppose the healthcare professional's access to such data. The current legal system does not explicit verbatim regulate the process of updating health data; it however allows for the correction or deletion of incorrect health data.

Liability

Healthcare professionals, in charge of the management of EHRs are responsible for the maltreatment of EHRs in accordance with the general civil liability regime, in accordance with which any person who unlawfully causes harm to another, shall compensate the damaged person. In most severe cases, health professionals managing EHRs could be held criminally liable. Hungarian legislation also protects against the unlawful access of personal data, which data covers EHRs. The heads of healthcare institutes are responsible for organising trainings for medical staff on the management and processing of personal data.

Secondary use

Hungarian legislation allows for the secondary use of health data for e.g. scientific, epidemiological, planning and evaluation purposes. Secondary use is subject to strict data protection rules under Act of Act XLVII of 1997, often allowing for the use of health data without reference to the identification of patients. Regarding archiving, it is noted that Hungarian legislation provides for the management and processing of patient data for a limited period of time. Following the lapse of such period, the data could be removed from the databases or could be transferred to the Semmelweis Medical History Museum, Library and Archives in cases when the data is of a significant scientific value.

Interoperability of data requirements

Current EHRs systems are not centralised, nor interoperable in Hungary. EHRs are collected at the local level and depending on the projected use of the data are shared with central level registries.

Links between EHRs and ePrescriptions

Pursuant to Article 14/A(1(a)) of Act XLVII of 1997, health professionals can prescribe medicines, medical devices and medical treatments electronically. Rules applicable to ePrescriptions are not detailed any further in Act XLVII of 1997. The draft law amending Act XLVII of 1997 does not regulate ePrescriptions in a detailed manner, but provides for rules regulating the relationship between ePrescriptions and the future National EHealth Services Platform.

3. Good practices

No response from stakeholders.

4. Legal barriers

No response from stakeholders.

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List of abbreviations

EHRs	Electronic Health Records
OEP registry	Electronic Health Records Registry operated by the National Health Insurance Fund Administration
OEP	National Health Insurance Fund Administration
ID number	Identity number
IT	Information technology
eHealth	Electronic Health
ePrescription	Electronic prescription
eConsultation	Electronic consultation
eTransfer	Electronic transfer

1. General context

1.1. EHR systems in place

Description of current EHRs systems in place

In Hungary there is no single Electronic Health Records (EHRs) System in place that allows different healthcare providers to access and update health data in order to ensure the continuity of patient care. Despite the absence of this type of nation-wide EHRs system, the collection of patient data through electronic form is common. Patient data is collected by healthcare providers, who often use different eHealth infrastructures, which are not interconnected, nor interoperable. Part of the data- collected by healthcare professionals- are submitted to national level registries.

There are many national level patient data registries in Hungary, including the National Cancer Registry (*Nemzeti Rákregiszter*), the National Registry of Congenital Disorders (*Veleszületett Rendellenességek Országos Nyilvántartása*) and a registry operated by the National Health Insurance Fund Administration (hereinafter referred to as 'OEP registry'). The OEP registry is the only EHRs system accessible for patients. Patients can access it through the 'Client Gate' portal¹ of the Government by using their social insurance ID number as a login name². The OEP registry contains a wide-range of (but not all) patient data, stored on the basis of the patient's social insurance ID number.

Other national EHRs systems are run by different organisations³. EHRs systems currently in place are not restricted to certain regions, professionals, health institutions or patients.

Governmental policies and projects in place to develop and implement EHRs

The Government's current health policy objectives, set out in the **National Cooperation Programme 2010-2014**⁴, aim at improving the efficiency of the country's healthcare system. The Government's aim is embedded in many strategic documents, including in the **Semmelweis Plan**, which is a professional concept, setting measures for the renewal of the healthcare sector. One of the measures foreseen by the Semmelweis Plan is the 'reconsideration and revision of applicable information technologies in the healthcare sector and the system-level development of health IT'⁵. The Semmelweis Plan acknowledges that there is a large quantity of health data available in the country, which is not sufficiently used, due mainly to the lack of 'single record' system. To overcome this issue the Plan foresees the development of a single sectoral IT system⁶.

The aim of developing a single sectoral IT system is reinforced by the **Digital Renewal Action Plan of Hungary (2010-2014)**⁷, which sets actions for developing Hungary's eHealth system. These actions are the followings:

- The establishment of the National Health Informatics (eHealth) system,
- The development of functionally integrated inter-institutional and regional IT systems,
- The development of an assessment methodology for mapping the national capacities and for monitoring the healthcare sector,
- The improvement of the patient identification system,

¹ Client Gate is a transactional gateway available through the Government's portal, which allows users to securely access governmental services online even without an electronic signature.

² Login description is provided on the [Governmental website](#).

³ The National Registry of Congenital Disorders is operated by the National Institute for Quality and Organizational Development in Healthcare and Medicines.

⁴ The [National Cooperation Programme 2010-2014](#) was the Government's programme for the period of 2010-2014.

⁵ [Resuscitated Health Care-Recovering Hungary- A Semmelweis Plan for the Rescue of Healthcare- A professional concept](#).

⁶ [Resuscitated Health Care-Recovering Hungary- A Semmelweis Plan for the Rescue of Healthcare- A professional concept pp.63-68](#).

⁷ [Digital Renewal Action Plan of Hungary \(2010-2014\)](#).

- The development of an IT system which allows for the use of citizen's cards in all segments of the healthcare sector,
- The development of electronic patient summaries,
- The development of ePrescriptions,
- The development of eHealth solutions supporting healthy lifestyles, including distance monitoring, distance diagnosis and telemedicines,
- The support of the use of modern electronic applications used for the promotion of healthy lifestyles.

The **National Info-Communication Strategy (2014-2020)**⁸ states that in order to become a digital state, there is a need for more investment in the provision of electronic services. To this end the strategy inter alia calls for the adoption of a National eHealth Action Plan by the end of 2014⁹.

Projects to develop the Hungarian eHealth system (including the single sectoral IT system) are foreseen by the **New Szechenyi Plan (2011-2013)**¹⁰. The New Szechenyi Plan is Hungary's economic recovery programme, aiming at the improvement of Hungary's competitiveness and at creating 1 million new jobs. To achieve these aims, the plan identified seven break-out points, which in line with the Government's current health policy and the Semmelweis Plan, aim inter alia at the restructuring of the current health system.

The Szechenyi Plan supports projects to achieve its objectives by providing public grants. As a few examples, the following strategic projects aim at the development of a single sectoral IT system:

- The development of the National Health Informatics (eHealth) System¹¹ by the end of 2014 (31 December 2014)¹²;
- The development of IT infrastructures necessary for ensuring the inter-institutional connection of local level systems¹³ by 30 September 2015¹⁴.

1.2. Institutional setting

In Hungary there is no single institution responsible for eHealth. National level organisations include the Government and competent Ministries responsible for healthcare or related issues (Ministry of Human Resources (*Emberi Erőforrások Minisztériuma*) and the Ministry of National Development (*Nemzeti Fejlesztési Minisztérium*)), and national level bodies supporting the different Ministries and other professional organisations.

Local and regional level EHRs systems are operated by healthcare providers.

- *The Hungarian Government*

Ministry of Human Resources

In Hungary the national healthcare system is managed by the Ministry of Human Resources and in particular by its State Secretariat for Health (*Egészségügyért Felelős Államtitkárság*). To ensure the co-ordination of the national healthcare system, the State Secretariat inter alia develops related policies and legislation. In 2012, the State Secretariat reinforced its commitment towards the development of

⁸ [National Info-Communication Strategy \(2014-2020\)](#).

⁹ No further information was found on the development of the National eHealth Action Plan.

¹⁰ The continuation of the Plan, under the name Szechenyi 2020, is still under consideration.

¹¹ More information on the strategic project is available at: [Website of the National Institute for Quality and Organisational Development in Healthcare and Medicines](#).

¹² [National Info-communication service provider- National Health Informatics System- the development of an electronic and authentic registry and of a sectoral portal](#).

¹³ [Information on the tendering procedure for the project 'Local infrastructural developments necessary for establishing a regional, functionally-integrated inter-institutional system as part of the National Health Informatics \(eHealth\) System'](#).

¹⁴ [Information on the tendering procedure for the project 'Local infrastructural developments necessary for establishing a regional, functionally-integrated inter-institutional system as part of the National Health Informatics \(eHealth\) System'](#).

the Hungarian eHealth system¹⁵. To this end a Programme Office responsible for eHealth (*eHealth Egészségügyi Informatikai Programiroda*) was created within the State Secretariat.

Ministry of National Development

The Ministry of National Development and in particular its State Secretariat for Info-communication (*Infokommunikációért Felelős Államtitkárság*) is responsible for the development and management of public administration IT technologies. The remit of the Ministry also covers the development and implementation of related strategies, such as the Digital Renewal Action Plan (2010-2014)¹⁶ and the National Info-Communication Strategy (2014-2020)¹⁷.

- Supporting bodies and professional organisations

National Health Insurance Fund Administration (Országos Egészségbiztosítási Pénztár-OEP)

The OEP is a separate administrative organisation operating under the supervision of the Ministry of Human Resources. Its main responsibilities include the administration of the state-funded universal health insurance system and the control and calculation of related payments. Regarding eHealth, OEP manages the biggest registry of patients' data in Hungary¹⁸.

National Institute for Quality and Organizational Development in Healthcare and Medicines (Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet): methodological centre established in 2011 by the merger of several national institutions, such as of the National Institute for Strategic Health Research or the National Centre for Healthcare Audit and Inspection. In its role of supporting the Ministry of Human Resources, the Institute is responsible for preparing national strategies for healthcare quality improvement and is in charge of managing health-sector related EU projects¹⁹. The Institute is currently in charge of implementing various eHealth-related projects, such as the one on the 'improvement of local infrastructures for developing the National Health Informatics (eHealth) System'²⁰.

National Public Health and Medical Officer Service (Állami Népegészségügyi és Tisztiorvosi Szolgálat): A public administration agency operating under the supervision of the Minister of Human Resources, responsible inter alia for the implementation and enforcement of public health policies and legislation.

Hungarian Standards Institution (Magyar Szabványügyi Testület): Hungary's national standardisation body is a non-profit body of public interests, established in 1921. Amongst others, the remit of the institution covers the development of standards related to health and eHealth. The national standards developed can be purchased on the institute's website²¹. The standardisation process is ongoing in Hungary²².

The funding of eHealth initiatives is mainly secured through EU Funds, the management of which fell under the responsibility of the ***National Development Agency (Nemzeti Fejlesztési Ügynökség)*** until 1 January 2014. In December 2013 the National Parliament gave a mandate for the Government to restructure the institutional set-up responsible for Hungary's development policies. In accordance with the mandate, since 1 January 2014, the ***Prime Minister's Office (Miniszterelnökség)*** acts are the legal successor of the National Development Agency²³.

¹⁵ [World Economics 'Hungary could become an eHealth super power' June 2012.](#)

¹⁶ [Digital Renewal Action Plan \(2010-2014\).](#)

¹⁷ [National Info-Communication Strategy \(2014-2020\).](#)

¹⁸ Article 6(4)(g) of Government Decree 319/2010 (XII.27) on the bodies responsible for health insurance.

¹⁹ [Description of the remit of the National Institute for Quality- and Organisational Development in Healthcare and Medicines.](#)

²⁰ [Call for application- National Health Informatics \(EHealth Programme\).](#)

²¹ [Hungarian Standards Institution- rules applicable to standards' sales.](#)

²² [Country brief Hungary- EHealth Strategies.](#)

²³ [Article published on the website of World Economy \(Hungarin newspaper\) on the abolition of the National Development Agency.](#)

In Hungary, there is no authority responsible exclusively for the protection of health data. The remit of Hungary's data protection authority, the *Hungarian National Authority for Data Protection and Freedom of Information (Nemzeti Adatvédelmi és Információszabadság Hatóság)*, however extends to the protection of health data. Pursuant to Article 3(3) of Act CXII of 2011²⁴, health data is considered as 'special data' under Hungarian law. The Authority is responsible for ensuring the special data is processed in accordance with the conditions set out in Article 6 of Act CXII of 2011, which sets that the processing of special data is subject to the written consent of the person concerned.

- **Regional and local level bodies**

Under the current system, the implementation and the running of the EHRs system fall under the responsibility of healthcare providers. In Hungary, healthcare providers include the family practitioners (GPs) and medical staff working in hospital care. The lowest level of hospital care is provided by territorial level hospitals, whereas regional/county-level hospitals provide more specialised care. University hospitals are teaching hospitals of medical universities and provide healthcare in almost all clinical fields. National medical institutes, such as the Institutes of Experimental Medicines are also part of the Hungarian healthcare system. Regional level and university hospitals as well as the national medical institutes are appointed as priority hospitals since 2006.

1.3. Legal setting and future legal development

Hungary does not have a single piece of legislation regulating the implementation of eHealth policies, neither does it have a single law regulating the management of EHRs or ePrescriptions. Act XLVII of 1997 on the processing and protection of health care data and associated personal data²⁵ to a certain extent covers these elements. It is noted however that this Act does not differentiate between paper-based and electronic patient data, moreover it contains only a short reference to ePrescriptions. Article 14(1a) of Act XLVII of 1997 provides that the minister responsible for health is in charge of developing the detailed rules applicable to the provision of ePrescriptions through a ministerial decree. As of today, the ministerial decree has not been adopted yet.

It is noted that in accordance with the policy developments described above, a major legislative development took place during the past year in Hungary. In October 2013 a public consultation on a proposed amendment to Act XLVII of 1997²⁶ was completed. The amendment, which has not been adopted yet, regulates the establishment and the functioning of the National EHealth Services Platform (*Egészségügyi Elektronikus Szolgáltatási Tér*). The Platform is intended to be an IT system that connects the IT systems of the different healthcare professionals. Once operational, it will allow for several functions, including the:

- Provision of eConsultations,
- Issuance of ePrescriptions,
- The storage and processing of health data,
- The eTransfer of patients, etc²⁷.

The proposed amendment, as described under Section 2.8, also regulates the writing and use of ePrescriptions.

Rules applicable to the protection of patients' health data are set out in Act XLVII of 1997 and in Act CXII of 2011²⁸. The latter Act constitutes Hungary's general data protection legislation. Pursuant to Article 3(3) of Act CXII of 2011, health data is considered as 'special data' under Hungarian law.

²⁴ [Act CXII of 2011 on the right of informational self-determination and on freedom of information.](#)

²⁵ [Act XLVII of 1997 on the processing and protection of health care data and associated personal data.](#)

²⁶ [The draft version of the law in Hungarian.](#)

²⁷ [The draft version of the law in Hungarian, completing the current version of Act XLVII of 1997 with Article 35/B.](#)

2. Legal requirements applying to EHRs in Hungary

2.1. Health data to be included in EHRs

2.1.1. Main findings

Hungarian legislation applicable to health records does not differentiate between electronic and non-electronic health records. Depending on the purpose of the use of the health data (e.g. data used for treatment, for statistical purposes, etc.), different bodies are responsible for the collection, management and the processing of data.

The term health data is defined by Article 3(a) of Act XLVII of 1997 as follows: data on the patient's physical, mental and emotional condition, addiction, the circumstance of illness and death, the cause of death, and any other data associated with the above (e.g. behaviour, environment, occupation). This definition implies that the definition of health data is not restricted to medical information.

Pursuant to Article 9(1) of Act XLVII of 1997, the patients' health data are collected by the competent healthcare providers, as part of the medical treatment. It is up to the healthcare professional to decide on the type of health data to be collected.

Articles 10 and 15(6) of Act XLVII of 1997 suggest that the patients' health and personal data are not necessarily linked in the EHRs systems. Pursuant to Article 10(1), the patients' health and personal data could be linked and shared within the healthcare system and with OEP. Health and patient data originating from different sources can only be linked for a certain duration, necessary for taking prevention, medical treatment, public health related measures. In some cases, the health data of the patient and his/her personal data are not linked in the system. Pursuant to Article 15(6), any person may ask for an anonymous HIV test, in which case the health data of the patient and his/her personal data are not linked together.

The level of confidentiality linked to the health data of patients is the same regardless of the type of health data (i.e. paper or electronic health data).

²⁸ [Act CXII of 2011 on the right of informational self-determination and on freedom of information.](#)

2.1.2. Table on health data

Questions	Legal reference	Detailed description
<i>Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)</i>		<p>Current legislation: Act XLVII of 1997 regulating the protection of health records does not contain the definition of EHRs. Instead, Article 3(a) of Act XLVII of 1997 defines health data as follows: data on the patient's physical, mental and emotional condition, addiction, the circumstance of illness and death, the cause of death, and any other data associated with the above (e.g. behaviour, environment, occupation). This definition is applicable both to paper-based and electronic health data.</p> <p>Draft legislation: It does not contain the definition of EHR.</p>
<i>Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?</i>		<p>Current legislation: Pursuant to Article 3(a) of Act XLVII of 1997, health data contains information also about circumstances that influence the medical condition of the patients. The list of circumstances and the meanings thereof are not exhaustively stated in Article 3(a). The circumstances referred to under Article 3(a) include e.g. the environment of the patient and his/her occupation.</p> <p>Draft legislation: It does not amend Article 3(a) of Act XLVII of 1997.</p>
<i>Is there a definition of EHR or patient's summary provided in the national legislation?</i>		<p>Current legislation: The terms EHR and patient summary are not defined in Hungarian legislation. Article 3(e) of Act XLVII of 1997, however provides for the term 'health documentation', which is similar to patient summary. Health documentation is any documentation, data stored in registries or outside thereof that contains the patients' health and personal data. Health documentations are accessible only for the patients and healthcare providers.</p> <p>Draft legislation: It does not contain the definitions of EHRs or patient's summary.</p>
<i>Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?</i>		<p>Current legislation: There are no legal requirements in place. Article 9(1) of Act XLVII of 1997 provides that besides those data the collection of which is mandatory (e.g. name of the patient, social security number) it is up to the doctor carrying out the medical treatment/intervention to decide on the type/range of health data to be collected.</p> <p>Draft legislation: It does not amend Article 9(1) of Act XLVII of 1997.</p>

<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>		<p>Current legislation: The requirement of using a common terminology is not defined in applicable legislation. In practice; however the IT systems currently in use require the use of common codes. Among the international coding systems, the following ones are inter alia in use while recording health data: ICD codes (International Statistical Classification of Diseases and Related Health Problems), ICPM codes (International Classification of Procedures in Medicine) and SNOMED codes (Systematized NOMenclature of MEDicine)²⁹.</p> <p>Draft legislation: The draft legislation does not require the use of common codes/terminologies.</p>
<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>		<p>Current legislation: First and foremost, EHRs is not defined in Hungarian legislation. Regarding the confidentiality of health data, the same rules apply regardless of the type/category of data.</p> <p>Draft legislation: It does not separate categories of health data with different levels of confidentiality.</p>
<p><i>Are there any specific rules on identification of patients in EHRs?</i></p>		<p>Current legislation: As explained under Section 1, under the current system, patients can access the OEP registry by using their social identity number as a login. By entering this data, the patients can access their own files.</p> <p>Draft legislation: It does not amend the identification of patients in the EHRs.</p>
<p><i>Is there is a specific identification number for eHealth purposes?</i></p>		<p>Current legislation: As referred to above, patients can access the OEP EHRs system by using their social identity number.</p> <p>Draft legislation: The draft legislation does not introduce changes in this respect.</p>

²⁹ [Medical coding systems in use in Hungary.](#)

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

Hungarian legislation allows for the collection and processing of health data for the purposes specified in Article 4(1)-(3) of Act XLVII of 1997. The purposes referred to under Article 4 allow for the first and secondary use of data. Pursuant to Article 4(1) of Act XLVII of 1997, the patients' health and personal data should primarily be used for:

- health prevention, health amelioration and maintenance,
- medical treatment,
- following the medical pathway of patients,
- public health and infection prevention purposes, and
- enforcing patients' rights.

Rules applicable to the secondary use of data are provided under Article 4(2)-(3) of Act XLVII of 1997 and are described under Section 2.6.

The patients' personal and health data are registered by healthcare professionals. The registered data are stored, managed and processed by them to the extent necessary for medical treatment (Article 10(1) of Act XLVII of 1997). The patients' health and personal data are forwarded to central EHRs registries, including to the OEP registry, which is responsible for the management and processing of health data at the central level.

In accordance with Article 7(1)-(2) of Act XLVII of 1997, bodies responsible for the management and processing of data are bound by professional secrecy rules, unless:

- The patient or his/her legal representative has provided his/her consent for the submission of his/her health and personal data to the competent authorities,
- The submission of the patients' health and personal data to the competent authorities is compulsory.

While registering, managing and processing health and personal data, the provisions set out in Article 6 of Act XLVII of 1997 should be complied with. Article 6 provides that the personal and health data of patients while being registered, managed and processed must be protected from negligent or intentional destruction, alteration, damage, public disclosure and unauthorised access.

No authorisation or licensing requirements are set for bodies responsible for the collection, management and processing of patient data.

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>	Articles 6 and 28(1) of Act XLVII of 1997	<p>Current legislation: Article 6 in combination with Article 28(1) of Act XLVII of 1997 provides that the personal and health data of patients while being registered, managed and processed must be protected from negligent or intentional destruction, alteration, damage, public disclosure and unauthorised access.</p> <p>Moreover, pursuant to Article 7 of Act XLVII of 1997 bodies responsible for the management and processing of data are bound by professional secrecy rules. The bodies are exempted from secrecy rules if:</p> <ul style="list-style-type: none"> - The patient or his/her legal representative has provided his/her consent for the sharing of his/her health and personal data with the competent authorities, - The sharing of the patients' health and personal data to the competent authorities is compulsory. <p>Draft legislation: It does not introduce any relevant rules.</p>
<i>Is there a need for a specific authorisation or licence to host and process data from EHRs?</i>		<p>Current legislation: Hungarian legislation does not provide for specific authorisation or licensing requirements.</p> <p>Draft legislation: It does not introduce any relevant rules.</p>
<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>		<p>Current legislation: Hungarian legislation does not provide for specific obligations that apply to institutions hosting and managing data from EHRs. It only sets a general obligation requiring that the personal and health data of patients while being registered, managed and processed must be protected from negligent or intentional destruction, alteration, damage, public disclosure and unauthorised access.</p> <p>Draft legislation: It does not introduce any relevant rules.</p>
<i>In particular, is there any obligation to have the information included in EHRs encrypted?</i>		<p>Current legislation: It is not a legal requirement to have the information included in the EHRs encrypted.</p> <p>Draft legislation: Article 17(2) introducing Article 35/H(3) provides that</p>

Questions	Legal reference	Detailed description
		ePrescriptions are encrypted (See Section 2.8).
<i>Are there any specific auditing requirements for institutions hosting and processing EHRs?</i>		<p>Current legislation: There is no reference to the specific auditing of institutions hosting or processing EHRs.</p> <p>Draft legislation: It does not introduce any relevant rules.</p>

2.3. Patient consent

2.3.1. Main findings

It is first worth noting that in Hungary there is not yet a single EHR system that allows for shared access to all health data. The consent for the creation of electronic records is implicit and is provided when the patient agrees to undertake a medical treatment. However the patients can explicit consent against the collection, processing and sharing of health data.

The mean of contesting the collection, processing and sharing of patient data is not always clearly stated in legislation. Pursuant to Article 12(2) of Act XLVII of 1997, the patient may contest the management of his/her data in form of a declaration. The exact meaning of the term ‘declaration’ is not specified in legislation. Regarding access to health data by healthcare professionals, the legislation is more specific. Article 11(3) provides that the patient’s doctor or general practitioner may access the health data of the patient, unless he/she contests it. Such request should be filed with OEP in person; via post or electronically. Regardless of the mean chosen, the request should be filed in writing (Article 5(2) of Act CXII of 2011).

In some cases the collection, processing and sharing of the patients’ health data is mandatory. These cases are specified under Article 13 of Act XLVII of 1997.

The draft law does not introduce major changes to the current version of Act XLVII of 1997.

2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
<p><i>Are there specific national rules on consent from the patient to set-up EHRs?</i></p>	<p>Article 12 of Act XLVII of 1997</p>	<p>Current legislation: As explained under Section 2.1., the term EHR is not defined, nor used in Hungarian legislation. Instead, the Hungarian legislation refers to health data, which is understood to cover both electronic and paper data.</p> <p>Article 9 of Act XLVII of 1997 provides that the registration of the patient's personal and health data is part of the treatment process. Pursuant to Article 12, it is up to the patient to decide whether or not he/she wishes to provide health and personal data to the healthcare provider. Exceptionally, in cases specified in Article 13 (see below), the provision of the health and personal data of the patient is mandatory.</p> <p>Article 12(2) provides that the patient's consent is assumed in cases, where he/she voluntarily visits healthcare professional. The patient, however may contest the provision of his/her data. The health professional must inform the patient about the fact that unless he/she contests it, his/her personal and health data are going to be managed.</p> <p>The term data management is not defined by Act XLVII of 1997. Pursuant to Article 37(1) of Act XLVII of 1997, to legal aspects not covered by its provisions, the rules set out in Act CXII of 2011 apply. Article 3(10) of Act CXII of 2011 defines data management as: any operation or the totality of operations performed on the data, regardless of the procedure applied; in particular, data collecting, recording, registering, classifying, storing, modifying, using, querying, transferring, disclosing, synchronising or connecting, blocking, deleting and destructing, as well as preventing the further use of the data, taking photos, making audio or visual recordings, as well as registering physical characteristics suitable for personal identification (such as, fingerprints or palm prints, DNA samples, iris scan)³⁰.</p> <p>In urgent cases, or in case of incapable patients, the law (Article 12(3) of Act</p>

³⁰ Source: [Act CXII of 2011 on informational self-determination and freedom of information.](#)

Questions	Legal reference	Detailed description
		<p>XLVII of 1997) assumes that the patient ‘voluntarily’ turned to the health professional, thus implicitly allows for the collection of the patients’ health data without their consents.</p> <p>Draft legislation: The draft legislation does not introduce specific rules in this respect.</p>
<i>Is a materialised consent needed?</i>	Article 5(2) of Act CXII of 2011	<p>Current legislation: Regarding the management of the patients’ health and personal data, the legislation assumes their consent (see above). Patients; however are allowed to contest the management of their health and personal data. In accordance with Article 5(2) of Act CXII of 2011 the patient must contest the management of his/her data in writing.</p> <p>Draft legislation: The draft legislation does not introduce specific rules in this respect.</p>
<i>Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?</i>		<p>Current legislation: Such requirement is not set out in legislation. However, Article 7(3) of Act XLVII of 1997 provides that patients are entitled to be informed about the data management linked to their medical treatment. Moreover, Article 12(2) of the same Act provides that the patient must be informed about the fact that unless he/she contests, it is assumed that he/she has given his/her consent for the management of his/her health and personal data. Hungarian legislation does not provide that the patient must be informed about the consequences of giving his/her consent.</p> <p>Draft legislation: The draft legislation does not introduce specific rules in this respect.</p>
<i>Are there specific national rules on consent from the patient to share data?</i>	Article 10 of Act XLVII of 1997	<p>Current legislation: Pursuant to Article 10(2) of Act XLVII of 1997, any health data of the patient could be shared for treatment purposes, unless the patient opposes in writing (material consent). The patient’s data must be shared in cases specified by Article 13 of Act XLVII of 1997 without patient consent. Article 13 refers to:</p> <ul style="list-style-type: none"> - Infectious diseases or poisoning specified in Annex I, - For the performance of screening and aptitude tests specific by Annex II, - Acute poisoning cases,

Questions	Legal reference	Detailed description
		<ul style="list-style-type: none"> - Occupational diseases specified in Annex III, - If data is needed for the protection, medical treatment or health maintenance of the foetus, or a minor person, - Data is needed to law enforcement purposes, - Data is needed for national security control purposes. <p>Pursuant to Article 10(2) and (3) , the shared data of the patient concerns his/her current medical treatment. Exceptionally, and only upon receipt of the patient’s consent, health data linked to the patient’s previous diseases (not specifically linked to the current medical treatment) may also be shared. Pursuant to Article 10(4) in urgent cases, any health data of the patient, linked to his/her treatment could be shared, even without his/her consent.</p> <p>Draft legislation: The draft legislation does not introduce specific rules in this respect.</p>
<i>Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?</i>	Articles 11(3) and 12 of Act XLVII of 1997	<p>There is an opt-out rule for the processing of health data including EHRs.</p> <p>See above (rules applicable to the set-up of EHR). The term data management as specified by Article 3(10) of Act CXII of 2011, also covers the processing of data.</p> <p>Besides the above, it is noted that the patient may forbid his/her doctor of general practitioner to access his/her health data. Pursuant to Article 11(3) of Act XLVII of 1997, the patient may refuse access to his/her health data by filing a request with OEP in person, or in writing via post of email.</p>
<i>Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?</i>	Article 10 of Act XLVII of 1997	<p>See above. Besides the above, there are no other opt-in/opt-out mechanisms identified.</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>Current legislation: It is not a legal requirement to inform the patient about the purpose of EHRs and the consequences of consent or withholding consent on the sharing of EHRs.</p> <p>Draft legislation: The draft legislation does not introduce specific rules in this respect.</p>

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>Current legislation: Legislation does not provide for such rule.</p> <p>Draft legislation: The draft legislation does not introduce specific rules in this respect.</p>
<i>Are there specific rules on patient consent to share data on a cross-border situation?</i>		<p>Current legislation: The general rules, described above, extend to cross-border data sharing.</p> <p>Draft legislation: The draft legislation does not introduce specific rules in this respect.</p>

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

Creation of data

Pursuant to Article 9(1) of Act XLVII of 1997, health data are registered by healthcare professionals as part of the medical treatment. The obligation of healthcare professionals to collect the patients' data is reinforced by Article 28(1) of the same Act. Pursuant to this provision, healthcare professionals shall collect patient data and note the sharing of such data. The legislation does not specify the place where health data are collected. Pursuant to Article 28(2) of Act XLVII of 1997, any device or method that ensures the protection specified under Article 6 can be used for the collection of health data. Article 6 provides that the personal and health data of patients while being registered managed and processed must be protected from negligent or intentional destruction, alteration, damage, public disclosure and unauthorised access.

Access to data

Under current applicable Hungarian law, access to health data (which as described under Section 2.1 encompasses EHRs) is allowed to the patients and to healthcare professionals, provided that the patient did not oppose the healthcare professional's access to such data. Healthcare providers in accordance with Article 11 of Act XLVII of 1997 are general practitioners and doctors. Health data can be downloaded electronically from the registry managed by OEP.

Pursuant to Article 23(1) of Act XLVII of 1997, the patient's doctor shall provide access to the patient's health and personal data to the bodies listed in the legal provision. The bodies referred to in Article 23(1) include inter alia law enforcement authorities carrying out criminal investigation or prosecution, criminal courts.

The draft law amending Act XLVII of 1997 will establish the National EHealth Services Platform, which will contain information similar to what the OEP registry currently provides for, in form of a so-called Central Event Inventory Platform. According to Article 17(1) of the draft law introducing Article 35/B(1)(c) of Act XLVII of 1997, the Central Event Inventory Platform will be accessible by all data management authorities. The term data management authority is defined by Article 7 of the draft law amending Article (3)(i) of the current text of Act XLVII of 1997, in a way that it covers all authorities that carry out data management activities (as defined by Article 3(1) of Act CXII of 2011) with respect to health and personal data. This term allows for a broad interpretation, covering also health professionals other than just the patient's doctor or GP.

Pursuant to Article 7(1) any person or body responsible for the management of patient data are bound by strict professional secrecy rules. This implies that data accessed cannot be disclosed legally under currently applicable rules. Moreover, Article 10(1) provides that while processing the data, the health and personal data should be linked only for a certain duration and for the purposes of preventive medicine, medical treatment and the promotion of public health.

Patients are allowed under both systems to access their patient data. It is expected that with the introduction of Act CXII of 2011, patients will be able to access a wider range of health data than now.

Update of EHR

The current legal system does not explicit verbis regulate the process of updating health data. This, however is understood to be covered by the general obligation of health professionals to register the patients' health data as part of the medical treatment (Article 9(1) of Act XLVII of 1997). The provision does not exclude the possibility of re-registering the patients' health data each time they visit their health professional. In this respect the draft law does not introduce new provisions. Both the current and the new version of Act XLVII of 1997 provides for the possibility of correcting and

erasing incorrect health data. The correction and the deletion of health data are privileges of the patients' doctors.

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

Questions	Legal reference	Detailed description
<p><i>Are there any specific national rules regarding who can create and where can EHRs be created?</i></p>	<p>Article 9(1) of Act XLVII of 1997</p>	<p>Current legislation: As explained under Section 2.1., the term EHR is not defined, nor used in Hungarian legislation. Instead, the Hungarian legislation refers to health data, which is understood to cover both electronic and paper data.</p> <p>Pursuant to Article 9(1) of Act XLVII of 1997, health data are registered as part of the medical treatment. The obligation of healthcare professionals to collect the patients' data is reinforced by Article 28(1) of the same Act. Pursuant to this provision, healthcare professionals shall collect patient data and note the sharing of such data.</p> <p>The legislation does not specify the place where health data are collected. Pursuant to Article 28(2) of Act XLVII of 1997, any device or method that ensures the protection specified under Article 6 can be used for the collection of health data. Article 6 provides that the personal and health data of patients while being registered managed and processed must be protected from negligent or intentional destruction, alteration, damage, public disclosure and unauthorised access.</p> <p>Draft legislation: It does not amend currently applicable rules.</p>
<p><i>Are there specific national rules on access and update to EHRs?</i></p>	<p>Article 31 of Act XLVII of 1997</p>	<p>Current legislation: There are no rules in Hungarian legislation on the updating of health data. However legislation specifies the rules applicable to the correction of collected health data. Pursuant to Article 31 of Act XLVII of 1997; incorrect health data should be corrected in a way that both the correct and the incorrect data are kept in the system.</p> <p>Regarding access to EHRs, the applicable rules are described in details below. It is noted that different rules determine the access to health data by health professionals, the patients and bodies outside of the health sector.</p> <p>Draft legislation: It does not amend currently applicable rules.</p>

Questions	Legal reference	Detailed description
<p><i>Are there different categories of access for different health professionals?</i></p>	<p>Articles 11(3) and 14/A(3) of Act XLVII of 1997, Article 9 of the draft law amending Article 11 of Act XLVII of 1997</p>	<p>Current legislation: Pursuant to Article 11(3) of Act XLVII of 1997, the patient's GP or any other doctor may access the patient's health data through the OEP system.</p> <p>Article 14/A(3) provides that pharmacists may request through the OEP system the following information about the patient: data not older than a year which relates to the pharmaceutical treatment of the patient, which data includes the pharmaceutical product's name, its quantity, and the date when it was purchased by the patient.</p> <p>Regardless of the health professional in question, the patient may decide to refuse access to his/her health data.</p> <p>Draft legislation: The draft legislation adds one additional provision regarding the access to health data by health professionals. Article 9 of the draft adding paragraph (5) to Article 11 provides that doctors writing the ePrescriptions are entitled to access the patient's health data to the extent necessary for writing the ePrescription. Such data are stored in the National EHealth Services Platform.</p>
<p><i>Are patients entitled to access their EHRs?</i></p>	<p>Articles 7 of Act XLVII of 1997, Article 8 of the draft law amending Article 7 of Act XLVII of 1997</p>	<p>Current legislation: Pursuant to Article 7(1) of Act XLVII of 1997, the patient in connection with his/her medical treatment is entitled to be informed about the management of any related data, may access his/her personal and health data, and receive –at his/her own expense- copies thereof. This provision suggests that patients may access all sorts of health data. In practice, existing national-level registry (OEP registry) allows access only to certain health data. Accessible health data concerns the medical pathways of patients (e.g. events of hospitalisation, doctor's consultation), but does not provide information on e.g. results of medical tests. This implies that despite the legal provision being in place, access to health data is somehow limited.</p> <p>In Hungary, OEP collects the most extensive list of patient data. Article 22(6) provides that data older than 15 years cannot be managed by OEP. Such data could be kept anonymously. This provision implies that patients, according to the currently applicable rules can access their data, which is not older than 15</p>

Questions	Legal reference	Detailed description
		<p>years. The legal obligation of OEP to keep health data is set out in Article 4(2)(g). Patients can access the following health data by using their social security number as a login:</p> <ul style="list-style-type: none"> - Healthcare services provided, - Information on used prescriptions, - Financial benefits received, e.g. during sick leave. <p>Patients can access the OEP system up to three times per day³¹.</p> <p>Draft legislation: Article 8 of the draft law adding paragraph (3a) to Article 7 provides that patients may receive information on any personal and health data stored on the National EHealth Services Platform, for free and if need be electronically. The rest of legal text of Article 7 remains the same.</p>
<i>Can patient have access to all of EHR content?</i>		<p>Current legislation: As referred to under Section 1, patients can only access the EHRs system operated by OEP. Patients cannot have access to all of the EHR content under currently applicable legislation. As an example, access to results of medical examinations is not possible under the current system. The list of accessible data is provided above.</p> <p>Draft legislation: The draft legislation does not introduce changes in this respect.</p>
<i>Can patient download all or some of EHR content?</i>		<p>Current legislation: under the current legislation, access to health data is limited to certain data sets. These health data is accessible and patients may request copies thereof. The legislation does not mention the possibility of downloading such data.</p> <p>Draft legislation: Pursuant to Article 8 of the draft law, amending Article 7 of Act XLVII of 1997, patients can access any health documentation managed by the National EHealth Services Platform. The legislation does not mention the possibility of downloading such data.</p>
<i>Can patient update their record, modify and erase EHR content?</i>		<p>Current legislation: Article 31 provides for the possibility of correcting or erasing incorrect health data from the system. This right; however is not provided to patients, but to health professionals.</p>

³¹ [Client Gate portal- access to OEP registry.](#)

Questions	Legal reference	Detailed description
<p><i>Do different types of health professionals have the same rights to update EHRs?</i></p>		<p>Draft legislation: The draft law does not amend the applicable rules.</p> <p>Current legislation: Act XLVII of 1997 does not contain reference to the process of updating health data. Updating health data; however is understood to be part of the medical treatment. Health professionals are under the obligation of registering the health data of patients as part of the medical treatment (Article 9(1) of Act XLVII of 1997). This provision suggests that there is a possibility for the subsequent entries of health data into the system during the whole duration of the medical treatment.</p> <p>Health professionals may correct or erase health data, in accordance with the provisions set out in Article 31 of Act XLVII of 1997. Article 31 does not differentiate between health professionals.</p> <p>Draft legislation: The draft law does not amend the applicable rules.</p>
<p><i>Are there explicit occupational prohibitions? (e.g. insurance companies/occupational physicians...)</i></p>		<p>Current legislation: There are no explicit occupational prohibitions in applicable legislation.</p> <p>Draft legislation: The draft law does not amend the applicable rules.</p>
<p><i>Are there exceptions to the access requirements (e.g. in case of emergency)?</i></p>	<p>Article 10(4) of Act XLVII of 1997</p>	<p>Current legislation: No exceptions to access requirements have been identified. It is noted however that pursuant to Article 10(4) of Act XLVII of 1997, in case of emergency, the sharing of the patient's data by healthcare professionals is allowed also in the absence of the patient's consent.</p> <p>Draft legislation: The draft law does not amend the applicable rules.</p>
<p><i>Are there any specific rules on identification and authentication for health professionals? Or are they aggregated?</i></p>		<p>Current legislation: It remains silent about the identification of doctors. It is noted however that in Hungary, each doctor receives an ID number which is indicated on his/her professional stamp. This is a five digit code, which is kept through the life of the doctor. These numbers are kept in a nation-wide registry, managed by the Office of Health Authorisation and Administration Procedures³².</p> <p>Healthcare institutions using different IT systems for the management of</p>

³² [Office of Health Authorisation and Administration Procedures.](#)

Questions	Legal reference	Detailed description
		<p>patient data have introduced different login systems for health professionals. These systems are not universally used across the country.</p> <p>Besides doctors, other health professionals do not have such ID numbers. However other health professionals in accordance with Article 110 of CLIV of 1990 should be registered prior to starting their activities. As a result of the registration process, health professionals receive a registration number.</p> <p>Draft legislation: Article 17(1) of the draft law, introducing Article 35/B to Act XLVII of 1997 provides that health professionals may access the National EHealth Services Platform through an electronic identification procedure, without following any registration procedures. General rules applicable to electronic identification procedures are set out in Act CXL of 2004. These rules; however are not specific to the health sector, thus it is not clear what the exact baseline for the electronic identification process will be.</p>
<i>Does the patient have the right to know who has accessed to his/her EHRs?</i>		<p>Current legislation: It does not provide for the right of patients to know who has accessed their health data.</p> <p>Draft legislation: The draft law does not amend the applicable rules.</p>
<i>Is there an obligation on health professionals to update EHRs?</i>		<p>Current legislation: There is no obligation on healthcare professionals to update the health data.</p> <p>Draft legislation: The draft law does not amend the applicable rules.</p>
<i>Are there any provisions for accessing data on 'behalf of' and for request for second opinion?</i>		<p>Current legislation: There are no such provisions in currently applicable legislation.</p> <p>Draft legislation: The draft law does not amend the applicable rules.</p>
<i>Is there in place an identification code system for cross-border healthcare purpose?</i>		<p>Current legislation: There is no identification code system in place for cross-border healthcare purposes.</p> <p>Draft legislation: The draft law does not amend the applicable rules.</p>

Questions	Legal reference	Detailed description
<p><i>Are there any measures that consider access to EHRs from health professionals in another Member State?</i></p>	<p>Article 19/A(1) of Act XLVII of 1997</p>	<p>Current legislation: Article 19/A(1) of Act XLVII of 1997 provides that the body responsible for cooperation with other EU Member States manages the following patient-related information: name, gender, date and place of birth, permanent and temporary address, social insurance identity number of patients and those health data that are necessary for enforcing those rights of the patients that are linked to the cross-border provision of health services. As referred to above, the term management captures inter alia the collection, processing and sharing of health data.</p> <p>Draft legislation: The draft law does not amend the applicable rules.</p>

2.5. Liability

2.5.1. Main findings

There are no specific medical liability requirements related to the use of or access to EHRs. Healthcare professionals, in charge of the management of EHRs are responsible for the maltreatment of EHRs in accordance with the general liability rules. These rules are set out in the general data protection legislation, notably in Act CXII of 2011, which provides that data managers shall be liable for any damages caused by the unlawful management of data and by breaching data security rules. The liability for damages caused is reinforced by Article 244 of Act CLIV of 1997, which specifies that healthcare professionals shall be held liable in accordance with the civil liability rules, which are provided in Act V of 2013 (Civil Code). Pursuant to Article 6:518 of Act V of 2013 (Civil Code) any person who unlawfully causes harm to another, shall compensate the damaged person. A person is exempt from liability rules, if he/she could prove that his/her conduct was not wrongful.

In most severe cases, health professionals managing EHRs could be held criminally liable. In accordance with Article 219 of Act C of 2012 (the Criminal Code) the following conducts constitute a crime, if committed with the purpose of financial gain or by causing considerable injuries: unauthorised use or use for purpose other than the original, failing to ensure safety.

The liability regime in place does not oblige doctors to consider all relevant information on EHRs. Legislation does not establish the liability of doctors for injuries associated with inaccurate or deficient summary reports provided by their medical staff. The currently applicable liability scheme, however allows for a broad interpretation.

Hungarian legislation also protects against the unlawful access of personal data, which covers EHRs. The general civil liability rules extend to illicit access, if such access results in damages. Moreover, in the most severe cases, illicit access to personal data gives rise to criminal liability, the applicable rules to which are set out in Article 422 of the Criminal Code.

There are no position papers, guidelines or recommendations available that cover liability issues related to EHRs. It is also noted, however, that pursuant to Article 32(1) of Act LXVII of 1997, the head of the health institute holds the overall responsibility within the health institute for the protection of the patients' health and personal data. In this role the head of the healthcare institute is responsible inter alia for ensuring that medical staff in charge of the management and processing of personal data receives the necessary training.

2.5.2. Table on liability

Questions	Legal reference	Detailed description
<p><i>Does the national legislation set specific medical liability requirements related to the use of EHRs?</i></p>		<p>Current legislation: There are no specific medical liability requirements related to the use of EHRs. Moreover it is noted that Hungarian legislation does not define or use the term ‘EHRs’. General data protection related liability rules however extend to medical professionals.</p> <p>In accordance with Article 23(1) of Act CXII of 2011, the data manager/controller shall be liable for any damages caused by the unlawful management of data or by breaching data security rules. The manager of the data is also liable for any damages caused by the user of the data. The data manager is exempt from liability if he/she could prove that the damages were caused by circumstance beyond his/her control.</p> <p>The definition of data manager, as set out in Article 3(j) of Act XLVII of 1997, covers healthcare professionals. The term ‘healthcare professional’ as provided by Article 3(1)(g) of the same act, covers doctor providing medical treatment, medical staff, any person carrying out activities related to the patient’s treatment, pharmacist.</p> <p>Article 244 of Act CLIV of 1997, specifies that healthcare providers are liable for damages caused in accordance with the Civil Code’s rules on ‘civil liability for damages caused by the breach of contractual obligations’. Pursuant to Article 6:518 of Act V of 2013 (Civil Code) any person who unlawfully causes harm to another, shall compensate the damaged person. A person is exempt from liability rules, if he/she could prove that his/her conduct was not wrongful.</p> <p>It is also noted that pursuant to Article 32(1) of Act LXVII of 1997, the head of the health institute holds the overall responsibility within the health institute for the protection of the patients’ health and personal data.</p> <p>In the most severe cases, the breach of the patients’ health data may lead to criminal liability. In accordance with Article 219 of Act C of 2012 (the Criminal Code) the following conducts constitute a crime, if committed with the purpose of</p>

Questions	Legal reference	Detailed description
		<p>financial gain or by causing considerable injuries: unauthorised use of personal data or use for purpose other than the original, failing to ensure safety. Health data is considered as a special personal data, in accordance with Article 3(3) of Act CXII of 2011. Pursuant to Article 219(2) of the Criminal Code, it constitutes an aggravated case, if the criminal offence, which is described above, concerns special data. The crime is punishable by up to two years of imprisonment.</p> <p>The liability regime in place does not oblige doctors to consider all relevant information on EHRs. Legislation does not establish the liability of doctors for injuries associated with inaccurate or deficient summary reports provided by their medical staff. The currently applicable liability scheme, however allows for a broad interpretation.</p> <p>Draft legislation: it does not introduce new rules.</p>
<i>Can patients be held liable for erasing key medical information in EHRs?</i>		<p>Current legislation: Patients are not entitled to erase key medical information.</p> <p>Draft legislation: it does not introduce new rules.</p>
<i>Can physicians be held liable because of input errors?</i>		See above- general liability rules.
<i>Can physicians be held liable because they have erased data from the EHRs?</i>		See above- general liability rules.
<i>Are hosting institutions liable in case of defect of their security/software systems?</i>	Article 32/A of Act XLVII of 1997, Article 6:518 of Act V of 2013, Article 23(1) of Act CXII of 2011	<p>Current legislation: Pursuant to Article 32/A of Act XLVII of 1997 the processing of the data could be carried out by bodies other than the managers of data. Their cooperation is subject to contractual arrangements. In accordance with the general liability rules (see above), towards third parties the manager of the data is liable and not the processor of the data, unless the data manager can prove that the damage was caused by circumstances beyond its control. Regarding the liability regime between the two parties the general liability rules of the Civil Code apply (see above- liability for contractual damages- Article 6:518 of Act V of 2013).</p> <p>Draft legislation: it does not introduce new rules.</p>
<i>Are there measures in place to limit the liability risks for health professionals</i>	Article 32(1) of Act XLVII of 1997	Current legislation: Article 32(1) of Act XLVII of 1997 provides that the head of the healthcare institute holds the overall responsibility within his/her health

Questions	Legal reference	Detailed description
<i>(e.g. guidelines, awareness-raising)?</i>		<p>institute for the protection of the patients' personal and health data. In this role, the head of the healthcare institute is responsible inter alia for ensuring the training of staff responsible for the management and processing of data.</p> <p>Draft legislation: it does not introduce new rules.</p>
<i>Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?</i>	Article 422 of Act C of 2012, 6:518 of Act V of 2013	<p>Current legislation: Pursuant to Article 422(1) of Act C of 2012 (Criminal Code), any person who with the purpose of unlawfully gaining access to personal data captures correspondence forwarded by means of electronic communication networks- including information systems- to another person and records the contents of such by technical means commits a felony and is punishable by imprisonment not exceeding three years. The same penalty is foreseen if the person discloses the personal data obtained. It constitutes an aggravated case and is therefore punishable by between one to five years of imprisonment if illicit access to data is committed by: a) unlawful impersonation of an authority, b) on a commercial scale, c) in criminal association with accomplices, d) causing a significant injury of interests.</p> <p>Health data is a special personal data, as set out in Article 3(3) of Act CXII of 2011. Article 422 of the Criminal Code, as opposed to Article 219 of the same Act (see above), does not provide extra protection to special data. Thus in terms of legal protection, the same rules apply to health data as to other personal data.</p> <p>The general civil liability rules (see above) extends to access to EHRs.</p> <p>Draft legislation: it does not introduce new rules.</p>
<i>Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?</i>		<p>Current legislation: Health professionals are not obliged under currently applicable rules to access EHRs before taking a decision involving the patient.</p> <p>Draft legislation: it does not introduce new rules.</p>
<i>Are there liability rules related to the misuse of secondary use of health data?</i>		See above- general liability rules.

2.6. Secondary uses and archiving durations

2.6.1. Main findings

Hungarian legislation allows for the secondary use of health data for e.g. scientific, epidemiological, planning and evaluation purposes. Secondary use is subject to strict data protection rules under Act of Act XLVII of 1997, often allowing for the use of health data without reference to the identification of patients. The draft law, if adopted, will introduce more stringent data protection rules, obliging the operator of the National EHealth Services Platform to accompany any patient health and personal data with a code. Competent authorities responsible for the secondary use of data will be able to access the coded version of the data that is separated from the patients' personal data through the National EHealth Services Platform. Data can also be used for scientific purposes in a way that scientific publications shall not reveal the identity of the patients studied.

Regarding archiving, it is noted that Hungarian legislation provides for the management and processing of patient data for a limited period of time. Following the lapse of such period, the data could be removed from the databases or could be transferred to the Semmelweis Medical History Museum, Library and Archives in cases when the data is of a significant scientific value.

Hungarian legislation also regulates cases where the body responsible for the collection of data closes before the lapse of the archiving period.

2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
<p><i>Are there specific national rules on the archiving durations of EHRs?</i></p>	<p>Article 16(4a), 30(1)-(2) and (7) of Act XLVII of 1997, Article 15 of the draft law amending Act XLVII of 1997</p>	<p>Current legislation: There are legal provisions that apply to specific health data. As an example, pursuant to Article 16(4a) of Act XLVII of 1997, data can be managed and processed by the National Registry of Congenital Disorders for a duration of up to 50 years, the calculation of which starts on the day when the last data about the concerned person was shared with the Registry. A similar rule applies to certain cardio-vascular diseases, such as to heart attacks. The National Heart Attack Registry can process and manage patient data for up to 50 years. Pursuant to Article 16(12) the data cannot be used in a way which allows for the identification of the patient.</p> <p>Regarding the archiving of non-disease specific data, Article 30(1) provides that health documentation must be kept for at least 30 years, whereas the final hospital report should be archived after 50 years. Exceptionally, for medical and scientific purposes the health data could be kept in the database for a longer period of time. If the extended storage is no longer necessary, the data could be destroyed.</p> <p>Rules applicable to certain diagnostics related data differ from the general rule. Pursuant to Article 30(2), health data gained as a result of picture based diagnostics shall be kept for a period of 10 years, whereas the related diagnosis must be kept for 10 years.</p> <p>If the health data is of scientific importance, following the expiry of the archiving time, the data should be handed over to the Semmelweis Medical History Museum, Library and Archives.</p> <p>Pursuant to Article 30(7) of Act XLVII of 1997, prescriptions are kept for a duration of five years. If the guarantee on the medicinal product concerned by the prescription is longer, the prescription should be kept for a duration that equals to the validity of the guarantee.</p> <p>Draft legislation: Pursuant to Article 15 of the draft law replacing the current version of Article 30(7) of Act XLVII of 1997 ePrescriptions should be kept by</p>

Questions	Legal reference	Detailed description
		<p>the National EHealth Services Platform for a period of five years. Paper-based prescriptions are kept by pharmacies for a period of five years.</p> <p>Article 15 introducing paragraph (3) of Article 30/A also provides that the manager of the National EHealth Services Platform may transfer scientifically significant data to the Semmelweis Medical History Museum, Library and Archives.</p>
<i>Are there different archiving rules for different providers and institutions?</i>	Article 16(4a), 30(1)-(2) and (7) of Act XLVII of 1997, Article 15 of the draft law amending Act XLVII of 1997	See above.
<i>Is there an obligation to destroy (...) data at the end of the archiving duration or in case of closure of the EHR?</i>	Article 30(1) of Act XLVII of 1997	<p>Current legislation: Pursuant to Article 30(1) of Act XLVII of 1997, after the archiving period lapses, the registered data should be deleted from the system.</p> <p>Draft legislation: It does not introduce new rules regarding the destruction of health data.</p>
<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>	Article 30(3)-(5) of Act XLVII of 1997	<p>Current legislation: As referred to above, in accordance with Article 30(3), scientifically significant data should be transferred to the Semmelweis Medical History Museum, Library and Archives.</p> <p>Article 30(4) of Act XLVII of 1997 regulates the legal status of health data after the closure of the body managing the data. It states that following the closure of the body without a legal successor the documentation shall be:</p> <ul style="list-style-type: none"> - In case of scientific importance transferred to the Semmelweis Medical History Museum, Library and Archives; - In any other cases transferred to the body designated by the Government. <p>Pursuant to Article 30(5) of Act XLVII of 1997 if the body's competences that closes without a legal successor are taken over by a different body</p> <ul style="list-style-type: none"> - The health data that was collected within 10 years before the closure of the data management body shall be shared with the new competent body, - The health data that does not fall under the previous point shall be shared with the bodies specified under Article 30(4). <p>Draft legislation: It does not introduce new rules.</p>

Questions	Legal reference	Detailed description
<i>Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?</i>	Articles 18-21 of Act XLVII of 1997, Article 13 of draft law replacing Article 18 of Act XLVII of 1997	<p>Current legislation: It provides for the secondary use of health data, which includes in accordance with:</p> <ul style="list-style-type: none"> - Article 18-19- epidemiological examinations and analysis, the planning of medical services and the quality and performance evaluation. - Article 20- statistical data management - Article 21- scientific research. <p>Draft legislation: It does not introduce new rules.</p>
<i>Are there health data that cannot be used for secondary use?</i>		<p>Current legislation: Restrictions in terms of use concern the person's personal data. Often health data can be used in a way that does not allow for the identification of the person.</p> <p>Draft legislation: It does not introduce new rules.</p>
<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>	Articles 18-21 of Act XLVII of 1997, Article 13 of draft law replacing Article 18 of Act XLVII of 1997	<p>Current legislation:</p> <ul style="list-style-type: none"> - Article 18(2) provides that while carrying out the professional evaluations, the head of the competent organisation must make sure that the health and personal data of the patient is accompanied with a code. The code will disable the competent authority to link the personal and the health data of the patient. Following the creation of the code, the competent authority shall delete the personal data of the patient from the system. - Article 20(1) provides that health data can only be used for statistical purposes in a way that does not allow for the identification of patients. - Article 21(1) provides that data cannot be quoted in scientific publications in a way that allows for the identification of patients. <p>Draft legislation: Article 13 of the draft law replacing the current text of Article 18 of Act XLVII of 1997 provides that professional evaluations must be carried out on the basis of the data stored on the National EHealth Services Platform. Pursuant to Article 35/C(1) of the future law, the operator of the National EHealth Services Platform shall link the patients' personal and health data with a code, replacing any information that could lead to the identification of the patient.</p>
<i>Does the law say who will be entitled to use and access this data?</i>	Articles 18-21 of Act XLVII of 1997, Article 13 of draft	<p>Current legislation:</p> <ul style="list-style-type: none"> - Articles 18-19- the body performing epidemiological examinations and

Questions	Legal reference	Detailed description
	law replacing Article 18 of Act XLVII of 1997	<p>analysis, the planning of medical services and the quality and performance evaluation.</p> <ul style="list-style-type: none"> - Article 20- The Central Statistical Office. - Article 21- Any person carrying out scientific work. <p>Draft legislation:</p> <ul style="list-style-type: none"> - Article 13 of the draft law amending Article 18 provides that health data could also be used by organisations responsible for planning patient pathways.
<i>Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?</i>		<p>Current legislation: The current legislation does not provide for opt-in/opt-out systems for the secondary use of eHealth data.</p> <p>Draft legislation: The draft legislation does not provide for opt-in/opt-out systems for the secondary use of eHealth data.</p>

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

Current EHRs systems are not centralised in Hungary. EHRs are collected at the local level and depending on the projected use of the data are shared with central level registries. The central level registries include e.g. the National Cancer Registry or the registry operated by the OEP, which contains information about the healthcare services provided to patients, the prescriptions that have been written for patients, and financial benefits received by patients. The mean of sharing the data with the central level registry is not specified in legislation, thus are not carried out in a systematic manner.

The current system at the local level is not interoperable, which means that healthcare providers at the local level cannot systematically exchange data. The connection of the local systems started with a regional pilot programme in 2006 under the EU initiative ‘IT development in healthcare in the disadvantaged regions’ (HEFOP 4.4.1 initiative)³³, connecting 38 healthcare institutions in three regions (Southern Trans-Danubia, Northern Hungary and Northern Great Plain). The initiative had three main components, notably the design of protocols and standards for the interoperability of electronic data sets and systems, the modernisation of the individual IT systems of each healthcare institute, the provision of trainings for health staff to improve IT literacy. Amongst the specific eHealth services, the initiative focused on EHRs, eConsultation and ePrescription. The budget provided was approximately 16 million EUR³⁴.

As referred to under Section 1, current policy initiatives also aim at improving the interoperability of EHRs systems. To achieve these aims there are two on-going projects aiming at the modernisation of current IT infrastructures (see above-Section 1). The interoperable EHR systems foreseen by the two projects are essential for developing the National EHealth Services Platform. The draft legislation amending Act XLVII of 1997 and establishing National EHealth Services Platform does not contain reference to interoperability.

³³ [HEFOP 4.4.1 initiative.](#)

³⁴ [The development of eServices in an enlarged EU: eGovernment and eHealth in Hungary.](#)

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>		Current legislation: It does not provide for the interoperability of EHRs. Draft legislation: It does not touch upon the question of interoperability.
<i>Are there any specific rules/standards on the interoperability of EHR?</i>		See above.
<i>Does the law consider or refer to interoperability issues with other Member States systems?</i>		Current legislation: It does not consider or refer to interoperability issues with other Member States systems.

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

The use of ePrescriptions in Hungary is at the planning phase. Policy documents, described under Section 1, envisage the introduction of ePrescriptions; however as of today no strategic project has been tendered under the framework of the new Szechenyi Plan to realise the system.

Pursuant to Article 14/A(1(a)) of Act XLVII of 1997, health professionals can prescribe medicines, medical devices and medical treatments electronically. Rules applicable to ePrescriptions are not detailed any further in Act XLVII of 1997. The development of applicable rules falls under the responsibility of the Minister responsible for health, who in accordance with 14/A(1(a)) of Act XLVII of 1997 shall develop such rules in form of a ministerial decree. As of today, the ministerial decree has not been adopted yet.

The draft law amending Act XLVII of 1997 does not regulate ePrescriptions in a detailed manner, but provides for rules regulating the relationship between ePrescriptions and the future National EHealth Services Platform. The most important linkages between the future National EHealth Services Platform and ePrescriptions are set out in Article 35/H of the draft law, which provides that:

- Only those health professionals can write ePrescriptions who can access the National Ehealth Services Platform.
- Eprescriptions are issued through the sub-platform of the National EHealth Services Platform, called Electronic Prescription Services.
- Patients may purchase the items prescribed by identifying themselves at the pharmacy, or by providing the pharmacist with the digital code received after the issuance of the ePrescription. The pharmacist should enter the data received into the National EHealth Services Platform, to see the corresponding information, including the name of the item prescribed, its quantity, etc.
- Following the purchase of the item, the pharmacists should inform the operator of the National EHealth Services Platform about the digital code used, data necessary for the identification of the patient and data related to the purchased item. Upon receipt of these data, the ePrescription used will be deleted by the operator of the National EHealth Services Platform from the pending ePrescriptions of the patient.

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>	Article 35/H(1) of draft law amending Act XLVII of 1997	<p>Current legislation: currently applicable legislation does not specify the linkages between the EHRs system and ePrescriptions.</p> <p>Draft legislation: Article 35/H(1) provides that doctors with access to the National EHealth Services Platform may issue ePrescriptions through the application 'Electronic Prescription Services'. This provision suggests that the existence of the EHR system will be the precondition for establishing the ePrescription system in Hungary.</p>
<i>Can an ePrescription be prescribed to a patient who does not have an EHR?</i>	Article 17 of the draft law, introducing Article 35/H(2)-(4) to Act XLVII of 1997	<p>Current legislation: currently applicable legislation does not specify the linkages between the EHRs system and ePrescriptions.</p> <p>Draft legislation: It can be derived from Article 17 of the draft law, introducing Article 35/H(2)-(4) that ePrescriptions can only be issued to patients who are in the EHRs system.</p> <p>Pursuant to Article 35/H(2) the operator of the EHRs system is entitled to process the personal and health data of the patients who have received ePrescriptions. It is noted that the new EHRs system has not been set up yet, thus the legislation does not specify the body responsible for the operation thereof. Article 35/H(3) provides that each ePrescription issued to patients is accompanied with a digital code which is provided to the patient. The patient can use this digital code while purchasing the prescribed medication, device or treatment. Following the purchase, the pharmacy informs the EHRs system about: the digital code used by the patient, data necessary for the identification of the patient, data related to the purchased item. Upon received of these data, the operator of the EHRs system, deletes the ePrescription from the list of ePrescriptions that the patient can use.</p>

- *Access*

Questions	Legal reference	Detailed description
<p><i>Do the doctors, hospital doctors, dentists and pharmacists writing the ePrescription have access to the EHR of the patient?</i></p>		<p>Current legislation: Currently applicable legislation does not specify the linkages between the EHRs system and ePrescriptions.</p> <p>Draft legislation: It can be derived from Article 17 of the draft law introducing Article 35/H(1) to Act XLVII of 1997 that doctors writing the ePrescription have access to the EHRs of patients. Pharmacists in Hungary will be able to access the National EHealth Services Platform while the patient is purchasing his/her medication. Pursuant to Article 17(2) of the draft law introducing Article 35/H(4) to Act XLVII of 1997, pharmacists will be able to access the system by entering a digital code that the patient received while his/her doctor prescribed the medication. By entering this code, pharmacists will be able to identify the prescribed medication. Access to the National EHealth Services Platform by pharmacists is considered as restricted, as pharmacists cannot access all EHRs of the patients.</p>
<p><i>Can those health professionals write ePrescriptions without having access to EHRs?</i></p>	<p>Article 35/H(1) of draft law amending Act XLVII of 1997</p>	<p>Current legislation: currently applicable legislation does not specify the linkages between the EHRs system and ePrescriptions.</p> <p>Draft legislation: Pursuant to Article 17 of the draft law, introducing Article 35/H(1) to Act XLVII of 1997, only health professionals with access to the EHRs system can write ePrescriptions.</p>

2.9. Other requirements

None

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

None of the stakeholder contacted responded.