

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

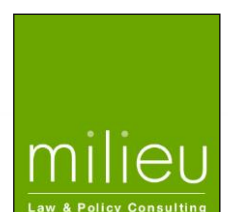
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Overview of the national laws on electronic health records in the EU Member States

National Report for Croatia



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Executive Summary

1. Stage of development of EHRs in Croatia

Croatia has a very advanced legal system regulating the Electronic Health Records (EHR) in place. Although not yet operational due to technical challenges, the Croatian authorities believe that the EHR system will be functioning in the second half of 2014 – first half of the 2015 period. The data contained in EHRs will be encoded and stored in a central information system called Central Information Health System of the Republic of Croatia (CEZIH). At the moment EHRs in Croatia contain only very general information such as information on insurance policies and selected doctors.

2. Summary of legal requirements applying to EHRs

Concerning the legal aspects of EHRs, the Croatian authorities adopted specific rules concerning EHRs. The Croatian legislation provides for the definition of EHRs and that they must include information on personal and family medical history; blood type; disabilities; current problems; and information on specific doctor visits (description of patients' state and doctors' conclusions). Currently, the Croatian legislation does not foresee different levels of confidentiality concerning different categories of data contained in the EHRs. Also, no specific rules on use of terminology in the EHRs and their interoperability with other EHR systems in the EU exist.

EHRs are hosted by the Central Information Health System of the Republic of Croatia. Specific authorisation for hosting the EHRs was not required.

Consent for creation of EHRs, their access, transfer and processing in another country, and use of anonymised data is given by signing the "Statement on selection/change of selected doctor". The signing of statement cannot be withheld and patients are not informed in writing and orally about the consequences of signing the statement in regards to EHRs. These shortcomings are recognised by the Croatian authorities and future relevant legal action is foreseen.

According to the current legislation, the medical data for each patient can be accessed and updated by a doctor selected by that patient. The patient can also access the data but the access is facilitated by the selected doctor. Furthermore, in theory the data can be accessed by health practitioners and health institutions in other countries. Aggregated and anonymised data is accessible to a number of government bodies in Croatia. Also, further amendments to the current legal framework are foreseen in the future.

Existence of separate legal provisions on liability and archiving concerning EHRs are limited. And finally, EHRs are expected to improve ePrescription, which was introduced in Croatia in 2011. In addition to being integrated with the ePrescription, the EHRs will be integrated with eReferral which are also used in Croatia at the moment of the drafting of this document.

3. Good practices

Since the EHR system in Croatia is not yet operational, good practices could not have been identified. However, the introduction of EHR is expected to introduce various improvements one of which is improving ePrescriptions, which were introduced in Croatia in 2011. The EHRs should enable better understanding and archiving of ePrescriptions (e.g. information to avoid polypharmacology¹).

¹ Drug molecules often interact with multiple targets, coined as polypharmacology, and the unintended drug-target interactions could cause side effects.

4. Legal barriers

The signature of the “Statement on selection/change of selected doctor” which does not provide information on the EHR system in place and the consequences of the creation of EHR allows the creation of EHRs, their processing, sharing of information and secondary use. The patient is therefore not informed about the consequences of the signature of this statement on the use of its health data,

The shortcomings of this approach have been identified by the competent authorities in Croatia that plan to amend the legislation to provide more information to patients on EHRs prior to the signature of the Statement on selection/change of selected doctor

No specific rules on use of terminology in the EHRs and their interoperability with other EHR systems in the EU exist. Currently, the only international terminology used is the tenth revised International Classification of Diseases codes, although this is not a legal requirement. Furthermore, a non-binding instrument containing different codes is available. Health professionals in another Member State are not able to access patients’ medical data since the current system in Croatia does not recognise health professionals practicing in another Member States (they would need a Croatian smart card and Croatian personal pin code).

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List of abbreviations

CEZIH	Central Information Health System of the Republic of Croatia
CEZIH PZZ	Information System of the Primary Health Care
EHRs	Electronic Health Records
HZZO	Croatian Health Insurance Fund
ICHA-HP	International Classification for Health Accounts- Classification of Health Care Providers

1. General context

1.1. EHR systems in place

The Central Information Health System of the Republic of Croatia (CEZIH), operated by the Croatian Health Insurance Fund is an integrated information system that hosts EHRs. It applies to the entire territory of Croatia as there are no EHR regional systems. The CEZIH is operational in regards to certain segments such as ePrescription and eReferral. The Croatian authorities believe that the CEZIH will successfully integrate the EHRs, not operational at the moment, in the existing system in the second half of 2014 – first half of the 2015 period..

1.2. Institutional setting

On 20 June 2006, the Minister competent for health protection published a Decision² appointing the unit for information technology of the **Croatian Health Insurance Fund (HZZO)**, as the operator of CEZIH. The HZZO is a public institution supervised by the **Ministry of Health of the Republic of Croatia**.

In accordance with the Decision on Readiness Check of the Programme Support for the Work of the CEZIH³), the check is carried out by a special committee consisting of representatives of the HZZO and **Croatian Health Insurance Fund for Health Protection at Work** (and representatives of the Ministry of Health). The check encompasses whether the programme support provided by the producers of programme support and used by the authorised system users is functioning properly and whether it is sufficiently well connected to the CEZIH. The check is carried out in accordance with a separate protocol. At the moment of drafting of this document, the committee was drafting the Action Plan for inclusion of information technology into the healthcare system. The final authorisation to the producer of programme support is given by the Minister of Health of the Republic of Croatia.

The **Croatian Personal Data Protection Agency**, in a capacity of an independent supervisory body, is monitoring the collection and processing of personal health data in accordance with Article 32 of the Law on Personal Data Protection.

Each health care institution and private healthcare practitioner, within the system of compulsory health insurance, is required to use CEZIH.

Currently, Croatia is participating in the epSOS project and has recently established ProRec.HR, a Croatian Electronic Health Record association. The ProREC.HR plans to become a member of the EuroRec⁴. Croatian authorities are participating in the work of the eHealth Network (e.g. input concerning the Guidelines on minimum/non exhaustive patient summary dataset for electronic exchange in accordance with the cross-border Directive 2011/24/EU, discussed and adopted on the Network's meeting on 19 November 2013).

1.3. Legal setting and future legal development

Article 37 of the Croatian Constitution (“O.G.”, No. 85/10 – consolidated text), guarantees personal data protection. According to this provision, personal data may only be collected processed and used

²² Decision on the Operator of the Information System of the Primary Health Care CEZIH PZZ, Set up of the Coordination Body CEZIH PZZ and its Powers (*Odluka o operateru Informatičkog sustava primarne zdravstvene zaštite – CEZIH PZZ, ustroju Koordinacijskog tijela CEZIH PZZ, te ovlastima istog*) (Ur.Broj:534-05-06-01/1-06-01).

³ (*Odluka o provedbi provjere spemnosti programske podrške za rad u Centralnom informacijskom sustavu zdravstva Republike Hrvatske*) (Ur.Broj:534-07-10-1)

⁴ EuriRec Institute promotes implementation and adoption of EHRs in Europe. - <http://www.eurorec.org/index.cfm>, accessed on 2 April 2014.

under the condition set in Law. Furthermore, personal data cannot be used for a different purpose to the one that they were collected for.

The main law for personal data protection in Croatia is the Law on Personal Data Protection⁵ which transposes provisions of the Directive 95/46/EC. According to Article 8 of the Law, collection and processing of data concerning health is prohibited. However, this general rule is subject to several exemptions. One of them states that collection and processing is allowed “if the processing is required for the purpose of preventive medicine, medical diagnosis, health protection or management of health services, under the condition that the data is processed by a health professional on the basis of rules and regulations adopted by competent authorities.

In regards to other aspects of EHRs, the main law is the Law on Health Protection⁶. The Law is the main legal act regulating health protection in Croatia. The Law, inter alia, transposes provisions of the Directive 2011/24/EU. Article 127(3) of the Law stipulates that the method to keep, store, and use medical documents will be regulated through Ministerial Ordinance. Various Ministerial Ordinances were passed on the basis of this Law, such as:

- Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form⁷ which contains specific rules on the content of EHRs;
- Ordinance on the Method of Keeping, Storage, Collection and Use of Patient’s Medical Documents Concerning Obligatory Health Insurance within the Central Information Health System of the Republic of Croatia⁸ regulates functioning of the CEZIH; and
- Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia⁹ regulates functioning of the CEZIH.

Another relevant Law is the Law on Compulsory Health Insurance¹⁰. This Law, inter alia, regulates the work of HZZO which is also regulated by the Statute of the HZZO¹¹. Various by-laws were passed on the basis of this Law, such as:

- Ordinance on Method of Establishment of a Right on Free Selection of Medical Doctors and Dentists of the Primary Health Care¹² that – contains provisions on the selection of doctors and dentists of the primary health care; and
- Decision on the Basis for Concluding Agreements for Carrying out Health Protection in the Areas of Compulsory Health Insurance¹³ – stipulates that each health care institution and private healthcare practitioner, as part of the obligatory health insurance, is required to use CEZIH and that programme support for connection to CEZIH must be authorised by the Minister of Health.

⁵ Law on Personal Data Protection (*Zakon o zaštiti osobnih podataka*) (“O.G.”, No. 106/12 – consolidated text)

⁶ Law on Health Protection (*Zakon o zdravstvenoj zaštiti*) (“O.G.”, No. 150/08, 71/10, 139/10, 22/11, 84/11, 154/11, 12/12, 35/12 – OUSRH, 70/12, 144/12, 82/13 and 159/13)

⁷ Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (*Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku*) (“O.G.”, No. 82/10)

⁸ Ordinance on the Method of Keeping, Storage, Collection and Use of Patient’s Medical Documents Concerning Obligatory Health Insurance within the Central Information Health System of the Republic of Croatia (*Pravilnik o načinu vođenja, čuvanja, prikupljanja i raspolaganja medicinskom dokumentacijom pacijenata iz obveznog zdravstvenog osiguranja u Centralnom informacijskom sustavu zdravstva Republike Hrvatske*) (“O.G.”, No. 82/10)

⁹ Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia (*Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske*) (“O.G.”, No. 14/10)

¹⁰ Law on Compulsory Health Insurance (*Zakon o obveznom zdravstvenom osiguranju*) (“O.G.”, No 80/13 and 137/13).

¹¹ Statute of the HZZO (“O.G.”, No 18/09, 33/10, 8/11 and 18/13)

¹² Ordinance on Method of Establishment of a Right on Free Selection of Medical Doctors and Dentists of the Primary Health Care (*Pravilnik o načinu ostvarivanja prava na slobodan izbor doktora medicine i doktora stomatologije primarne zdravstvene zaštite*) (“O.G.”, No. 41/07, 4/10, 13/10, 41/12 and 50/13)

¹³ *Odluka o osnovama za sklapanje ugovora o provođenju zdravstvene zaštite i obveznog zdravstvenog osiguranja* (“O.G.”, No. 156/13)

Other relevant laws include:

- Law on Medical Practice¹⁴ (– relevant for access to information contained in EHRs by patients and responsibilities of doctors; and
- Law on Protection of a Patient’s Rights¹⁵ - relevant for access to information contained in EHRs by patients.

Concerning policies documents, the significance of the National Health Care Strategy (*Nacionalna strategija zdravstva*) for 2012 – 2020 and the Strategic Plan for the Development of Public Health (*Strateški plan razvoja javnog zdravstva*) 2013- 2015, has been recognised on numerous occasions in this Document. For example, the National Health Care Strategy for 2012 – 2020 calls for common code lists, recognising the necessity to achieve interoperability of information systems in health care with all state administration bodies (joint services), as well as with the EU countries¹⁶.

¹⁴Law on Medical Practice (*Zakon o liječništvu*) (“O.G.”, No. 121/03 and 117/08)

¹⁵Law on Protection of a Patient’s Rights (*Zakon o zaštiti prava pacijenta*) (“O.G.”, No. 169/04 and 37/08)

¹⁶ National Health Care Strategy for 2012 – 2020 (English version), p. 67.

2. Legal requirements applying to EHRs in Croatia

2.1. Health data to be included in EHRs

2.1.1. Main findings

The EHRS system in Croatia is not operational at the moment of drafting of this document. However, Croatian legislation already contains provisions on EHRs. In Croatia, the EHRs are defined as the basic medical documents of a person with a compulsory health insurance using health care [insured person] kept in an electronic form [e-record]. Furthermore, specific rules on the content of EHRs exist. The EHRs will contain, inter alia, information on personal and family (parents and other ancestors, siblings and other relatives, descendants) medical history; blood type; disabilities; current problems; and information on specific doctor visits (description of patients' state and doctors' conclusions). Currently, the Croatian legislation does not foresee different levels of confidentiality concerning different categories of data contained in the EHRs.

No specific rules on use of terminology in the EHRs and their interoperability with other EHR systems in the EU exist. However Croatia is planning to work on it in the future. Currently, the only international terminology used is the tenth revised International Classification of Diseases codes, although this is not a legal requirement. Finally, on this note, a non-binding instrument containing different codes to be used entitled the Information System of Primary Health Care of the Republic of Croatia – Specification of Data in the Electronic Health Records¹⁷, is available. This document includes code lists for health care providers; diagnosis; blood type; Rh factor; etc. The codes used originate from various sources such as ICHA-HP (International Classification for Health Accounts-Classification of Health Care Providers)¹⁸, medical publications in Croatia¹⁹, etc.

Authorised persons will be able to access patients' EHRs through the use of identification number of the insured person (*matični broj osigurane osobe*)²⁰.

¹⁷ http://www.cezih.hr/pzz/dokumentacija/ISPZZ_Specifikacija_podataka_el_zdr_karton_RevB.pdf, accessed on 19 March 2014.

¹⁸ Please see A System of Health Accounts, 2011 edition, OECD, Eurostat, WHO, available at http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-30-11-270/EN/KS-30-11-270-EN.PDF, accessed on 6 April 2014.

¹⁹ Anamnesis and physical examination (*Anamneza i fizikalni pregled*), Fedor Čustović, Školska knjiga – Zagreb, 2000; ISBN 953-0-31531-7.

²⁰ Interview with the representative of the Croatian Health Insurance Fund that took place on 24 February 2014.

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>	Articles 3 – 9 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)	The specific rules on the content of EHRs are stipulated in the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form.
<i>Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?</i>	Articles 3, 5, 6, 7 and 8 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)	<p>EHRs do not include only medical data.</p> <p>According to Article 3 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form, EHRs contain the following non-medical data:</p> <ul style="list-style-type: none"> - insured person’s work and profession related data; - data on the basis for insurance concerning compulsory health insurance; - data on the type of health insurance; - data on the insurance provider.. <p>According to Article 5 of the Ordinance, insured person’s work and profession related data includes work status; degree; activity; profession; title and the address of the employer.</p> <p>According to Article 6 of the Ordinance, data on the basis for insurance is entered in accordance with legislation on compulsory health insurance.</p> <p>According to Article 7 of the Ordinance, data on the type of health insurance consists of: insurers’ identifiers; identification number of the</p>

Questions	Legal reference	Detailed description
		<p>insured person (<i>matični broj osigurane osobe</i>); insured person's number; start date of the insurance; policy status; and type of policy.</p> <p>According to Article 8 of the Ordinance, data on the insurance provider consists of: insurer's personal identifier; insurer's title; address; insurer's town code; name of the town; postal code; status; and insurance type.</p>
<p><i>Is there a definition of EHR or patient's summary provided in the national legislation?</i></p>	<p>Article 2 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) ("O.G.", No. 82/10)</p>	<p>Definition of an EHR is provided in Article 2 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form.</p> <p>Article 2 of the Ordinance stipulates that "personal health records are the basic medical documents of a person with a compulsory health insurance using health care [insured person] kept in an electronic form [e-record]".</p>
<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>	<p>Articles 4 and 9 and Annexes I and II of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) ("O.G.", No. 82/10)</p>	<p>In addition to non-health data listed in the row 2 of this section, the relevant legislation in Croatia requires medical data to be included in the EHRs. The medical data is listed below.</p> <p>According to Article 4 of the Ordinance, insured person's personal data is stipulated in Annex I of the Ordinance. Annex I of the Ordinance²¹ contains data that is not changed frequently and is filled out during the medical history interview with the patient. Insured person's personal data contains, inter alia, the following:</p> <ul style="list-style-type: none"> - alerts; <ul style="list-style-type: none"> o medical notices; <ul style="list-style-type: none"> ▪ allergic reactions; ▪ habits (smoking; alcohol drinking); ▪ addiction to drugs; ▪ blood type;

²¹ Content of the Annex I of the Ordinance is available on CEZIH's website. Content of the Annex I is available only in Croatian version (joined Document containing specifications stipulated in Annex I (Section 1.1 of the Document) and Annex II (Section 1.2. of the Document) of the Ordinance) http://www.cezih.hr/pzz/dokumentacija/ISPZZ_Specifikacija_podataka_el_zdr_karton_RevB.pdf, accessed on 19 March 2014.

Questions	Legal reference	Detailed description
		<ul style="list-style-type: none"> ○ disabilities; ○ medical history (personal and family (parents and other ancestors, siblings and other relatives, descendants)) medical history); and ○ current problems (list of chronicle illnesses; list of psycho-social problems). <p>According to Article 9 of the Ordinance, insured person's state of health data is stipulated in Annex II of the Ordinance. Annex II of the Ordinance²² contains data concerning each visit of the patient to the health system and use of the system resources. Person's state of health data contains, inter alia, the following:</p> <ul style="list-style-type: none"> - code of the doctor examining the patient; - code of the medical institution; - reason for patient's visit; - description of patient's physical state; and - conclusion (diagnosis).
<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>Strategic Plan for the Development of Public Health (<i>Strateški plan razvoja javnog zdravstva</i>) 2013- 2015</p> <p>National Health Care Strategy (<i>Nacionalna Strategija Zdravstva</i>) for 2012 – 2020</p>	<p>According to the information acquired through an interview²³, no specific rules on the use of a terminology or a coding system to identify diseases, disorders, symptoms, etc. exist. The tenth revised International Classification of Diseases codes are used alongside general medical terms for conditions and allergies included in EHRs²⁴. However, this is not a legal requirement.</p> <p>Also, it is important to note that a list of codes is included in the document entitled Information System of Primary Health Care of the Republic of Croatia – Specification of Data in the Electronic Health Records²⁵. This document also contains Annex I and II of the Ordinance</p>

²² Content of the Annex II of the Ordinance is available on CEZIH's website. Content of the Annex II is available only in Croatian version (joined Document containing specifications stipulated in Annex I (Section 1.1 of the Document) and Annex II (Section 1.2. of the Document) of the Ordinance) http://www.cezih.hr/pzz/dokumentacija/ISPZZ_Specifikacija_podataka_el_zdr_karton_RevB.pdf, accessed on 19 March 2014.

²³ Interview with the representative of the Croatian Health Insurance Fund that took place on 24 February 2014.

²⁴ Written response received from the Croatian Medical Chamber, received on 18 March 2014.

²⁵ http://www.cezih.hr/pzz/dokumentacija/ISPZZ_Specifikacija_podataka_el_zdr_karton_RevB.pdf, accessed on 19 March 2014.

Questions	Legal reference	Detailed description
		<p>on the Method of Keeping of Personal Health Record in the Electronic Form. However, no legal instrument requires certain codes to be used and therefore, codes contained therein are not legally binding.</p> <p>Several policy documents already call for establishment of interoperability between health registers²⁶ and standardisation of data models, common code lists, recognising the necessity to achieve interoperability of information systems in health care with all state administration bodies (joint services), as well as with the EU countries²⁷.</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>No specific provisions</p>	<p>The content of the EHRs stipulated in Articles 3 - 9 and Annexes I and II of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form.</p> <p>The current Croatian legislation does not foresee different levels of confidentiality for different categories of data contained in the EHRs.</p>
<p><i>Are there any specific rules on identification of patients in EHRs?</i></p>	<p>No specific provisions</p> <p>Article 7 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) ("O.G.", No. 82/10)</p>	<p>No specific legal provisions exist on identification of patients in EHRs.</p> <p>According to the information acquired through an interview²⁸ identification number of the insured person (<i>matični broj osigurane osobe</i>) will be used to identify patients in EHRs.</p> <p>According to Article 7 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form, data on the identification number of the insured person (<i>matični broj osigurane osobe</i>) is included in the EHRs.</p>
<p><i>Is there is a specific identification number for eHealth purposes?</i></p>	<p>Article 7 of the Ordinance on the Method of Keeping of</p>	<p>Authorised persons will be able to access patients' EHRs through the use of identification number of the insured person (<i>matični broj osigurane osobe</i>)²⁹. Patients will not be able to access their EHRs directly on line.</p>

²⁶ Strategic Plan for the Development of Public Health 2013- 2015, p. 34 and 35.

²⁷ National Health Care Strategy for 2012 – 2020 (English version), p. 67.

²⁸ Interview with the representative of the Croatian Health Insurance Fund that took place on 24 February 2014.

²⁹ Interview with the representative of the Croatian Health Insurance Fund that took place on 24 February 2014.

Questions	Legal reference	Detailed description
	Personal Health Record in the Electronic Form <i>(Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku)</i> ("O.G.", No. 82/10)	According to Article 7 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form, data on the identification number of the insured person (<i>matični broj osigurane osobe</i>) is included in the EHRs.

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

CEZIH is an integrated information system consisting of hardware and software components. On 20 June 2006, the Minister competent for health protection, passed the Decision on the Operator of the Information System of the Primary Health Care CEIZH PZZ, Set up of the Coordination Body CEZIH PZZ and its Powers. In accordance with this decision, the HZZO, more specifically, its unit for information technology was appointed as the operator of CEZIH. The work of HZZO, a public institution supervised by the Croatian Ministry of Health, is regulated by the Law on Compulsory Health Insurance and the Statute of the HZZO.

CEZIH hosts EHRs. A specific authorisation for hosting and processing of data by CEZIH is not required. The functioning of CEZIH is regulated in several legal instruments such as the Ordinance on Use and Protection of Data from a Patient's Medical Documents within the Central Information Health System of the Republic of Croatia (and the Law on Personal Data Protection). The data contained in CEZIH is encoded. The companies providing software for the proper functioning of CEZIH are required to provide software meeting the requirements established by the Croatian authorities and published in the Croatian Official Gazettes. These requirements are also referred to when signing a contract with the software providers.

Data contained in EHRs is accessed and used by health care institution and private healthcare practitioners.

A special committee consisting of representatives of the HZZO and Croatian Health Insurance Fund for Health Protection at Work (and representatives of the Ministry of Health) is conducting checks on whether the programme support provided by the producers of programme support and used by the authorised system users is functioning properly and whether it is sufficiently well connected to the CEZIH. The final authorisation to the producer of programme support is given by the Minister of Health of the Republic of Croatia.

Information on staff and their qualifications are contained in specific internal organisation acts of HZZO and healthcare institutions.

2.2.2. Table on requirements on the institutions hosting EHRs data

Questions	Legal reference	Detailed description
<p><i>Are there specific national rules about the hosting and management of data from EHRs?</i></p>	<p>Decision on the Operator of the Information System of the Primary Health Care CEIZH PZZ, Set up of the Coordination Body CEZIH PZZ and its Powers (<i>Odluka o operateru Informatičkog sustava primarne zdravstvene zaštite – CEZIH PZZ, ustroju Koordinacijskog tijela CEZIH PZZ, te ovlastima istog</i>) (Ur.Broj:534-05-06-01/1-06-01)</p> <p>Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia (<i>Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske</i>) (“O.G.”, No.</p>	<p>CEZIH is operated by the HZZO, more specifically, its unit for information technology, in accordance with the Decision on the Operator of the Information System of the Primary Health Care CEIZH PZZ, Set up of the Coordination Body CEZIH PZZ and its Powers.</p> <p>The Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia regulates method of use and protection of medical data contained in the CEZIH.</p> <p>According to the carried out interviews³⁰, the companies providing software for the proper functioning of CEZIH are required to provide software meeting the requirements established by the Croatian authorities and published in the Croatian Official Gazettes. These requirements are also referred to when signing a contract with the software providers.</p> <p>No further specific EHR related legal requirements exist.</p>

³⁰ Interview with the representative of the Croatian Health Insurance Fund that took place on 24 February 2014.

Questions	Legal reference	Detailed description
<p><i>Is there a need for a specific authorisation or licence to host and process data from EHRs?</i></p>	<p>14/10)</p> <p>Decision on Readiness Check of the Programme Support for the Work of the CEZIH) (<i>Odluka o provedbi provjere spemnosti programske podrške za rad u Centralnom informacijskom sustavu zdravstva Republike Hrvatske</i>) (Ur.Broj:534-07-10-1)</p> <p>Article 15 of the Decision on the Basis for Concluding Agreements for Carrying out Health Protection in the Areas of Compulsory Health Insurance (<i>Odluka o osnovama za sklapanje ugovora o provođenju zdravstvene zaštite I obveznog zdravstvenog osiguranja</i>) (“O.G.”, No. 156/13)</p>	<p>The data is contained in CEZIH. A specific authorisation for hosting and processing of data by CEZIH is not required.</p> <p>In accordance with the Decision on Readiness Check of the Programme Support for the Work of the CEZIH, the check for programme support for the system is carried out by a special committee consisting of representatives of the HZZO and Croatian Health Insurance Fund for Health Protection at Work (and representatives of the Ministry of Health). The check encompasses whether the programme support provided by the producers of programme support and used by the authorised system users is functioning properly and whether it is sufficiently well connected to the CEZIH. The check is carried out in accordance with a separate protocol. The final authorisation to the producer of programme support is given by the Minister of Health of the Republic of Croatia.</p> <p>This is confirmed in the Decision on the Basis for Concluding Agreements for Carrying out Health Protection in the Areas of Compulsory Health Insurance,</p>
<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>	<p>Decision on the Operator of the Information System of the Primary Health Care CEIZH PZZ, Set up of the Coordination Body CEZIH PZZ and its Powers (<i>Odluka o</i></p>	<p>CEZIH is operated by the HZZO, more specifically, its unit for information technology, in accordance with the Decision on the Operator of the Information System of the Primary Health Care CEIZH PZZ, Set up of the Coordination Body CEZIH PZZ and its Powers. Provisions on the staff and their work obligations are indicated in the specific internal organisation act.</p>

Questions	Legal reference	Detailed description
	<p><i>operateru Informatičkog sustava primarne zdravstvene zaštite – CEZIH PZZ, ustroju Koordinacijskog tijela CEZIH PZZ, te ovlastima istog) (Ur.Broj:534-05-06-01/1-06-01)</i></p> <p>Decision on Readiness Check of the Programme Support for the Work of the CEZIH) (<i>Odluka o provedbi provjere spemnosti programske podrške za rad u Centralnom informacijskom sustavu zdravstva Republike Hrvatske) (Ur.Broj:534-07-10-1)</i></p>	<p>As for the each health care institution and private healthcare practitioner, in accordance with the Decision on Readiness Check of the Programme Support for the Work of the CEZIH, the check of programme support for the system is carried out by a special committee consisting of representatives of the HZZO and Croatian Health Insurance Fund for Health Protection at Work (and representatives of the Ministry of Health). The check is carried out in accordance with a separate protocol. The final authorisation to the producer of programme support is given by the Minister of Health of the Republic of Croatia. Provisions on their staff and their work obligations are indicated in their specific internal organisation acts.</p>
<p><i>In particular, is there any obligation to have the information included in EHRs encrypted?</i></p>		<p>The data contained in CEZIH is encoded³¹. The data is not readable if taken outside of the server. However such obligation is not mentioned in the legislation.</p>
<p><i>Are there any specific auditing requirements for institutions hosting and processing EHRs?</i></p>	<p>Law on Compulsory Health Insurance (<i>Zakon o obveznom zdravstvenom osiguranju) (“O.G.”, No 80/13 and 137/13)</i></p> <p>Statute of the HZZO (“O.G.”, No 18/09, 33/10,</p>	<p>CEZIH is managed by the HZZO. The work of HZZO is a public institution supervised by the Croatian Ministry of Health.</p> <p>The Croatian Personal Data Protection Agency is carrying out supervision over collection and processing of personal health data.</p> <p>No other specific auditing requirements were identified.</p>

³¹ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

Questions	Legal reference	Detailed description
	8/11 and 18/13)	

2.3. Patient consent

2.3.1. Main findings

The signature of the “Statement on selection/change of selected doctor” allows the creation of EHRs, their processing, sharing of information and secondary use.

The Statement is a document required to be filled by each compulsory health insurance user to select his/her primary health care doctor. However, the Statement does not inform the patient that by signing the Statement, s/he is also conceding to have his/her data stored in EHRs. Also, a legal requirement to inform the patient of the consequence of signing the Statement and a legal requirement enabling the patient to withhold its consent for the creation of EHRs and the sharing of health data do not exist for the moment.

In the future, with the foreseen legislative amendments, the data will be stored into the EHRs but patient will be empowered to control their access (from no access at all to access to all users), and will be informed concerning the EHRs.

2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
<p>Are there specific national rules on consent from the patient to set-up EHRs?</p>	<p>Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)</p> <p>Article 2(2)(2) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia (<i>Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske</i>) (“O.G.”, No. 14/10)</p>	<p>The Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form contains specific national rules requesting consent from the patient for his/her data to be entered into EHRs, processed and used. This is also confirmed in the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the CEZIH.</p> <p>Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form stipulates the following: “By signing the Statement on selection/change of selected doctor in accordance with the regulation on compulsory health insurance, the insured person is also giving consent for filling out, collection, processing and use of personal and health data in accordance with the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia”.</p> <p>Article 2(2)(2) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia stipulates that “it is prohibited to collect, process or use personal data of citizens/users of the health services without a special written consent of the user/citizen, and that data may be used in a way and in accordance with the purpose of their collection.”</p> <p>However, the patient cannot refuse to sign the statement in case s/he wants to have a primary healthcare doctor. Furthermore, there is not a legal requirement to inform her/him (in writing or orally) of the consequences of signing the statement. These shortcomings of the existing system are recognised by the competent authorities.</p>

Questions	Legal reference	Detailed description
		In the future, with the foreseen legislative amendments, the data will be stored into the EHRs but the patient will be empowered to control their access (from no access at all to access to all users) ³²
<i>Is a materialised consent needed?</i>	<p>Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)</p> <p>Article 2(2)(2) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia (<i>Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske</i>) (“O.G.”, No.</p>	<p>The Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form and the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the CEZIH require that consent be given in a form of a written consent. According to a stakeholder³³ patients are not presented with a separate clause asking for permission for the data to be used in the EHRs and the consent is automatically given by signing the Statement. According to the stakeholder, this should be changed through introduction of new legal requirements.</p> <p>Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form stipulates the following: “[b]y signing Statement on selection/change of selected doctor in accordance with regulation on compulsory health insurance, the insured person is also giving consent for filling out, collection, processing and use of personal and health data in accordance with the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia”.</p> <p>Article 2(2)(2) of the Ordinance on Use and Protection of Data from A Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia stipulates that “it is prohibited to collect, process or use personal data of citizens/users of the health services without a special written consent of the user/citizen, and that data may be used in a way and in accordance with the purpose of their collection.”</p>

³² Written response received from the representative of the Croatian Health Insurance Fund, received on 19 March 2014.

³³ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

Questions	Legal reference	Detailed description
	14/10)	In the future, with the foreseen legislative amendments, the data will be stored into the EHRs but patient will be empowered to control their access (from no access at all to access to all users) ³⁴ ,
<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>	<p>Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)</p> <p>Article 126 of the Law on Compulsory Health Insurance (<i>Zakon o obveznom zdravstvenom osiguranju</i>) (“O.G.”, No. 80/13 and 137/13)</p> <p>Law on Health Protection (<i>Zakon o zdravstvenoj zaštiti</i>) (“O.G.”, No. 150/08, 71/10, 139/10, 22/11, 84/11, 154/11, 12/12, 35/12 – OUSRH, 70/12, 144/12, 82/13 and 159/13)</p> <p>Ordinance on Method of Establishment of a Right</p>	<p>The Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form does not foresee a requirement to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs.</p> <p>Since the consent from the patient to set up EHR is given when selecting medical doctors and dentist of the primary health care, Article 126 of the Law on Compulsory Health Insurance is important. The Article provides a legal basis for adoption of a general act by the HZZO detailing selection of medical doctors and dentist of the primary health.</p> <p>This general act has not been adopted at the moment of drafting of this document. Until the moment of the adoption of the general act, according to Article 157 of the Law on Compulsory Health Insurance, the legally binding instrument is the Ordinance on Method of Establishment of a Right on Free Selection of Medical Doctors and Dentists of the Primary Health.</p> <p>Neither the Law nor the Ordinance contains on obligation to inform the patients about the consequence of the consent or purpose of the EHRs.</p> <p>However, shortcomings of the existing system are recognised by the competent authorities. In the future, legal amendments are foreseen. In accordance with these amendments, the patients should be provided with more information concerning their EHRs.</p>

³⁴ Written response received from the representative of the Croatian Health Insurance Fund, received on 19 March 2014.

Questions	Legal reference	Detailed description
	<p>on Free Selection of Medical Doctors and Dentists of the Primary Health Care (<i>Pravilnik o načinu ostvarivanja prava na slobodan izbor doktora medicine i doktora stomatologije primarne zdravstvene zaštite</i>) (“O.G.”, No. 41/07, 4/10, 13/10, 41/12 and 50/13)</p>	
<p><i>Are there specific national rules on consent from the patient to share data?</i></p>	<p>Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)</p> <p>Articles 1(3), 2(2)(2) and 2(2)(9) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia (<i>Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu</i>)</p>	<p>Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form stipulates the following: “[b]y signing Statement on selection/change of selected doctor in accordance with regulation on compulsory health insurance, the insured person is also giving consent for filling out, collection, processing and use of personal and health data in accordance with the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia”.</p> <p>Article 1(3) of the Ordinance on Use and Protection of Data from Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia stipulates that authorised institutions and individuals consist of:</p> <ul style="list-style-type: none"> - health institutions in agreement with relevant authorities; - private practitioners in agreement with relevant authorities; - HZZO; - Croatian Health Insurance Fund for Health Protection at Work; - Croatian National Institute for Public Health; and - Ministry of Health of the Republic of Croatia. <p>Article 2(2)(2) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia stipulates that “it is prohibited to</p>

Questions	Legal reference	Detailed description
	<p><i>zdravstva Republike Hrvatske</i> (“O.G.”, No. 14/10)</p> <p>Article 2(2) and Title VI (Article 13 and 13a) of the Law on Personal Data Protection (<i>Zakon o zaštiti osobnih podataka</i>) (“O.G.”, No. 106/12 – consolidated text)</p>	<p>collect, process or use personal data of citizens/users of the health services without a special written consent of the user/citizen, and that data may be used in a way and in accordance with the purpose of their collection.” Furthermore, Article 2(2)(9) of this Ordinance also states that data may be given to health professional with the aim of providing health services to the patient.</p>
<p><i>Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?</i></p>	<p>Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)</p> <p>Article 2(2)(2) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia (<i>Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom</i></p>	<p>The Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form and the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia contain specific national rules requesting consent from the patient for his/her data to be processed.</p> <p>Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form stipulates the following: “[b]y signing Statement on selection/change of selected doctor in accordance with regulation on compulsory health insurance, the insured person is also giving consent for filling out, collection, processing and use of personal and health data in accordance with the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia”.</p> <p>Article 2(2)(2) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia stipulates that “it is prohibited to collect, process or use personal data of citizens/users of the health services without a special written consent of the user/citizen, and that data may be used in a way and in accordance with the purpose of their collection.”</p>

Questions	Legal reference	Detailed description
	<i>informacijskom sustavu zdravstva Republike Hrvatske</i> (“O.G.”, No. 14/10)	In theory, the patients are giving their consent for their information to be entered into EHRs by signing the “Statement on selection/change of selected doctor”. Therefore, the system in Croatia is an opt-in system. However, the patient cannot refuse to sign the statement in case s/he wants to have a primary healthcare doctor. Furthermore, there is not a legal requirement to inform her/him is not informed (in writing or orally) of the consequences of signing the statement. These shortcomings of the existing system are recognised by the competent authorities.
<i>Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?</i>	Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)	No separate rules exist apart from the ones indicated in rows 4 and 5 of this section. By signing the “Statement on selection/change of selected doctor”, the patient is also giving its consent for the information to be shared, in accordance with the relevant legislation. Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form stipulates the following: “By signing Statement on selection/change of selected doctor in accordance with regulation on compulsory health insurance, the insured person is also giving consent for filling out, collection, processing and use of personal and health data in accordance with the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia”.
<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>	Article 12 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10) Article 126 of the Law on Compulsory Health Insurance (<i>Zakon o obveznom zdravstvenom</i>	No such requirements exist at the moment. The Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form does not foresee a requirement to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to share EHRs. However, this is expected to change. According to interviewees the Ordinance will be amended so that patients will have to be informed about the purpose of EHRs and should be given a possibility to withhold their consent to share their EHRs.

Questions	Legal reference	Detailed description
	<p><i>osiguranju</i>) (“O.G.”, No. 80/13 and 137/13).</p> <p>Ordinance on Method of Establishment of a Right on Free Selection of Medical Doctors and Dentists of the Primary Health Care (<i>Pravilnik o načinu ostvarivanja prava na slobodan izbor doktora medicine i doktora stomatologije primarne zdravstvene zaštite</i>) (“O.G.”, No. 41/07, 4/10, 13/10, 41/12 and 50/13)</p>	
<p><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>		<p>When signing Statement on selection/change of selected doctor, the patient also gives its consent for the data to be used in cross-border situations. However, there is no legal provision enabling patient to withhold giving consent for his/her data to be shared in case the patient wants to have a primary health doctor. Also, the law does not mention that the patient must be informed in writing or orally of the consequence of signing the statement in regards to access to its EHRs by health practitioners or health institutions outside of Croatia.</p>
<p><i>Are there specific rules on patient consent to share data on a cross-border situation?</i></p>		<p>Specific rules on patient consent to share data in cross-border situations do not exist.</p>

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

At the moment, the EHRs are not operational. According to the current legislation, the medical data for each patient can be accessed and updated by a general/family doctor, dentist, paediatrician, gynaecologist and school doctor. The patient can also access the data but the access is facilitated by the selected doctor. Aggregated data is accessible to a number of government bodies in Croatia.

The access by doctors to patients' medical data is possible only with the use of smart cards and personal PIN codes³⁵. At the moment, these cards and codes are handed out only to doctors³⁶. Each time the doctor intends to access a patient's medical data, s/he needs to use its smart card and enter his/her PIN code. The authorised users will be able to introduce data into EHRs.

Since patients are not given smart cards and PIN codes, they cannot access directly their EHRs and updated, modify and erase their content. The access by patients to their EHRs is facilitated by their selected doctors. Patients can ask information to health professionals on who accessed his/her EHR. Croatian legislation does not contain provisions on exceptions to access (e.g. emergency); accessing data on behalf of and for request for second opinion; and identification code system for cross-border healthcare purpose.

Finally, although in theory, health professionals in another Member State should be able to access patients' personal medical data, in practice this is impossible due to the smart card and personal pin code system in place for access to data.

The current system is expected to be amended. The amendments will provide a patient with a possibility to choose from the four different options concerning the access to data:

- access to EHR is not permitted at all by the patient;
- access to EHR is permitted only to the patient's selected doctor (primary health care);
- access to EHR is permitted to all doctors within the primary health care and other users with the additional approval;
- access to EHR is permitted to all the users³⁷.

This means that, if permitted by the patient, the authorised users will be able to access all the data. On the other hand, without patient's permission, none of the data will be accessible. It is unclear what consequences these amendments will have on transboundary access to medical data.

³⁵ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

³⁶ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

³⁷ Written response received from the representative of the Croatian Health Insurance Fund, received on 19 March 2014.

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

Questions	Legal reference	Detailed description
<i>Are there any specific national rules regarding who can create and where can EHRs be created?</i>	Articles 10 and 11(1) of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)	<p>The EHRs are created within CEZIH after the signature of the Statement on selection/change of selected doctor.</p> <p>Article 10 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form stipulates that “[d]ata of the insured person in the EHR shall be entered by the selected general/family doctor, dentist, paediatrician, gynaecologist and school doctor”.</p> <p>Article 11 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form stipulates that “[d]ata shall be entered by the doctor stipulated in Article 10 of the Ordinance during the selection, and change of the selected doctor and when providing health protection to the insured person”.</p>
<i>Are there specific national rules on access and update to EHRs?</i>	<p>Articles 10 and 11(1) of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)</p> <p>Article 3(1) of the Ordinance on the Method of Keeping, Storage, Collection and Use of Patient’s Medical Documents Concerning Obligatory Health Insurance within the Central Information Health System of the Republic of</p>	<p>Medical data for each patient can only be accessed and updated by a doctor selected by that patient with the use of doctor’s smart card and personal pin code³⁸</p> <p>Article 10 of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form stipulates that “[d]ata of the insured person in the EHR shall be entered by the selected general/family doctor, dentist, paediatrician, gynaecologist and school doctor”.</p> <p>Article 11(1) of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form stipulates that “[d]ata shall be entered by the doctor stipulated in Article 10 of the Ordinance during the selection, and change of the selected doctor and when providing health protection to the insured person”.</p>

³⁸ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

Questions	Legal reference	Detailed description
	<p>Croatia (<i>Pravilnik o načinu vođenja, čuvanja, prikupljanja i raspolaganja medicinskom dokumentacijom pacijenata iz obveznog zdravstvenog osiguranja u Centralnom informacijskom sustavu zdravstva Republike Hrvatske</i>) (“O.G.”, No. 82/10)</p> <p>National Health Care Strategy (<i>Nacionalna strategija zdravstva</i>) for 2012 – 2020</p>	
<p><i>Are there different categories of access for different health professionals?</i></p>	<p>No specific provisions</p>	<p>At the moment, the system is not operational and the patient is not entitled to control the access following the signing of the statement on selection of doctors. The system is envisaged in a way that the patient will be able to choose from the four different options concerning the access to data:</p> <ul style="list-style-type: none"> - access to EHR is not permitted at all by the patient; - access to EHR is permitted only to the patient’s selected doctor (primary health care); - access to EHR is permitted to all doctors within the primary health care and other users with the additional approval; - access to EHR is permitted to all the users³⁹. <p>This means that, if permitted by the patient, the authorised users will be able to access all the data. On the other hand, without patient’s permission, none of the data will be accessible.</p> <p>The access to information will be possible only with the use of smart cards and personal PIN codes⁴⁰. At the moment, these cards and codes</p>

³⁹ Written response received from the representative of the Croatian Health Insurance Fund, received on 19 March 2014.

⁴⁰ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

Questions	Legal reference	Detailed description
		<p>should be handed out only to doctors⁴¹. Each time the doctor intends to access a patient's medical data, s/he needs to use its smart card and enter his/her PIN code.</p> <p>However, these options and procedures are not stipulated in the Croatian legislation at the moment of drafting of this document.</p>
<p><i>Are patients entitled to access their EHRs?</i></p>	<p>Article 23(3) of the Law on Medical Practice (<i>Zakon o liječništvu</i>) ("O.G.", No. 121/03 and 117/08)</p> <p>Article 23(1) and (2) of the Law on Protection of a Patient's Rights (<i>Zakon o zaštiti prava pacijenta</i>) ("O.G.", No. 169/04 and 37/08)</p> <p>Article 19(1)(3) and (4) of the Law on Personal Data Protection (<i>Zakon o zaštiti osobnih podataka</i>) ("O.G.", No. 106/12 – consolidated text)</p>	<p>Patients are entitled to access their EHRs. The patient cannot access his/her EHR directly online. The access is facilitated through the selected doctor.</p> <p>According to Article 23(3) of the Law on Medical Practice doctors are required to present to the patient all the medical documents concerning diagnosis and treatment of his/her illness. This Article does not specify EHRs, but the same principle may be applied.</p> <p>Furthermore, according to Article 23(1) and (2) of the Law on patient's Rights, a patient has a right to access entire medical documents concerning diagnose and treatment of his/her illness as well as a copy of the medical documents.</p> <p>Also, according to Article 19(1)(3) and (4) of the Law on Personal Data Protection, a patient has access to its personal data and may request to be provided with a copy of the data.</p> <p>From the IT point of view, access to patient's data is only granted to the patient's selected doctor with the use of his/her smart card and personal PIN code⁴².</p>
<p><i>Can patient have access to all of EHR content?</i></p>	<p>Article 23(3) of the Law on Medical Practice (<i>Zakon o liječništvu</i>) ("O.G.", No. 121/03 and 117/08)</p>	<p>A patient has access to all of its EHRs content.</p> <p>According to Article 23(3) of the Law on Medical Practice doctor is required to present to the patient all the medical documents concerning</p>

⁴¹ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

⁴² Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

Questions	Legal reference	Detailed description
	<p>Article 23(1) and (2) of the Law on Protection of a Patient's Rights (<i>Zakon o zaštiti prava pacijenta</i>) ("O.G.", No. 169/04 and 37/08)</p> <p>Article 19(1)(3) and (4) of the Law on Personal Data Protection (<i>Zakon o zaštiti osobnih podataka</i>) ("O.G.", No. 106/12 – consolidated text)</p>	<p>diagnosis and treatment of his/her illness. This Article does not specify EHRs, but the same principle may be applied.</p> <p>Furthermore, according to Article 23(1) and (2) of the Law on patient's Rights, a patient has a right to access entire medical documents concerning diagnose and treatment of his/her illness as well as a copy of the medical documents.</p> <p>Also, according to Article 19(1)(3) and (4) of the Law on Personal Data Protection, a patient has access to its personal data and may request to be provided with a copy of the data.</p>
<i>Can patient download all or some of EHR content?</i>	No legal reference	Since access to patient's data is only granted to the patient's selected doctor with the use of his/her smart card and personal PIN code ⁴³ , the patient cannot download the EHR content.
<i>Can patient update their record, modify and erase EHR content?</i>	No legal reference	<p>In practice, access to patient's data is only granted to the patient's selected doctor with the use of his/her smart card and personal PIN code⁴⁴. Therefore, the patients cannot update, modify and erase their EHR content.</p> <p>Croatian legislation does not contain a provision which would enable patients to update, modify and erase EHR content. Also this is not covered by relevant policy documents.</p>
<i>Do different types of health professionals have the same rights to update EHRs?</i>	No legal reference	Since access to patient's data is only granted to the patient's selected doctor with the use of his/her smart card and personal PIN code ⁴⁵ only selected doctors can update the EHR.
<i>Are there explicit occupational prohibitions? (e.g. insurance</i>	No legal reference	These explicit prohibitions are not indicated in Croatian legislation and policy documents. However, since access to patient's data is only

⁴³ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

⁴⁴ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

⁴⁵ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

Questions	Legal reference	Detailed description
<i>companies/occupational physicians...)</i>		granted to the patient's selected doctor with the use of his/her smart card and personal PIN code ⁴⁶ , this indirectly excludes all the other interested parties from access to patients' medical data.
<i>Are there exceptions to the access requirements (e.g. in case of emergency)?</i>	No legal reference	Croatian legislation does not contain a provision concerning this issue. Also this is not covered by relevant policy documents.
<i>Are there any specific rules on identification and authentication for health professionals? Or are they aggregated?</i>	No legal reference	No such rules exist. However, in practice, access to patient's data should be only granted to the patient's selected doctor with the use of his/her smart card and personal PIN code ⁴⁷ .
<i>Does the patient have the right to know who has accessed to his/her EHRs?</i>	Article 19(1)(5) of the Law on Personal Data Protection (<i>Zakon o zaštiti osobnih podataka</i>) ("O.G.", No. 106/12 – consolidated text) National Health Care Strategy (<i>Nacionalna strategija zdravstva</i>) for 2012 – 2020	According to Article 19(1)(5) of the Law on Personal Data Protection each person can ask information on who accessed and made use of his/her data and on which legal basis. This is in compliance with the objective of the National Health Care Strategy which states that "[e]ach health care user must have a possibility of complete and easy insight into the information on to whom, when, and which of the patient's data were given to use, and based on which right or authority".
<i>Is there an obligation on health professionals to update EHRs?</i>	Article 11(1) of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) ("O.G.", No. 82/10)	Article 11 of the Ordinance stipulates that "EHRs are updated by doctors and when providing care to the insured person.
<i>Are there any provisions for accessing data on 'behalf of' and for request for second opinion?</i>		Croatian legislation and policy documents do not foresee this option.
<i>Is there in place an identification</i>	National Health Care Strategy	Such system is not in place at the moment of drafting of this document.

⁴⁶ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

⁴⁷ Written response received from the Croatian Personal Data Protection Agency, received on 12 March 2014.

Questions	Legal reference	Detailed description
<i>code system for cross-border healthcare purpose?</i>	<i>(Nacionalna strategija zdravstva) for 2012 – 2020</i>	<p>However, policy documents call for the establishment of such system.</p> <p>The National Health Care Strategy for 2012 – 2020 calls for further standardisation of data models, common code lists, recognising the necessity to achieve interoperability of information systems in health care with all state administration bodies (joint services), as well as with the EU countries⁴⁸.</p>
<i>Are there any measures that consider access to EHRs from health professionals in another Member State?</i>	Article 2(2) and Title VI (Article 13 and 13a) of the Law on Personal Data Protection (<i>Zakon o zaštiti osobnih podataka</i>) (“O.G.”, No. 106/12 – consolidated text)	<p>Personal data may be transferred out of Croatia in accordance with Title VI of the Law on Personal Data Protection. In accordance with the provisions contained therein, personal data may be transferred, for further processing, to countries and international organisations which have adequate data protection system in place. The European Commission is publishing a list of countries which have adequate data protection system in place. This list includes EU Member States, Norway, Liechtenstein and Iceland. However, practicality of access to data from health professionals in another Member State is questionable due to a complex system of access to personal medical data (smart cards and personal pin codes).</p> <p>Processing of data includes, inter alia, adjustment or change, access to, use and deletion.</p>

⁴⁸ National Health Care Strategy for 2012 – 2020 (English version), p. 67.

2.5. Liability

2.5.1. Main findings

Patients cannot be held liable for erasing key medical data in their EHRs because they cannot access their information directly. The access is facilitated by their selected doctors. However, doctors can be held liable for their input errors and erasing data from EHRs. CEZIH is not liable for defects of security and software systems.

Legal obligations for doctors to access EHRs prior to taking a decision involving the patient do not exist.

2.5.2. Table on liability

Questions	Legal reference	Detailed description
<i>Does the national legislation set specific medical liability requirements related to the use of EHRs?</i>	Article 11(2) of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)	<p>Croatian legislation does not require doctors to consider all relevant data in the EHRs concerning each patient’s medical and treatment history as such.</p> <p>However, in accordance with the Article 11(2) of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form, doctors are liable for completeness and accuracy of the data entered into the EHR</p> <p>Article 11(2) of the Ordinance stipulates that “[t]he insured person and the doctor stipulated in paragraph 1 of this article, are responsible for completeness and accuracy of the data entered into the EHR”.</p>
<i>Can patients be held liable for erasing key medical information in EHRs?</i>		Patients cannot access the data in the EHRs on their own, they cannot be held liable for erasing the data as such.
<i>Can physicians be held liable because of input errors?</i>	Article 11(2) of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)	<p>Article 11(2) of the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form provides that</p> <p>The doctor, are responsible for completeness and accuracy of the data entered into the EHR.</p>
<i>Can physicians be held liable because they have erased data from the EHRs?</i>	Article 2(2)(3) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the	Article 2(2)(3) of the Ordinance stipulates that doctors “shall not damage, alter, erase, destroy or make unusable automatically processed data or calculation programmes contained in CEZIH.”

Questions	Legal reference	Detailed description
	<p>Republic of Croatia (<i>Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske</i>) (“O.G.”, No. 14/10)</p> <p>Article 23(1) of the Law on Medical Practice (<i>Zakon o liječništvu</i>) (“O.G.”, No. 121/03 and 117/08)</p>	
<p><i>Are hosting institutions liable in case of defect of their security/software systems?</i></p>		<p>According to the carried out interviews⁴⁹, the companies providing security/software for the proper functioning of CEZIH are responsible for security/software systems’ defects. The responsibility is established on the basis of publication of specifications concerning the relevant systems by the Croatian authorities in the Croatian Official Gazettes as well as subsequently signed contracts.</p>
<p><i>Are there measures in place to limit the liability risks for health professionals (e.g. guidelines, awareness-raising)?</i></p>		<p>No such measures exist in Croatia.</p>
<p><i>Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?</i></p>	<p>Article 2(2)(4) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the</p>	<p>Article 2(2)(4) of the Ordinance on Use and Protection of Data from Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia contains liability rules related to breach of access to EHRs.</p> <p>According to this Article, authorised institutions and individuals “shall not, when this is not justifiable by providing basic health protection</p>

⁴⁹ Interview with the representative of the Croatian Health Insurance Fund that took place on 24 February 2014.

Questions	Legal reference	Detailed description
	Republic of Croatia <i>(Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske)</i> (“O.G.”, No. 14/10)	services, access without authorisation calculation data bases or access without authorisation processed information or calculation programmes contained in CEZIH”. In case of breach of access to EHRs, a liability procedure under the Croatian legislation is initiated.
<i>Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?</i>	Article 23(1) of the Law on Medical Practice (<i>Zakon o liječništvu</i>) (“O.G.”, No. 121/03 and 117/08)	In accordance with the principles of the medical profession, prior to providing treatment and advice, each doctor is required to analyse the available documents ⁵⁰ . However, sometimes the documents may not be available due to technical or other reasons ⁵¹ . According to Article 24 of the Law on Medical Practice, a doctor may issue a medical certificate only after a medical check-up and access to medical documents of the patient. This provision does not require doctors to access EHRs but a similar reasoning may be used.
<i>Are there liability rules related to the misuse of secondary use of health data?</i>	National Health Care Strategy (<i>Nacionalna Strategija Zdravstva</i>) for 2012 – 2020 Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia (<i>Pravilnik o uporabi i</i>	No such rules exist. However, the data from EHRs will be used for drafting of various health and statistical reports ⁵² . The data will be used by authorised institutions and individuals in accordance with Article 1(3) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia. These consists of: <ul style="list-style-type: none"> - health institutions in agreement with relevant authorities; - private practitioners in agreement with relevant authorities; - HZZO;

⁵⁰ Written response received from the Croatian Medical Chamber, received on 18 March 2014.

⁵¹ Written response received from the Croatian Medical Chamber, received on 18 March 2014.

⁵² National Health Care Strategy for 2012 – 2020 (English version), p. 68.

Questions	Legal reference	Detailed description
	<i>zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske</i> (“O.G.”, No. 14/10)	<ul style="list-style-type: none"> - Croatian Health Insurance Fund for Health Protection at Work; - Croatian National Institute for Public Health; and - Ministry of Health of the Republic of Croatia. <p>According to the carried out interviews, the data will be anonymised prior to their secondary use.</p>

2.6. Secondary uses and archiving durations

2.6.1. Main findings

There are no specific provisions on archiving duration of EHRs.

A doctor, or other responsible person, is required to keep the data on treatment of patients for a period of 10 years following the cessation of the treatment. Following this period, the provisions on keeping of documents are applicable. These provisions could also be applicable on EHRs.

However, the data can and is intended to be used for drafting of carious health and statistical reports. This data will be anonymised.

2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
<i>Are there specific national rules on the archiving durations of EHRs?</i>	Article 23(3) of the Law on Medical Practice (<i>Zakon o liječništvu</i>) (“O.G.”, No. 121/03 and 117/08)	There are no specific provisions on archiving duration of EHRs. Article 23(3) of the Law on Medical Practice stipulates that a doctor, or other responsible person, is required to keep the data on treatment of patients for a period of 10 years following the cessation of the treatment. Following this period, the provisions on keeping of documents are applicable. These provisions could also be applicable on EHRs.
<i>Are there different archiving rules for different providers and institutions?</i>		Croatian legislation does not contain different archiving rules for different providers and institutions concerning EHRs.
<i>Is there an obligation to destroy (...) data at the end of the archiving duration or in case of closure of the EHR?</i>		Croatian legislation does not contain provisions concerning this issue.
<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>		Croatian legislation does not contain provisions concerning the use of data at the end of the archiving duration or in case of closure of the HER.
<i>Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?</i>	National Health Care Strategy (<i>Nacionalna Strategija Zdravstva</i>) for 2012 – 2020 Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia	The data from EHRs will be used for drafting of various health and statistical reports ⁵³ . The data will be used by authorised institutions and individuals in accordance with Article 1(3) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia. These consists of: <ul style="list-style-type: none"> - health institutions in agreement with relevant authorities; - private practitioners in agreement with relevant authorities; - HZZO; - Croatian Health Insurance Fund for Health Protection at Work;

⁵³ National Health Care Strategy for 2012 – 2020 (English version), p. 68.

Questions	Legal reference	Detailed description
	<i>(Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske)</i> (“O.G.”, No. 14/10)	<ul style="list-style-type: none"> - Croatian National Institute for Public Health; and - Ministry of Health of the Republic of Croatia.
<i>Are there health data that cannot be used for secondary use?</i>		Croatian legislation and policy documents do not foresee exemption concerning the use of data for secondary use.
<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>		According to the carried out interviews ⁵⁴ , the data for secondary use will be anonymised. No further rules exist.
<i>Does the law say who will be entitled to use and access this data?</i>	Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia (<i>Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske</i>) (“O.G.”, No. 14/10)	<p>The data will be used by authorised institutions and individuals in accordance with Article 1(3) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia. These consists of:</p> <ul style="list-style-type: none"> - health institutions in agreement with relevant authorities; - private practitioners in agreement with relevant authorities; - HZZO; - Croatian Health Insurance Fund for Health Protection at Work; - Croatian National Institute for Public Health; and - Ministry of Health of the Republic of Croatia.
<i>Is there an opt-in/opt-out system for the secondary uses of eHealth data included in EHRs?</i>	Article 12 of the Ordinance on the Method of Keeping of Personal	There is no specific opt-in/opt-out system for secondary use of data included in the EHRs. The consent given for the use of data in EHRs, with all its noted shortcomings, also covers the secondary use of data.

⁵⁴ Interview with the representative of the Croatian Health Insurance Fund that took place on 24 February 2014.

Questions	Legal reference	Detailed description
	<p>Health Record in the Electronic Form (<i>Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku</i>) (“O.G.”, No. 82/10)</p> <p>Article 2(2)(2) of the Ordinance on Use and Protection of Data from a Patient’s Medical Documents within the Central Information Health System of the Republic of Croatia (<i>Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske</i>) (“O.G.”, No. 14/10)</p>	<p>The medical data is anonymised before being used for secondary purposes.</p>

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

There is only one system in Croatia, CEZIH. As also indicated in section 2.8 below, ePrescriptions have been in use in Croatia since 2011. In addition to ePrescriptions, eReferrals were also implemented in Croatia. eReferrals are used for laboratory tests and for referral to secondary healthcare specialists (cardiologists, etc.). EHRs in Croatia will be incorporated with ePrescriptions and eReferrals and will contain information on prescribed drugs, lab tests and findings of the secondary healthcare specialists⁵⁵.

Several policy documents call for interoperability of CEZIH with other Member States' EHR systems, although activities undertaken in this regard are limited. The interoperability would include standardisation of data models and common code lists.

⁵⁵ Written response from the representative of the Croatian Health Insurance Fund received on 19 March 2014.

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>	Strategic Plan for the Development of Public Health (<i>Strateški plan razvoja javnog zdravstva</i>) 2013- 2015 National Health Care Strategy (<i>Nacionalna Strategija Zdravstva</i>) for 2012 – 2020	No such obligations exist in the Croatian legislation. EHRs in Croatia will be incorporated with ePrescription and eReferral and will contain information on prescribed drugs, lab tests and findings of the secondary healthcare specialists ⁵⁶ . However, this is not yet stipulated in legal documents. Furthermore, several policy documents call for establishment of interoperability between health registers ⁵⁷ and standardisation of data models, common code lists, recognising the necessity to achieve interoperability of information systems in health care with the other EU Member States ⁵⁸ .
<i>Are there any specific rules/standards on the interoperability of EHR?</i>		No such rules exist.
<i>Does the law consider or refer to interoperability issues with other Member States systems?</i>		The legislation does not cover this issue.

⁵⁶ Written response from the representative of the Croatian Health Insurance Fund received on 19 March 2014.

⁵⁷ Strategic Plan for the Development of Public Health 2013- 2015, p. 34 and 35.

⁵⁸ National Health Care Strategy for 2012 – 2020 (English version), p. 67.

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

At the moment of drafting of this document, EHRs are not operational while ePrescriptions have been in use since 2011. Since its introduction, over 50 million of e-prescriptions are issued through CEZIH system each year. In the future, ePrescription will be issued through EHRs. This should enable better understanding of ePrescription (e.g. information on polypharmacology).

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>		ePrescription was introduced in Croatia in 2011. Since its introduction, over 50 million of e-prescriptions are issued through CEZIH system each year ⁵⁹ . In the future, ePrescription will be issued through EHRs.
<i>Can an ePrescription be prescribed to a patient who does not have an EHR?</i>		ePrescription was introduced in Croatia in 2011. Since its introduction, over 50 million of e-prescriptions are issued through CEZIH system each year ⁶⁰ .

- *Access*

Questions	Legal reference	Detailed description
<i>Do the doctors, hospital doctors, dentists and pharmacists writing the ePrescription have access to the EHR of the patient?</i>		According to the carried out interviews ⁶¹ , ePrescription will be improved with the introduction of EHRs. At the moment, EHRs are not operational while ePrescriptions have been in use since 2011. In the future, ePrescription will be issued through EHRs. This will enable better understanding of ePrescription (e.g. information on polypharmacology).
<i>Can those health professionals write ePrescriptions without having access to EHRs?</i>		At the moment, EHRs are not operational while ePrescriptions have been in use since 2011. In the future, ePrescription will be issued through EHRs.

⁵⁹ National Health Care Strategy for 2012 – 2020 (English version), p. 51.

⁶⁰ National Health Care Strategy for 2012 – 2020 (English version), p. 51.

⁶¹ Interview with the representative of the Croatian Health Insurance Fund that took place on 24 February 2014.

2.9. Other requirements

No other requirements were observed.

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

It is hard to identify good practices in Croatia because the EHRs system is not operational at the moment of drafting of this document. One of the identified benefits of the EHRs will be its contribution to the effectiveness of ePrescription. According to the carried out interviews⁶², authorised persons which will have access to EHR will also have access to ePrescription and this will enable better understanding of the patient use and consumption of medicines (e.g. information on polypharmacology).

On the other hand, already some issues of concern have been identified.

In Croatia, consent from the patient for the data to be entered into EHRs and further processed, shared and used (including secondary use) is automatically given by signing the “Statement on selection/change of selected doctor”. However, at the same time, a legal requirement to inform the patient of the consequence of signing the Statement and a legal requirement enabling the patient to withhold its consent for his/her information to be entered into EHRs or shared both within Croatia and with other EU Member States, do not exist.

At the moment, the medical data for each patient can only be accessed and updated by general/family doctors, dentists, paediatricians, gynaecologists and school doctors.

Currently patients do not have direct access through an online data base to their EHRs but they are entitled to request access to the information to their selected doctor. Access to patients’ data will be a subject to future legislative amendments. These amendments should enable the patient to choose who can access his/her EHRs including full prohibition of access to his/her EHRs. Also, in the future, the patient will be informed of the significance and consequences of the EHRs.

Also, although interoperability with EHRs systems in other EU Member States is welcomed and legally possible, its implementation will be challenging. Terminology used is not coded which prevents the use of medical data in other Member States. At the moment, the only international terminology used is the tenth revised International Classification of Diseases codes, although this is not a legal requirement. Furthermore, at the moment, access to medical data should be possible only through the use of smart cards and personal pin codes which are handed out to doctors in Croatia. This could prevent access to data from healthcare practitioners in other Member States.

⁶² Interview with the representative of the Croatian Health Insurance Fund that took place on 24 February 2014.