Questions and Answers – Commission makes it easier for citizens to access health data securely across borders

What are the objectives of the Recommendation?

The Recommendation aims to allow EU citizens to access securely their health records across Member States more easily. In particular it aims at the creation of a European format that will allow electronic health records being shared in a secure manner at the same time as adhering to data protection rules.

Member States have already taken the first steps in making some parts of the health records interoperable, such as patient summaries and e-prescriptions. The Recommendation takes this action further and proposes that Member States extend this work into three new areas of the health record: laboratory tests, medical discharge reports and images, and imaging reports. Moreover, the text sets the basis for the necessary technical specifications that should be used in health record exchanges.

The initiative also aims to place the future development of the work into a clear framework by setting down principles for the exchange of health information across EU borders and a governance process involving the Commission, Member States and relevant stakeholders.

How will the Recommendation benefit to citizens, doctors and medical practitioners?

The possibility to exchange health records across borders will help citizens to have better health care as they move around the European Union. For example, it can provide important health history about an individual in the event of an accident, or other need for unplanned health care while abroad. Subsequently, once the citizen returns home the records of the treatment abroad can be integrated into the existing health record.

Furthermore, health systems will benefit significantly from exchanging health records, since this would enable access to a patient's recent laboratory or radiology tests. This will help a hospital in another Member State to avoid repeating such tests and thus save patients' time and reduce hospital costs. This could increase the efficiency and sustainability of healthcare systems.

Moreover, as electronic health records become more interoperable across borders, more health data will be available to support the integration of Artificial Intelligence (AI) systems that can assist medical decision making. This should have positive impact both on the quality of health care received and the efficiency of health care systems.

How can access to Electronic Health Record be helpful in real life

situations?

Let's take a concrete example: Davide is a 59 -year old who has lived and worked abroad for the last 30 years. He suffers from a particular heart condition and would like his doctors in his native country to have access to his full medical records built-up abroad over the last 30 years. The new Recommendation will make this possible.

Another example would be of a citizen, who is seeking referral to a specialist medical centre in another Member State, such as for a rare condition or for treatment for an advanced cancer. The possibility to exchange his or her Electronic Health Record across-borders will be of great support.

How does the Recommendation make sure that health data are fully protected?

Security and privacy are essential to ensure trust and are at the core of this Recommendation. It encourages Member States to ensure that citizens are able to choose to whom they provide access to their electronic health data, and which health information details are shared.

Moreover, the exchange of Electronic Health Records (EHR) needs to be implemented in full compliance with the General Data Protection Regulation (GDPR). This is the framework for the protection of personal data and which sets out directly applicable rules for the processing of individuals' personal data, including health data.

Moreover, the Directive on security of network and information systems (the NIS Directive) sets out a range of measures for Member States to provide a level of security for network and information systems, including health information systems.

Access, security and trust in EHR systems should be also enhanced by the use of secure electronic identification and authentication means.

The Recommendation proposes that Member States create National Digital Health Networks in order to, inter alia, ensure that the security of national health systems is enhanced and to support the cross border secure exchange of health data.

Does the Recommendation cover the use of health data for research purposes?

The purpose of the Recommendation is to develop the systems that can support citizens and the health care they receive when travelling through the EU. By improving the interoperability of EHRs, it will also support health research (as well as diagnostics and prevention), by enabling the use of advanced technological solutions, such as Artificial Intelligence and high performance computing.

What else is the Commission doing in order to promote an exchange of Electronic Health Records across the EU?

There is ongoing work both within Member States and at European level in

order to build infrastructures for health data exchange. There is considerable accumulated knowledge and experience to build upon in particular through the eHealth Digital Service Infrastructure (eHDSI) established under the CEF Programme. A number of Member States[1] have agreed to exchange Patient Summaries and ePrescriptions between health professionals across borders. Some of them have already started these exchanges: at this moment, Finland has already made their ePrescriptions available abroad and Estonia has accepted ePrescriptions coming from another European country. Luxembourg will soon accept patient summaries from other European countries and the Czech Republic will made its patient summaries available abroad. The other countries will join these exchanges later.

ePrescription (and eDispensation) allows citizens in Europe to retrieve their medication in a pharmacy located in another European country, thanks to the online transfer of their electronic prescription from their country of affiliation to their country of travel. The country of residence is informed about the medicine the patient retrieves in the country of travel (eDispensation). The **Patient Summary** can provide information on important health related aspects such as allergies, current medication, previous illness, major surgeries in the past 6 months, implants, medical devices, pregnancy (if relevant), social history, physical findings, diagnostic tests etc. The digital Patient Summary is meant to provide doctors with essential information in their own language concerning the patient, when the patient comes from another EU country and there may be a linguistic barrier. However, it is not mandatory that all the above information exists, is known or can be translated.

These elements represent parts of electronic health records. These agreements provide a firm basis and will eventually enable citizens to access and exchange their full electronic health records throughout the European Union.

The Commission is also putting forward a new Implementing Decision on the management and functioning of the eHealth Network.

Will the specifications of the EU Electronic Health Records exchange format be further elaborated?

The specifications of the European Electronic Health Record exchange format should be regularly reviewed and updated in order to further define the granularity of the health data and respond to technological developments. Relevant stakeholders will be involved in revising and updating the specifications.

On which principles are the technical specifications established?

The specifications cover an initial set of healthcare information categories to which Member States should aim to provide cross border secure digital access.

The technical specifications have been established on the basis of the work of the e-Health Digital Service Infrastructure (eHDSI), and the process has been implemented by the European Commission together with Member States.

Therefore, several services for cross-border health data exchange are currently been deployed under the Connecting Europe Facility (CEF) Programme. The eHDSI uses established industry specifications that have been adopted by the participating Member States.

The exchange format which is being proposed is designed in such a way that would allow flexibility both in terms of technological choices and in relation to individual Member State's readiness to engage. This flexibility is also required due to the dynamic nature of the technical specifications, and the fast pace of advancements in the area of digital technology.

What are the specifications for the Electronic Health Record exchange format?

The Recommendation comprises an initial set of two categories

1. Health information domains to be exchanged, covering, inter alia, patient's summaries, ePrescriptions, laboratory results reports, medical imaging reports and images, Hospital discharge reports.
2. Specifications for the exchange of data within these health information domains.

How will the implementation of the European Electronic Health Record exchange format be governed?

The exchange format is a baseline to be revised periodically through a joint coordination process with Member States and other relevant stakeholders. The aim is to ensure that the process remains up-to-date, sustainable and constantly develops in a way that addresses the needs of citizens, health systems and society more widely.

The process to further develop the European EHR exchange format should be steered through a joint coordination process. This should be based on a shared roadmap that identifies agreed priorities and tasks for further specifications to be considered in the years ahead.

In addition to implementing further improvements to the interoperability of EHR systems, the Joint Coordination Process should also monitor and assess progress and allow for horizon scanning with regard to technological and methodological innovations and their incorporation into EHR systems.

The eHealth Network, comprising e-health agencies in Member States and coordinating the exchange of patient summaries and e-prescriptions through the eHealth Digital Service Infrastructure, will have an essential role in taking the format forward by developing specific guidelines and monitoring its implementation.

More Information

Press release: Commission makes it easier for citizens to access health data securely across borders

Commission Recommendation on a European electronic Health Record exchange format

Infographic Impact of European Exchange format of Electronic Health Records

Synopsis report of the public consultation on building a European data economy

Public Consultation on Health and Care in the Digital Single Market

General Data Protection Regulation

Proposal for a Regulation on Privacy and Electronic Communications

Electronic cross-border health services

Digital Exchange of ePrescriptions and Patient Summaries

[1] 22 Member States: Austria, Belgium, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovenia, Spain and Sweden.

European Commission publishes practical arrangements for Commissioners participating in European Parliament elections

The Guidelines will ensure the coherent application of the revised Code of Conduct for Members of the European Commission. President **Juncker** proposed in November 2016 a new Code of Conduct in order to explicitly allow Commissioners – all of them experienced and high-calibre politicians – to actively participate in the campaign for the European Parliament elections, including as lead candidates for the position of President of the Commission, without having to temporarily withdraw from their duties in the Commission. The amended Code of Conduct entered into force in January 2018.

Commenting on today's Guidelines, President **Juncker** said: "*From the very beginning, I wanted this Commission to be a political one. Commissioners take full political ownership and responsibility for all decisions of this Commission. At the same time, I expect them to engage fully and personally with citizens. Actively participating in the upcoming European Parliament elections is part and parcel of this engagement. Therefore, I have changed the Code of Conduct to allow Commissioners to campaign without having to leave the Commission – provided that they keep their campaigning activities clearly separate from their institutional ones.*"

In line with the Guidelines, Commissioners taking part in the European Parliament elections campaign:

- Must **inform the President** that they **intend to participate** in the European Parliament election campaign and of the role they expect to play in the campaign.
- Must **ensure institutional continuity and arrange for the continued performance of their duties**. This concerns in particular the participation in the decision-making process of the Commission, for example regular attendance of the weekly College meeting, and the exercise of portfolio and institutional duties such as participation in trilogues or the exercise of empowerments. This is of particular importance at this very moment when many important legislative files are being finalised by the European Parliament and the Council.
- Are not allowed to use the **Commission's human or material resources for activities linked to the campaign.** For example, they should make sure that the costs of travelling for campaign purposes are not borne by the Commission, or that Commission staff is not involved in the organisation of campaign events.
- When speaking in public, Commissioners should distinguish between **statements made in their institutional capacity and statements made in their role of campaign participants**. At all times, while participating in the campaign, Commissioners must continue to act with the required independence, integrity, dignity, loyalty and discretion. In the same vein, they must not be taking positions that would question their duty of confidentiality or infringe the principle of collegiality. They must notably not criticise or dissociate themselves from decisions or positions taken by the Commission.
- When it comes to Commissioners' social media presence, they should once again **make a clear distinction between activity in their capacity of campaign participants and activity in their institutional capacity**.
- In the same vein, Commissioners **cannot use their Commission website** for the purposes of the campaign. Neither are they allowed to use Commission premises for their meetings with interest representatives for campaign purposes.

Today's guidance furthermore makes it clear that all financial or material support for the campaign and its participants must be directed to the party or campaign organisation itself.

Finally, if ever a situation were to arise which might reasonably be perceived as a conflict of interest in the meaning of the Code of Conduct, Commissioners shall inform the President who will then take any measure he considers appropriate.

The Guidelines, which take into account the opinion of the Independent Ethical Committee following its consultation, have been discussed by Commissioners on 9 January and were unanimously endorsed today. They will enter into effect immediately.

For More Information:

– Guidelines on Ethical Standards for the Participation of the Members of the European Commission in the European Elections (06 February 2019)

– Press release “New Code of Conduct strengthening ethical rules for Members of the European Commission enters into force” (31 January 2018)

– Code of Conduct for Commissioners of 2018 (31 January 2018)

– Framework Agreement on relations between the European Parliament and the European Commission (17 February 2018)

– Text of Article 245 of the Treaty on the Functioning of the EU

ANNEX

Article 10 of the Code of Conduct for Commissioners of 2018

Participation in European politics during the term of office

1. Members may participate in European politics as members of European political parties or organisations of the social partners at European level provided that this does not compromise their availability for service in the Commission and the priority to be given to their Commission duties over party commitment. Participation as members of European political parties or organisations of the social partners at European level includes the holding of political, honorary or non-executive functions in bodies of the party structure, but excludes management responsibilities. Political contacts in the capacity as Member of the Commission remain unaffected.

2. Members may participate in electoral campaigns in elections to the European Parliament, including as candidates. They may also be chosen by European political parties as lead candidate (‘Spitzenkandidat’) for the position of President of the Commission.

3. Members shall inform the President of their intention to participate in an election campaign within the meaning of paragraph (2) and the role they expect to play in the campaign.

4. The President shall inform the European Parliament in due time whether one or more Members will stand as candidates in electoral campaigns for elections to the European Parliament, as well as of the measures taken to ensure the respect of the principles of independence, integrity and discretion provided by Article 245 of the Treaty on the Functioning of the European Union and this Code of Conduct.

5. Members standing as candidates or participating in an electoral campaign within the meaning of paragraph (2) may not use the Commission’s human or material resources for activities linked to the electoral campaign.

6. Members shall abstain from making public statements or interventions on behalf of any European political party of which they are members, except when standing for election or participating in an election campaign in accordance with paragraphs (3) and (4). This is without prejudice to the right of

Members to express their personal opinions. Members so participating in electoral campaigns shall undertake to refrain from adopting a position in the course of the campaign that would not be in line with the duty of confidentiality or infringe the principle of collegiality.

Simpler EU rules for derivatives will reduce costs and regulatory burdens for market participants

This regulation was adopted in 2012 following the financial crisis to better manage and monitor the risks arising from derivatives markets for financial stability. Today's reform will provide simpler and more proportionate rules for over-the-counter derivatives, helping to reduce costs and regulatory burdens for market participants without compromising financial stability. First presented by the Commission in 2017, this initiative builds on the results of the Commission's Call for Evidence, a public consultation looking at the cumulative effect of the new financial sector rules put in place since the crisis, and is a prime example of better regulation in practice: the revised rules improve the efficiency of the market while maintaining prudential objectives.

Valdis **Dombrovskis**, Vice-President responsible for Financial Stability, Financial Services and Capital Markets Union said: *"The European Market Infrastructure Regulation is one of the key EU's financial reforms. Today's political agreement is a tangible deliverable of the Commission's Call for Evidence – we will reduce the regulatory burden for the real economy to a minimum, while ensuring that EMIR keeps achieving its objective of reducing systemic risk in the derivatives market."*

The reform of the European Market Infrastructure Regulation will bring more proportionate rules for corporates. It exempts the smallest financial counterparties from the clearing obligation, while ensuring that the overwhelming majority of trades in the relevant classes of derivatives continues to be cleared in central counterparties. The reporting requirements which ensure that supervisors dispose of full information on derivatives markets are streamlined and will be more proportionate while the quality of the reported data is ensured. Some more time is granted to developing solutions for pension funds before they have to start clearing derivatives in central counterparties. The progress towards these clearing solutions will be carefully monitored.

Next Steps

This political agreement will be followed by further technical work before the European Parliament and the Council can formally adopt the final texts.

Background

A derivative is a financial contract linked to the future value or status of the underlying to which it refers (e.g. the development of interest rates or of a currency value). Derivatives redistribute risk and can be used both to protect against legitimate risk and for speculative purposes. Most derivative contracts are not traded on an exchange but are instead privately negotiated between two counterparties (OTC). The global outstanding notional value of OTC amounted to USD 595 trillion at the end of June 2018 (Source: Bank for international settlements).

EMIR implements the 2009 G20 commitment to increase the stability of the OTC derivatives market in the EU. The main objective of EMIR is to reduce systemic risk by increasing the transparency of the OTC derivatives market, by mitigating the counterparty credit risk and by reducing the operational risk associated with OTC derivatives. It includes several measures: that all standardised OTC derivatives contracts be cleared through central counterparties (CCPs) and that OTC derivatives contracts be reported to trade repositories (TRs).

The need to eliminate disproportionate costs and burdens and to simplify rules without putting financial stability at risk were identified in an extensive assessment of EMIR by the Commission. It included a public consultation in 2015 and Call for Evidence on the EU Regulatory framework for financial services carried out between September 2015 and January 2016 that led, in November 2016, to the adoption by the Commission of a general report on EMIR and to the proposal for a targeted reform of rules on 4 May 2017.

Use of UK data in ESMA databases in case of a no-deal Brexit

Download PDF

Use of UK data in ESMA databases in case of a no-deal Brexit

Download PDF