EN 2019

NO 07

Special Report

# EU actions for cross-border healthcare: significant ambitions but improved management required

(pursuant to Article 287(4), second subparagraph, TFEU)


EUROPEAN
COURT
OF AUDITORS

# Contents


| | Paragraph |
|---|---|
| **Executive summary** | I-IX |
| **Introduction** | 01-16 |
| Patients' rights to cross-border healthcare | 02-07 |
| Cross-border exchanges of health data | 08-11 |
| Cross-border initiatives for rare disease patients | 12-16 |
| **Audit scope and approach** | 17-21 |
| **Observations** | 22-65 |
| The Commission has ensured that the EU Cross-Border Healthcare Directive has been put into practice | 22-32 |
| The Commission has monitored and enforced transposition of the Directive | 23-25 |
| The Commission has reported on the operation of the Directive in a timely manner | 26-28 |
| The Commission guided the National Contact Points in improving the information on cross-border healthcare | 29-32 |
| Exchanging patients' health data across borders: high expectations had not been matched by results at the time of the audit | 33-47 |
| The 2018 eHealth Strategy did not include an implementation plan | 34-37 |
| The Commission underestimated the difficulties involved in deploying EU-wide eHealth Infrastructure | 38-44 |
| The Commission overestimated the likely take-up of the eHealth Digital Service Infrastructure | 45-47 |
| European Reference Networks for rare diseases are an ambitious innovation but their sustainability has not been demonstrated | 48-65 |
| The Commission has not updated its framework for EU actions on rare diseases | 49-51 |
| The Commission did not apply all lessons learned from the European Reference Networks pilots | 52-53 |
| The Commission supported the establishment of 24 European Reference Networks but did not create an effective system to assess participants | 54-57 |

The EU budget does not contain a specific budget line for the European Reference Networks 58-62

Despite delays, the Commission is now launching an EU wide platform for rare disease registries 63-65

Conclusions and recommendations 66-72

Annexes

Annex I – Comparison of patients' rights to cross-border healthcare under the Directive and the Regulation

Annex II – State of play of planned deployment for cross-border health data exchanges in the EU

Annex III – List of European Reference Networks

Acronyms and abbreviations

Glossary

Replies of the Commission

Audit team

# Executive summary

I While cross-border healthcare remains marginal in comparison to healthcare delivered domestically, in some situations, the most accessible or appropriate care for patients is available in a Member State other than their home country. Patients' ability to make a free and informed choice to access cross-border healthcare can improve their healthcare.

II The 2011 Cross-border Healthcare Directive seeks to guarantee EU patients' right of access to safe and high-quality healthcare across national borders within the EU, and their rights to be reimbursed for such care. The Directive facilitates closer cooperation in a number of areas: notably the cross-border exchange of patients' data and access to healthcare for patients with rare diseases.

III Approximately 200 000 patients a year take advantage of the systems put in place under the Directive to receive healthcare treatments abroad: less than 0.05 % of EU citizens. In recent years, France reported the highest number of outgoing patients and Spain the highest number of incoming patients. The majority of patient mobility has been between neighbouring Member States.

IV We examined whether the Commission has overseen the implementation of the Directive in the Member States well and provided guidance to the National Contact Points responsible for informing patients about their right to cross-border healthcare. We assessed whether the results achieved for cross-border exchanges of patients' data were in line with expectations and demonstrated benefits to patients. We also examined key recent EU actions in the field of rare diseases focusing on the creation of the European Reference Networks. These networks seek to share knowledge, provide advice on diagnosis and treatment through virtual consultations between healthcare providers across Europe, and thus raise standards of care.

V We conclude that while EU actions in cross-border healthcare enhanced cooperation between Member States, the impact on patients was limited at the time of our audit. These actions are ambitious and require better management.

VI The Commission has overseen the implementation of the Cross-border Healthcare Directive well. It has guided the National Contact Points towards providing better information on cross-border healthcare, but there remains some scope for improvement.

**VII** At the time of our audit, no exchanges of patients' data between Member States had taken place and no benefits to cross-border patients from these exchanges could be demonstrated. The Commission did not establish an implementation plan with timelines for its new eHealth strategy and did not estimate the volumes of potential users before deploying the cross-border health data exchanges.

**VIII** The concept of European Reference Networks for rare disease is widely supported by EU stakeholders (patients' organisations, doctors and healthcare providers). However, the Commission has not provided a clear vision for their future financing and how to develop and integrate them into national healthcare systems.

**IX** Based on our conclusions, we make recommendations focusing on the Commission's support for National Contact Points, the deployment of cross border exchanges of health data, and EU's action in the field of rare diseases.

# Introduction

**01** The Cross-border Healthcare Directive ("the Directive")[1]:

— sets out EU patients' rights to access safe and high-quality healthcare across national borders within the EU, and their rights to be reimbursed for such healthcare;

— establishes National Contact Points to provide citizens with information on their rights to cross - border healthcare;

— seeks to facilitate closer cooperation on eHealth, including cross-border exchanges of patients' data and

— seeks to facilitate patients' access to healthcare for rare diseases, notably by the development of European Reference Networks (ERNs).

## Patients' rights to cross-border healthcare

**02** Healthcare is a national competence and Member States finance, manage and organise their health systems[2]. The Directive sets out the conditions under which a patient may travel to another EU country to receive planned medical care which will be reimbursed under the same conditions as in their Member State. It covers healthcare costs, as well as the prescription and delivery of medications and medical devices, and complements the legal framework already set out in the EU Regulation on the coordination of social security systems[3] (see ***Annex I*** for the comparison of patients' rights under the Directive and the Regulation). The Directive aims to facilitate access to safe and high-quality cross-border healthcare based on the free and informed choice of patients, as in some situations, the most accessible or appropriate care for patients is only available in a Member State other than their home country. However, the Directive does not encourage patients to receive treatment abroad.

---

[1] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

[2] Article 168 of the Treaty on the Functioning of the EU (TFEU).

[3] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ L 166, 30.4.2004, p. 1). This Regulation is of relevance to cross-border healthcare in the context of labour mobility and tourism and their links between healthcare and social security systems.

**03** Patients seeking to receive healthcare in another Member State are entitled to relevant information on standards of treatment and care, on reimbursement rules and on the best legal pathway to use. Each National Contact Point should provide this information. Member States can require prior authorisation for certain types of healthcare, mainly for treatment which involves either an overnight hospital stay or the use of highly specialised infrastructure or equipment. They do so in around 1 % of cases.

**04** The Directive confirms that patients seeking healthcare abroad should be reimbursed for that healthcare by their home country, provided that they are entitled to that healthcare at home. The level of reimbursement for treatment abroad is set at the level of cost that would have been incurred by the home country. The requirement for upfront payment by patients, while intrinsic to the design of the Directive, is widely recognised as a significant challenge that patients face[4]. However, the Directive offers the option for Member States to provide patients with an estimate of healthcare costs.

**05** The number of citizens claiming reimbursement for medical care received abroad under the Directive is low (approximately 200 000 claims a year – fewer than 0.05 % of EU citizens) compared to those making use of the Regulation on the coordination of social security systems (approximately 2 million claims a year for unplanned treatments abroad). Expenditure on cross-border healthcare incurred under the Directive is estimated at 0.004 % of the EU-wide annual healthcare budget[5]. A 2015 Eurobarometer survey reported that fewer than 20 % of citizens were aware of their rights regarding cross-border healthcare. The Commission has no recent data on the awareness of citizens regarding the Directive.

**06** The use of the Directive varies among the Member States. For cross-border healthcare services not requiring prior authorisation, France had the greatest number of outgoing patients (close to 150 000 patients in 2016), with Spain, Portugal and Belgium treating the highest numbers of incoming patients[6]. ***Table 1*** shows patient mobility in all EU and EEA countries under the Directive in 2016, which covers both

---

[4] According to results by the survey of NCPs carried out by the Cross-border Healthcare Expert Group in May 2017 and confirmed by the ECA's own survey of Cross-border Healthcare Expert Group members.

[5] Commission report on the operation of Directive 2011/24/EU on the application of patient rights in cross-border healthcare, COM(2018) 651 final.

[6] Annex B of Commission report on the operation of Directive 2011/24/EU, COM(2018) 651 final.

cross-border healthcare services and products. The numbers include patient mobility for both, treatments not requiring Prior Authorisation (in total 209 534 patients) and those requiring Prior Authorisation (in total 3 562 patients).

## Table 1 – Patient mobility under the Directive in 2016

| Outgoing patients in 2016 | |
|---|---|
| **Country** | **Number of patients** |
| **FRANCE** | 146 054 |
| **DENMARK** | 25 343 |
| **FINLAND** | 11 427 |
| **NORWAY** | 10 301 |
| **POLAND** | 8 647 |
| **SLOVAKIA** | 6 110 |
| **SLOVENIA** | 1 835 |
| **UNITED KINGDOM** | 1 113 |
| **IRELAND** | 791 |
| **CZECHIA** | 401 |
| **LUXEMBOURG** | 277 |
| **ITALY** | 201 |
| **CROATIA** | 200 |
| **ROMANIA** | 130 |
| **ESTONIA** | 80 |
| **ICELAND** | 53 |
| **BELGIUM** | 30 |
| **LATVIA** | 27 |
| **LITHUANIA** | 19 |
| **CYPRUS** | 13 |
| **SPAIN** | 11 |
| **GREECE** | 10 |
| **AUSTRIA** | 9 |
| **BULGARIA** | 5 |
| **PORTUGAL** | 5 |
| **MALTA** | 4 |
| **GERMANY** | no data |
| **HUNGARY** | no data |
| **NETHERLANDS** | no data |
| **SWEDEN** | no data |
| **Total** | **213 096** |

| Incoming patients in 2016 | |
|---|---|
| **Country** | **Number of patients** |
| **SPAIN** | 46 138 |
| **PORTUGAL** | 32 895 |
| **BELGIUM** | 27 457 |
| **GERMANY** | 27 034 |
| **LUXEMBOURG** | 12 530 |
| **CZECHIA** | 12 300 |
| **ESTONIA** | 10 044 |
| **ITALY** | 9 335 |
| **POLAND** | 6 545 |
| **SWEDEN** | 6 162 |
| **GREECE** | 5 639 |
| **HUNGARY** | 4 169 |
| **AUSTRIA** | 2 437 |
| **CROATIA** | 1 680 |
| **NETHERLANDS** | 1 653 |
| **UNITED KINGDOM** | 1 646 |
| **ROMANIA** | 1 003 |
| **BULGARIA** | 686 |
| **IRELAND** | 674 |
| **MALTA** | 463 |
| **FINLAND** | 403 |
| **FRANCE** | 371 |
| **LITHUANIA** | 369 |
| **NORWAY** | 327 |
| **SLOVAKIA** | 259 |
| **CYPRUS** | 254 |
| **DENMARK** | 198 |
| **LATVIA** | 167 |
| **ICELAND** | 141 |
| **SLOVENIA** | 117 |
| **Total** | **213 096** |

*Source:* ECA based on Report on Member State data on cross-border patient healthcare following Directive 2011/24/EU – Year 2016 available on the Commission's website.

**07** The Commission supports cross-border cooperation in healthcare by means of numerous studies and initiatives, including via Interreg[7], funded under the European Structural and Investments Funds. Member States are responsible for managing their

[7] European Territorial Cooperation (ETC), better known as Interreg, is one of the two goals of the EU cohesion policy and provides a framework for joint actions and policy exchanges between national, regional and local stakeholders from different Member States.

health systems, and for any cooperation arrangements between Member States. Such cooperative arrangements often develop without the involvement of the Commission. The recent Commission study on activities and EU investment in cross-border cooperation in healthcare identified 423 EU-funded projects[8] in support of cross-border collaboration initiatives in healthcare in the period from 2007 to 2017.

## Cross-border exchanges of health data

**08** The Directive mandates the Commission to support Member States cooperation on eHealth and establishes a voluntary network of Member State authorities (eHealth Network) to support the development of common standards for transferring data in cross-border healthcare. eHealth is also a key part of the European Commission's Digital Single Market strategy and its development in the EU is structured around the actions listed in the Commission's Actions Plans for eHealth and in the 2018 strategy on eHealth[9]. The Commission also launched a Task Force in 2017 which is examining incentives and obstacles to achieve secure exchange of health data across the EU.

**09** The Commission, together with the Member States, is building an EU-wide voluntary eHealth Digital Service Infrastructure (eHDSI), to enable the exchange of patients' health data – specifically ePrescriptions and Patient Summaries – across national borders. This project involves 22 Member States[10] and aims at connecting their eHealth systems to the EU eHealth Infrastructure through a dedicated "portal" known as the National Contact Point for eHealth (NCPeH) (see ***Figure 1*** showing the procedure for cross-border exchange of ePrescriptions).

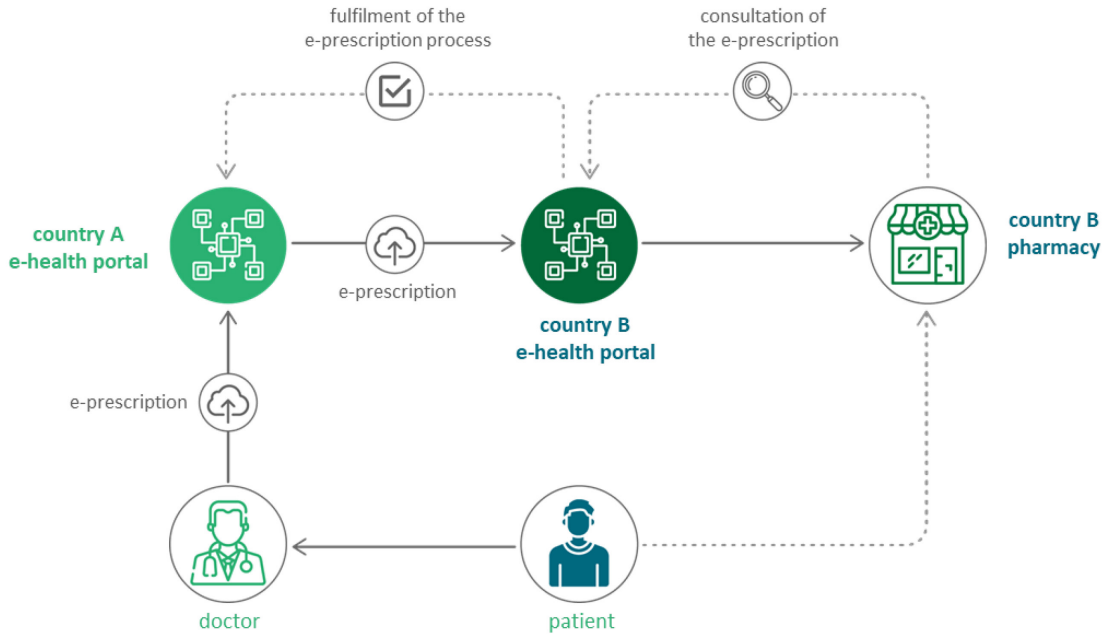
---

[8] Study on Cross-Border Cooperation. Capitalising on existing initiatives for cooperation in cross-border regions – Commission study published in March 2018. The list of projects and their objectives as identified by the study may be accessed online here.

[9] Commission's Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society of 25 April 2018, COM(2018) 233 final. The Communication resulted from the mid-term review of the Digital Single Market Strategy.

[10] Belgium, Czechia, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Slovenia, Finland, and Sweden.

## Figure 1 – Cross-border exchange of an ePrescription




*Source:* ECA.

**10** In some Member States[11], the use of ePrescriptions is common. Other Member States however have only recently started to pilot or implement ePrescriptions services. Reduced availability of eHealth services at national levels is one of the main challenges associated with the deployment of the EU-wide eHealth Infrastructure. In addition some Member States do not participate at all (e.g. Denmark – see ***Box 1*** on eHealth applications for patients) or only participate in some of the services of the EU-wide eHealth Infrastructure.

### Box 1 – eHealth applications for patients in Denmark

The national eHealth portal – Sundhed.dk (https://www.sundhed.dk) allows Danish patients to access their medication profiles, view scheduled consultations with healthcare providers, and re-order certain medication themselves. In 2018, the Danish authorities were working on a pilot project to add further features to the eHealth portal so as to make it easier for patients who consult the doctor frequently (e.g. for chronic disease patients) to schedule their appointments.

In addition, the "Medicinkortet" mobile application allows patients to request an extension for their existing digital prescriptions. All medical prescriptions issued in Denmark are digital.

[11] Ten Member States reported more that 90 % as national coverage for ePrescriptions in 2017 (Croatia, Czechia, Denmark, Estonia, Finland, Greece, Italy, Portugal, Spain and Sweden).

**11** The EU finances eHealth Infrastructure through the Connecting Europe Facility building on a pilot project for cross-border exchanges of health data[12]. Member States that wish to start cross-border exchanges of health data need to go through a testing and auditing process following which a Member States Expert Group (eHMSEG) makes a recommendation. The eHealth Network then takes a final decision on which countries can 'go live' in cross-border health data exchanges.

## Cross-border initiatives for rare disease patients

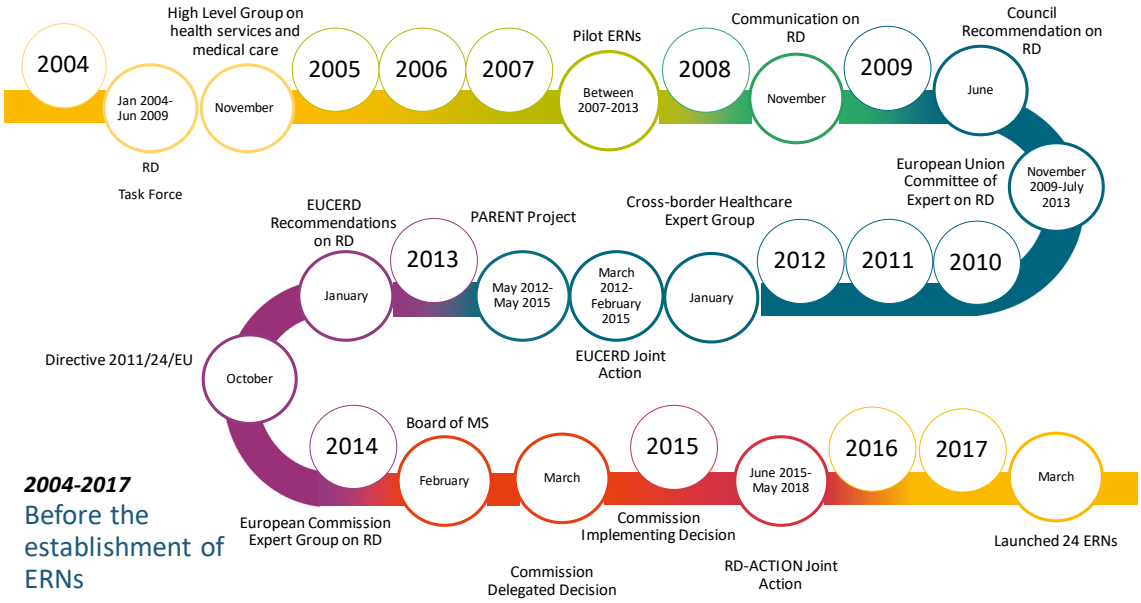
**12** The Directive defines a rare disease as any disease affecting fewer than five people in 10 000. An estimated 6 000 to 8 000 rare diseases affect between 6 % and 8 % of the EU population, i.e. between 27 and 36 million people. The specificities of rare diseases – a limited number of patients and a scarcity of relevant knowledge and expertise – led the Council of the European Union to single out cooperation in this field as "as a unique domain of very high added value of action at Community level"[13].

**13** The Commission put forward a specific policy framework to tackle rare diseases, notably through the creation of the European Reference Networks, in its 2008 Communication "rare diseases: Europe's challenge". The Directive mandates the Commission to support the Member States in the development of the ERNs. ***Figure 2*** shows successive policy developments leading to their establishment.

[12] epSOS – Smart Open Service for European Patients – project funded under the Competitiveness and Innovation Programme (CIP) theme 3: Sustainable and interoperable health services.

[13] Council Recommendation of 8 June 2009 on an action in the field of rare diseases.

## Figure 2 – Successive policy developments leading to the establishment of the European Reference Networks




*Source:* ECA.

**14** The ERNs are intended to reduce time to diagnosis and improve access to appropriate care for rare disease patients and provide platforms for the development of guidelines, training and knowledge sharing. 24 Networks were launched in 2017 for different classes of rare diseases. Each receives €1 million funding over five years from the EU Health Programme. The Commission also finances patient registries and support activities for the ERNs as well as the development of IT tools, notably through the Connecting Europe Facility (CEF).

**15** When a patient case is referred to an ERN, a "virtual" panel of medical experts is convened via the Clinical Patient Management System (CPMS), a web-based application provided by the Commission in November 2017. The application enables doctors to share information, data and images on individual patients, subject to their consent, and to get support in the diagnosis and treatment. 73 % of ERN members had registered to use the application and 333 panels had been created by December 2018 (see ***Box 2*** showing examples of rare disease patients' cases consulted by the ERNs).

### Box 2 – Examples of a rare disease patients cases consulted by a European Reference Network

In 2018, the ERN for Paediatric Cancer was presented with cases concerning two Lithuanian children with rare paediatric cancer. Following advice received from specialists via the ERN, new treatments were provided to these children.

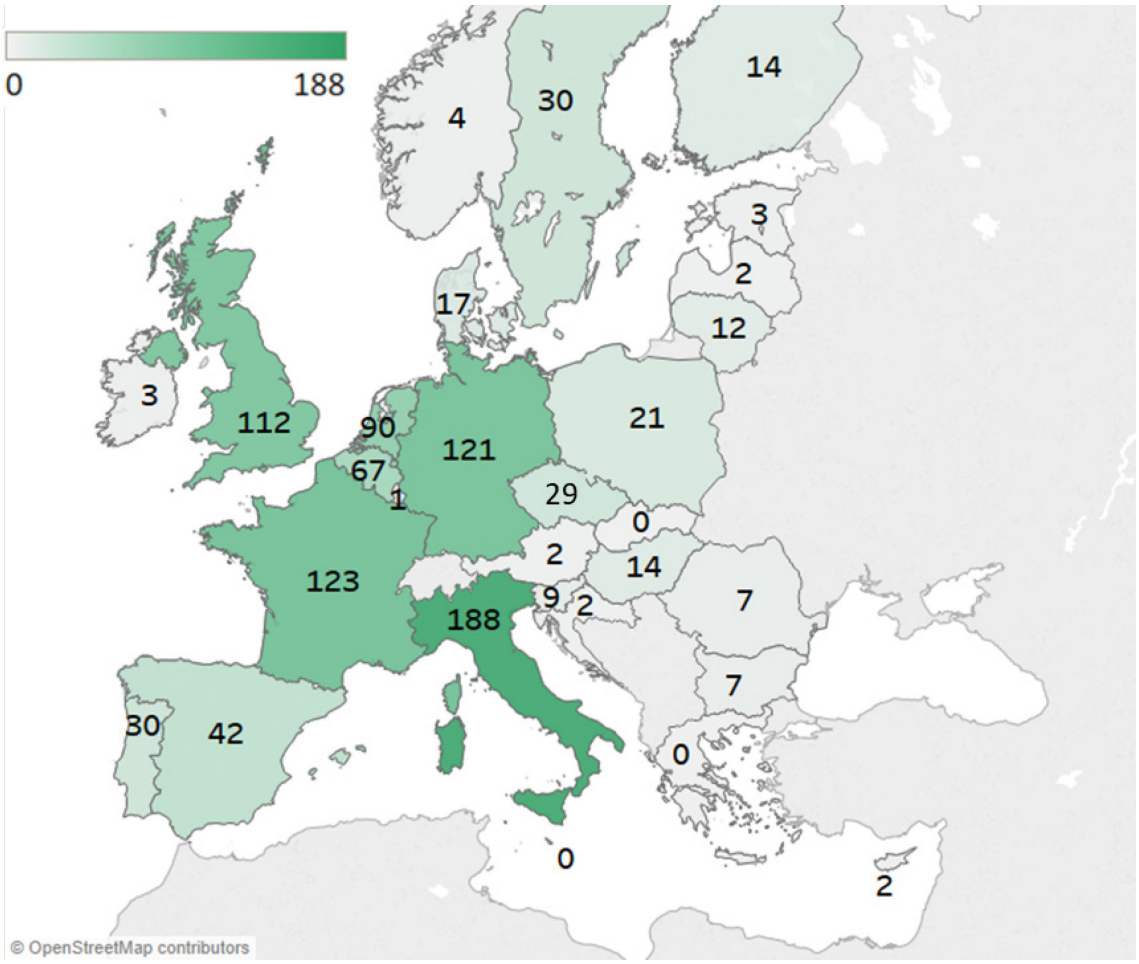
In 2017, the ERN for Rare and Complex Epilepsy was presented with the case of a 4-year-old Finnish boy who had a specific brain abnormality causing severe epilepsy. His doctor in Finland consulted the specialists in the ERNs to seek advice on the right treatment. Specialists from at least six other countries were involved in the discussions and knowledge sharing on the boy's treatment.

In both cases, the ERNs provided valuable advice on patient treatment.

**16** The Board of Member States for ERNs[14] approves the creation and membership of the Networks. By the end of 2018 there were 952 healthcare providers (i.e. institutes, hospital units) in over 300 hospitals participating in the ERNs, spread out over the EU. No ERN covered more than 19 Member States. ***Figure 3*** shows that the distribution of healthcare provider members of the ERNs varies across the EU. The highest number of HCPs participating in the ERNs comes from Italy. This Member State has a longstanding national strategy for rare disease actions and a national network of specialised hospitals and centres qualified to assist patients with rare diseases.

[14] The Board of Member States for ERNs was created by the Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79).

## Figure 3 – Distribution of healthcare provider members of European Reference Networks across the EU




*Source:* ECA based on data on health care provider members to European Reference Network per Member State provided by the Commission, February 2019.

# Audit scope and approach

**17** One of the strategic goals of the European Court of Auditors (ECA) is to examine performance in areas where EU action matters to citizens[15]. Improving Europe's health infrastructure and services and their accessibility and effectiveness is an area in which EU action can add value for EU citizens. We launched our audit 10 years after the Commission approved its strategy on rare diseases and the main EU pilot project for cross-border exchanges of healthcare data started. Our audit sought to answer the following question:

**Do EU actions in cross-border healthcare deliver benefits for patients?**

**18** We examined whether:

(a) the Commission oversaw the implementation of EU cross-border healthcare Directive in the Member States well;

(b) the results achieved so far in terms of cross-border exchanges of health data are in line with expectations;

(c) EU actions on rare diseases add value to Member States efforts to facilitate patients' access to cross-border healthcare.

**19** Our audit covered the period from the adoption of the Commission's rare disease strategy and the launch of the EU's main pilot project for cross-border exchanges of health data in 2008. We performed the audit work between February and November 2018 and held interviews with the Commission representatives form Directorate-General for Health and Food Safety (DG SANTE), Directorate-General for Communications Networks, Content and Technology and Directorate-General Joint Research Centre (DG JRC) and with five Member States'[16] authorities responsible for implementing the Directive. Our choice of Member States considered the main EU funded projects for cross-border exchanges of health data.

**20** We also surveyed all Member States' representatives in the Cross-border Healthcare Expert Group to obtain their opinions on main developments and challenges hampering patients' access to cross-border healthcare and representatives of the eHealth Network on their opinion on the Commission's work on cross-border

---

[15] ECA strategy 2018-2020.

[16] Denmark, Italy, Lithuania, the Netherlands and Sweden.

exchanges of patients' data. We received 15 responses from the Cross-border Healthcare Expert Group and 10 from the eHealth Network.

**21** We audited EU funded projects which aimed to facilitate access to cross-border healthcare, including those for exchanging health data across borders and for developing and maintaining the European Platform on Rare Diseases Registration. We organised an Expert Panel to obtain independent advice on the EU's rare disease policy and the European Reference Networks.

# Observations

## The Commission has ensured that the EU Cross-Border Healthcare Directive has been put into practice

**22** In order to oversee the implementation of the Directive, the Commission needs to monitor and enforce its transposition by the Member States through completeness and compliance checks. The Commission also has to report on the operation of the Directive and appropriately guide the National Contact Points responsible for provision of information to patients on cross-border healthcare.

### The Commission has monitored and enforced transposition of the Directive

**23** Following the Directive's transposition deadline of 25 October 2013 and the Commission's completeness checks of the transposition by the Member States, the Commission opened 26 infringement procedures for late or incomplete notification of transposition measures. In addition, the Commission initiated 21 infringement procedures on late or incomplete transposition of the Implementing Directive on the recognition of medical prescriptions issued in another Member State[17]. After all Member States provided complete notifications of transposition measures, the Commission closed these procedures by November 2017.

**24** The Commission checks Member States' legislation to establish whether they had correctly transposed the Directive's provisions. In order to target these checks, the Commission identified four priority areas that act as barriers to cross-border patients: reimbursement systems, the use of prior authorisation, administrative requirements and the charging of incoming patients. Following these checks, the Commission opened 11 own-initiative infringement cases, four of which had been closed by November 2018, after Member States amended national transposition measures.

**25** We consider that the Commission's checks has led to improvements in the systems and practices employed by the Member States.

---

[17] Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State (OJ L 356, 22.12.2012, p. 68).

## The Commission has reported on the operation of the Directive in a timely manner

**26** The Commission is required to draw up a report every three years, starting in 2015, on the operation of the Directive[18]. These reports should include information on patient flows and the costs associated with patients' mobility. While the Directive does not oblige Member States to collect data on patients' flows, it specifies that they shall provide the Commission with assistance and all available information for preparing the report. In 2013, Member States agreed to provide specific data to the Commission on an annual basis.

**27** The majority of Member States were late in the adoption of the national transposition measures (see paragraph ***23***) and this delayed their provision of data to the Commission in 2015. In 2017, 26 Member States provided it but for six of them, data was incomplete. In addition, data was not comparable from one country to another as some Member States reported all reimbursements without specifying whether they were granted under the Directive or the Regulation on the coordination of social security systems. The Commission recognised the limited accuracy of data included in the reports. For example, the overview of patient flows was incomplete. ***Table 1*** shows that four Member States did not provide data on outgoing patient flows in 2016.

**28** Despite these challenges, the Commission met its reporting obligation on time. It adopted its recent report in September 2018 and presented an overview of patient flows and of the financial impact of cross-border healthcare under the Directive.

## The Commission guided the National Contact Points in improving the information on cross-border healthcare

**29** The Commission supports and guides the National Contact Points with the aim of providing clear and comprehensive information on patients' rights to cross-border healthcare. To do that the Commission published a number of relevant studies[19]. Prior

[18] Article 20 of the Directive.

[19] These studies include: 2012 Study on a best practice based approach to National Contact Point websites with recommendations to Member States and the Commission on how to provide the appropriate information on various essential aspects of cross-border healthcare through NCPs; 2014 Study on the impact of information on patients' choice within the context of the Directive; 2015 Evaluative study on the operation of the Directive containing *inter alia* a review of NCP websites.

to the Directive's transposition deadline, in 2013 the Commission sent a guidance note to the Member States on cross-border healthcare treatment pathways available for patients: the Cross-border Healthcare Directive and the Regulation on the Coordination of Social Security systems.

**30** However, fewer than half of the National Contact Point websites explained the two different ways for patients to obtain healthcare in other countries[20]. In March 2018, the Commission sought to address the potential for confusion between the two pieces of legislation by holding a capacity-building workshop for NCPs and by developing a practical toolbox to help NCPs pass the information on to patients. Our survey showed that the competent authorities in the Member States welcomed the toolboxes, but that further work is needed to help explain the difference to patients.

**31** A recent Commission study[21] considered that the information available to patients on NCPs websites was generally adequate and met the requirements of the Directive, but that the websites could provide more information on incoming patient rights and on the reimbursement of cross-border healthcare costs for outgoing patients. In addition, a report on the Directive by the European Parliament noted that "in-depth information on patients' rights was generally lacking on the NCPs websites"[22].

**32** NCPs are not required by the Directive to include information on European Reference Networks on their websites. We found that some NCPs did provide such information, and others were considering how to do so. German, Irish, Estonian, Lithuanian and UK representatives have already expressed interest in liaising with the ERN Board of Member States for ERNs[23]. The rare disease experts that we consulted considered that NCPs should provide such information about the Networks.

---

[20] According to a survey of NCPs carried out by the Commission for its Report on the operation of the Directive.

[21] Study on cross-border health services: enhancing information provision to patients published on 20 July 2018.

[22] The report on the implementation of the Cross-Border Healthcare Directive of 29 January 2019 by the Committee on the Environment, Public Health and Food Safety.

[23] The report from the meeting of NCPs of 5 May 2017.

## Exchanging patients' health data across borders: high expectations had not been matched by results at the time of the audit

**33** Creating mechanisms to exchange patients' health data within the EU requires a clear strategic and governance framework, supported by the Member States. Clear objectives should be set and performance monitored regularly. Before launching the large-scale projects, the Commission with the support of the Member States should estimate the volumes of potential users. Lessons should be learnt from the earlier pilot projects.

### The 2018 eHealth Strategy did not include an implementation plan

**34** The Commission's eHealth Action Plans set out its approach to eHealth, including to cross-border exchanges of patients' health data. The current Action Plan runs from 2012 until 2020. In April 2018, the Commission adopted a new eHealth strategy[24], which is broader in scope than the current Action Plan. It notably includes the possible expansion to cross-border exchange of electronic health records.

**35** In 2014, the Commission published an interim evaluation of the eHealth Action Plan[25]. While positive overall, the evaluation noted some weaknesses and recommended that the Commission should update the plan to include the most relevant issues, provide a clear governance structure and create a monitoring and coordination mechanism.

**36** The Commission implemented most of the actions foreseen in the eHealth Action Plan. It has not followed the 2014 evaluation recommendation to update its Action Plan nor revised it to reflect the 2018 eHealth Strategy. Therefore, the plan does not include relevant issues, such as the introduction of the General Data Protection Regulation. In addition, the Commission has not set out responsibilities for the plan's implementation.

---

[24] Commission's Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society of 25 April 2018, COM(2018) 233 final. The Communication resulted from the mid-term review of the Digital Single Market Strategy.

[25] Interim evaluation of the eHealth Action Plan 2012-2020, Deloitte study prepared for the Commission.

**37** The 2018 eHealth strategy refers to new challenges such as the introduction of the General Data Protection Regulation and cybersecurity threats. However, this strategy did not include an implementation plan with timelines for expected results and outputs that would show the Commission's approach to implementing the eHealth strategy. When the Commission launched its 2018 strategy on eHealth the only evaluation of its 2012-2020 Action Plan dated from 2014.

## The Commission underestimated the difficulties involved in deploying EU-wide eHealth Infrastructure

**38** The Commission has worked on exchanges of patient health data between Member States in two stages: a pilot project (epSOS)[26] from 2008 to 2012, costing €18 million and an ongoing deployment project (EU-wide eHealth Infrastructure) with a budget of €35 million[27] launched in 2015.

**39** epSOS's goal was to develop an Information and Communication Technology framework and infrastructure to enable secure cross-border access to patient health information. The pilot was to test the functional, technical and legal feasibility and acceptance of the proposed solution for cross-border health data exchanges. It was intended to "demonstrate the practical implementation of the solution in a number of settings in a number of participating states".

**40** The project developed the definitions of data content of Patient Summaries and ePrescriptions (see paragraph ***09***) as well as mechanisms for testing, reviewing and approving exchanges of health data across borders. It has contributed to the development of eHealth interoperability specifications and guidelines. It has also provided common standards to foster these exchanges and demonstrated Member States commitment to cooperation in this area.

**41** The project planning phase did not set the scope and scale of testing required before practical implementation. Testing of the feasibility of the proposed solution consisted of 43 transfers of patient data. This meant that the project provided a limited practical demonstration of the proposed solution. In the final review of the project, external evaluators concluded that the number of real Patient Summaries and ePrescriptions was "too low to consider the epSOS services as operational and

---

[26] The total project budget was €38 million of which the EU agreed to co-finance €18 million. In total 24 countries participated in the project.

[27] The amount includes IT services for the ERNs.

robust"[28]. However, this exchange, while limited, was considered by the Commission a sufficient proof of concept for the eHDSI.

**42** The Commission assessed the epSOS project in 2014. This assessment noted that "although the expectations about statistically relevant numbers of patients' encounters have not been met in the epSOS project so far, the concept of the epSOS approach for cross-border interoperability has been proven to be valid"[29]. In addition, interoperability problems at legal, organisational and semantic levels had proven to be a greater challenge than expected. The Commission also identified ineligible costs claims from the project's contractors, mostly linked to personnel costs. At the time of our audit, the Commission was in the process of recovering ineligible expenses, amounting to 42 % of financing provided.

**43** Despite these challenges, in 2015 the Commission decided to use this pilot project's outputs as the basis for the development of the large scale EU-wide eHealth Infrastructure (eHDSI). The eHDSI architecture, technical and semantical specifications, legal, organisational and policy agreements among the participating Member States are based on epSOS deliverables.

**44** We identified weaknesses in the Commission's preparation for this complex project, notably insufficient estimation of the volumes of potential users (patients and providers, i.e. pharmacies and hospitals) of the cross-border eHealth services that eHDSI provides and an insufficient assessment of the cost-effectiveness of these services before launching the eHDSI. Therefore, we find that the Commission underestimated difficulties involved in deploying an EU-wide eHealth Infrastructure.

## The Commission overestimated the likely take-up of the eHealth Digital Service Infrastructure

**45** Commission announcements on the likely level of health data exchanges across borders have been overoptimistic (see ***Box 3***).

---

[28] Final technical review report of EpSOS of 12 November 2014

[29] In 2014, DG SANTE's Information Systems Unit carried out an epSOS project assessment in order to obtain an overview of what the project delivered in terms of output and achievements and to summarise the conclusions about the maturity of the project for potential further large-scale implementation.

### Box 3 – The Commission's announcements on the take-up of EU-wide eHealth Infrastructure

In December 2017 the Commission announced that: "In 2018, twelve EU Member States will start exchanging patient data on a regular basis"[30].

On its website on eHealth Infrastructure governance, the Commission stated that "It is expected that towards 2019, the EU's cross-border health data exchange starts to be an accepted practice of the national healthcare systems ..."[31].

When assessing its own performance, the Commission reported in 2017, ten Member States as "having capacity to the health data exchange and join the Cross-Border eHealth Information Services"[32]. This figure was based on Member States' self-reporting on a question about the establishment of their national eHealth portals and included Member States which had only started to build their portals, but had not confirmed their readiness to exchange health data across borders.

**46** By the time of our audit (November 2018), exchanges of patients' health data across borders had not yet started via the EU eHealth Infrastructure (see ***Annex II***, which shows the planned 'going-live' deployment dates for cross-border health data exchanges in the Member States). By this time, the Commission had assessed the capacity of seven Member States[33] to 'go live' in cross-border exchanges. Four of these Member States (Czechia, Estonia, Luxembourg and Finland) had undergone follow up checks. In October 2018, the eHMSEG recommended that they 'go live', provided that all corrective actions had been taken. ***Figure 4*** presents the process by which Member States join the Cross-border eHealth Information Service and the 2018 state of play.

---

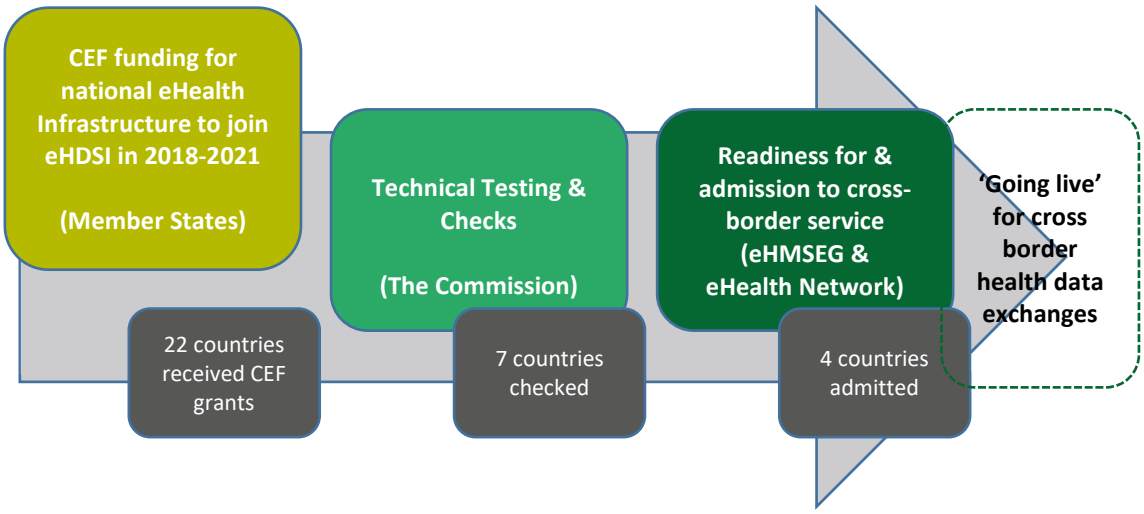
[30] Commission's website: Cross-border digital prescription and patient data exchange are taking off.

[31] Commission's website: eHDSI governance.

[32] Annex of the 2016 Annual Activity Report (AAR) – Health and Food Safety. In its 2017 AAR, the Commission reported nine Member States, as Denmark withdrew from the Cross-Border eHealth Information Services (see paragraph ***10*** and ***Box 1***).

[33] Czechia, Estonia, Croatia, Luxembourg, Malta, Portugal, and Finland.

## Figure 4 – The process of joining the Cross-border eHealth Information Service – state of play 2018




*Source:* ECA based on information provided by the Commission.

**47** We also found that these four Member States were admitted to the EU-wide eHealth Infrastructure to operate different types of eHealth services. At the time of the audit, Finland was ready to send ePrescriptions, while Estonia could receive them (in early 2019 this was the only exchange of ePrescription available in Europe). According to the Commission, 550 ePrescriptions were settled this way between January and the end of February 2019. Czechia and Luxembourg were ready to receive Electronic Patient Summaries from abroad, but no Member States could yet send them via eHDSI. In addition, at the start only some national Healthcare Providers and pharmacies in these countries will use the system. ***Box 4*** explains how patients could benefit from cross-border exchanges of ePrescriptions and Electronic Patient Summaries.

**Box 4 – Cross-border exchanges**

**ePrescriptions (the case of Finland and Estonia),**

When a patient with an ePrescription issued in Finland goes to an Estonian pharmacy to get their medicine, the pharmacy should register the patient's ID. The pharmacy should then send the prescription data, provided patient consent is available, to the Estonian eHealth portal (NCPeH) which should forward it to the Finnish eHealth portal. After the medicine is dispensed to the patient by the Estonian pharmacy, the Finnish eHealth portal should be informed that the ePrescription has been processed (see ***Figure 1***).

**and Electronic Patient Summaries.**

When an individual has a medical emergency or makes an unplanned visit to a healthcare provider abroad, medical personnel could electronically access basic medical information about the patient in the patient's home country via the EU eHealth portal. The Patient Summary may include information on the patient's allergies to medication and can facilitate patient's diagnosis abroad.

## European Reference Networks for rare diseases are an ambitious innovation but their sustainability has not been demonstrated

**48** For the Commission to effectively support the Member States in the development of the European Reference Networks, such support needs to be provided in the context of the legal framework, and with a coherent strategy and a clear roadmap.

### The Commission has not updated its framework for EU actions on rare diseases

**49** The development of the European Reference Networks is part of the EU's wider policy on rare diseases, which includes such elements as support for the development of national rare disease plans, improved standardisation of rare disease nomenclature and support for research on rare diseases. The Commission's 2008 Communication on rare disease aimed to "encourage cooperation between the Member States and if necessary to lend support to their action". The objective was to set out "an overall Community strategy for support to Member States"[34] in tackling rare diseases. The

[34] Commission Communication "on Rare Diseases: Europe's challenge", COM(2008) 679 final.

Council endorsed this approach in its Recommendation on an action in the field of rare diseases of 8 June 2009[35].

**50** The Commission published an implementation report on both, the Communication and the Council Recommendation in 2014. The report concludes that "by and large, the objectives of the Communication and the Council Recommendation have been reached". These objectives included the establishment of a clear definition of rare diseases or improvement of their codification in the healthcare systems. The report does caution that "there is still a long way to go" to ensure rare disease patients across the EU get the care they need and points to the lack of rare disease strategies in some Member States as an area requiring further work. It lists 11 actions envisaged by the Commission including continued support for the European platform for rare diseases and for the development of rare disease plans.

**51** Despite the conclusion that the objectives had been reached, nine of the 11 envisaged actions are a continuation of existing initiatives. The Commission has not updated its rare disease strategy since 2008, although it is managing important initiatives such as the Networks and the EU wide platform for rare diseases registries.

## The Commission did not apply all lessons learned from the European Reference Networks pilots

**52** The Commission funded ten pilot Reference Networks between 2007 and 2013.The Commission's consultative committee on rare diseases (EUCERD)[36] evaluated these pilot ERNs and published a "Preliminary analysis of the outcomes and experiences of pilot European Reference Networks for rare diseases" in 2011. However, when the Commission set up the ERNs, they tackled only some of the issues raised in the 2011 evaluation e.g. support for patient registries, the need for a dedicated Information and Communication Technology tool and for each Network member to have quality control processes for its care practices. Outstanding issues include:

— sustainability of the Networks beyond their initial funding period;

— the development of a continuous monitoring and quality control system for the Network members;

---

[35] Council Recommendation of 8 June 2009 on an action in the field of rare diseases.

[36] European Union Committee of Experts on Rare Diseases (EUCERD) set up by the European Commission Decision of 30 November 2009 (2009/872/EC).

— the administrative challenges and financial costs of expanding a Network and

— sustainable support for patient registries.

**53** The Board of Member States for the Networks has, since its launch in 2014, continued to work on these outstanding points. It has made progress on continuous monitoring and quality control (for which in September 2018 it approved a set of core indicators collected by the ERNs). However, new issues such as the integration of the Networks into national healthcare systems and collaboration with industry have emerged and have yet to be resolved. ***Figure 5*** illustrates the different challenges facing the Networks, which the Commission, the Board of Member States or the Networks Coordinators Group are currently trying to address.

## Figure 5 – Challenges to the European Reference Networks development


*Source:* ECA, based on Board of Member States for European Reference Networks minutes.

## The Commission supported the establishment of 24 European Reference Networks but did not create an effective system to assess participants

**54** The Directive mandated the Commission to establish specific criteria and conditions which Healthcare Providers must fulfil in order to join an ERN[37]. The Commission used a consultant to develop a set of guidelines for applicants as well as for the Independent Assessment Body (IAB), which evaluated the ERNs and individual Healthcare Provider applications. The Commission worked to raise awareness of the launch of the ERNs among relevant stakeholders and its initial objective to support the establishment of ten ERNs[38] was exceeded as 24 were created (see ***Annex III*** showing a list of European Reference Networks).

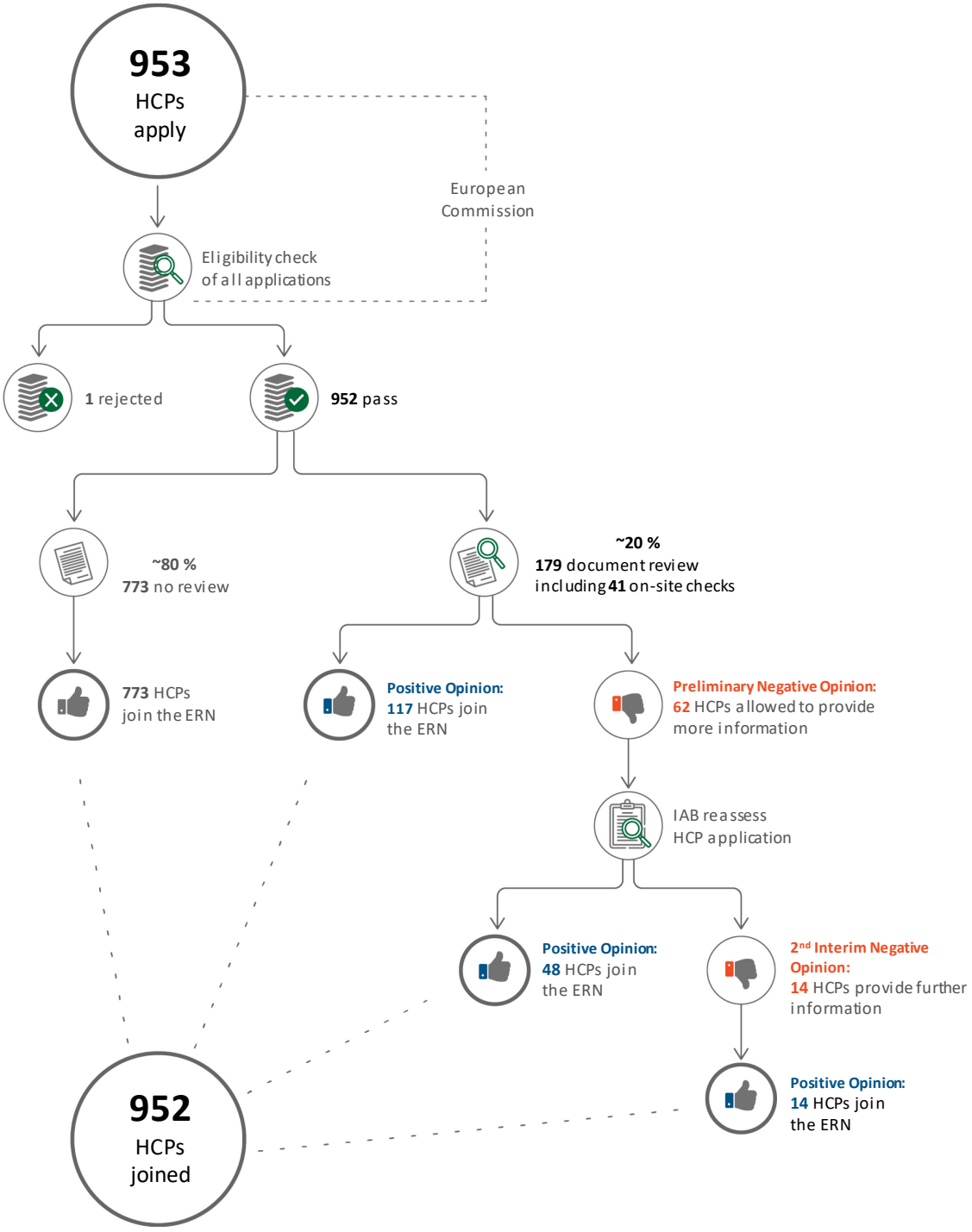
**55** ***Figure 6*** illustrates the assessment process of Healthcare Provider's applications to join the ERNs. Before submitting an application, every Healthcare Provider had first to be endorsed by their Member State's competent authority. The assessment procedure at the EU level was limited to an eligibility check of applications and the assessment of a sample of 20 % of individual applications.

---

[37] The Commission developed the framework for this work in the Implementing and delegated decisions of 10 March 2014.

[38] DG SANTE 2016 AAR (Annex A, p. 169) indicates an interim milestone of ten ERNs under the result indicator 1.5.A: number of established ERNs.

## Figure 6 – Decision tree for the eligibility check and assessment process for Healthcare Provider (HCP) applications to join European Reference Networks




*Source:* ECA analysis based on documents provided by Consumer, Health, Agriculture and Food Executive Agency.

**56** The Independent Assessment Body produced 62 negative preliminary reports. For all these cases, the applicants provided information[39] on outstanding issues which enabled the Assessment Body to give a positive opinion. However, our examination of a sample[40] of assessment reports found that in many cases, the Assessment Body awarded its final positive opinion on the basis of incomplete information. The final outcome of the assessment process was that 952 Healthcare Providers out of the 953 that applied were accepted into the ERNs. We conclude in practice that this assessment process added limited value to the establishment of the ERNs.

**57** The sample-based system of assessment was not originally complemented by any other monitoring or assessment measures. The Commission has been working with the Member States representatives and ERN coordinators since December 2016 on developing a system of continuous monitoring by the Commission and periodic self-evaluation for all ERNs members. However, at the time of the audit they had not decided what measures should be taken if this monitoring system identifies under-performing Healthcare Providers. The Commission also plans to evaluate the ERNs at the end of their five-year financing period[41].

## The EU budget does not contain a specific budget line for the European Reference Networks

**58** The Directive required the Commission to support Member States in the development of the ERNs. The EU budget does not contain a specific budget line for the ERN costs. To support the ERNs' operations, the Commission has provided funding from different spending programmes (Health Programme, Connecting Europe Facility) and through different spending mechanisms (calls for proposals and tenders). The Commission did not set out a comprehensive spending plan for the period 2017-2021 and communicate it to the ERNs and budgetary authority.

**59** In November 2017, the Commission provided the Networks with the Clinical Patient Management System for sharing and consulting patients' data (see paragraph ***15***). Patients' consultations using this system is one of the significant aspects of the ERNs' operations. However, the use of cross-border consultations

---

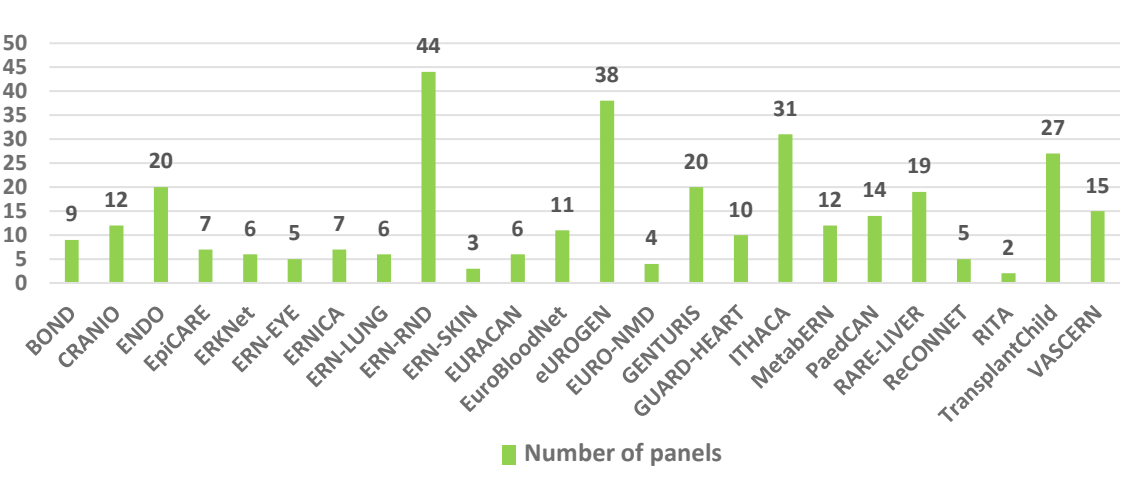
[39] Article 4(5) of Commission Implementing Decision 2014/287/EU.

[40] In our sample of 50 Healthcare Providers assessment reports from 23 ERNs, we found that 30 Healthcare Providers did not provide information on clear action plan.

[41] Article 14 of Commission Implementing Decision 2014/287/EU of 10 March 2014.

through CPMS highlighted the issue of recognising doctors' time spent on the diagnosis and treatment of patients in another Member State. ***Figure 7*** shows the number of consultation panels created in the System per ERN between November 2017 and December 2018.

## Figure 7 – Consultation panels are a sign of ERN operation




*Source:* Commission's CPMS report 12.2018

**60** Each ERN coordinator currently receives €1 million over a period of five years in EU funding[42] for administrative costs. There were often delays in the payment of the annual administrative funding to the ERNs. A Commission survey of ERN coordinators in January 2018, to which 20 ERNs responded, showed that sustainability of financing is one of the top two challenges facing the ERNs[43]. 17 of the 24 ERNs have included identification of other funding sources within their objectives or risk-mitigation strategies.

**61** In addition to this administrative funding the Commission provided grants to the ERNs to support the achievement of their objectives. It launched procurement procedures to develop activities to support the establishment and development of the Networks. By the end of 2018, these included:

— the use of the eHealth solutions, i.e. Clinical Patient Management System (€5 million allocated from the Connecting Europe Facility fund);

— the development of the Clinical Practice Guidelines (in total €4 million from the Health Programme);

[42] 3rd Health Programme.

[43] Board of Member States for ERNs, 6 March 2018.

— the ERNs' registries (in total €2 million for five ERNs in 2018 from the Health Programme);

— the provision of training and tools for ERN coordinators (call for tender to external company with estimated value: €400 000);

— the provision of secretarial support to the ERN coordinators Working Group (call for tender to external company with estimated value: €380 000);

— the development of templates of the ERNs' documents (call for tender to external company with estimated value: €100 000).

**62** The ERN coordinators consider that participating in the numerous calls for proposals run by the Commission imposed significant administrative burden. Moreover, the long-term sustainability of the ERNs' registries, currently financed with Health Programme funds, is unclear despite the Commission emphasising the risk of project based funding for registries in its 2008 Communication on rare diseases.

## Despite delays, the Commission is now launching an EU wide platform for rare disease registries

**63** In its 2008 Communication on rare diseases, the Commission highlighted the importance of databases and registries to enable epidemiological and clinical research on rare diseases. It further stressed the importance of ensuring the long-term sustainability of these systems. In response to this challenge, in 2013, DG JRC started to develop the European Platform for Rare Diseases Registries co-funded by the Health Programme[44] and open to all European rare disease registries. The JRC's platform aims to deal with the fragmentation of data contained in rare disease patient registries across Europe by promoting EU-level standards for data collection and providing interoperability tools for rare disease data exchanges.

**64** We found that, in parallel to the JRC platform, the Commission funded another project, RD-Connect from research and innovation funding programme (Seventh Framework Programme), which had as one of its objectives the creation of a directory of patient registries for rare disease research. Both projects have a similar aim of connecting registries in the EU to make it easier for researchers to access data on rare diseases. As a result, the Commission is funding two projects with potentially overlapping outputs.

---

[44] Based on the Administrative Agreement between DG SANTE and the JRC.

**65** At the time of the audit the JRC platform was due to go live in February 2019, more than two years later than initially planned. One of the reasons for the delay was that, the development of the JRC platform also included transferring two existing networks[45] to the JRC, which required more time and resources than anticipated. We found that the original timing and budget allocation planned for the platform were unrealistic. Furthermore, DG SANTE's funding provided to the JRC platform currently covers approximately 45 % of the costs of the work but there is no provision for the financial sustainability of the platform or planning to ensure that the platform is successful other than a dissemination plan drafted in the fourth quarter of 2017.

[45] The EUROCAT (European Surveillance of Congenital Anomalies) and SCPE (Surveillance of Cerebral Palsy in Europe).

# Conclusions and recommendations

**66** We examined the Commission's oversight of the transposition of the Cross-border Healthcare Directive in the Member States and the results achieved so far for cross-border exchanges of health data. We also assessed EU actions in the field of rare disease policy. We sought to answer the following question:

**Do EU actions in cross-border healthcare deliver benefits for patients?**

**67** We conclude that while EU actions in cross-border healthcare were ambitious and enhanced Member States collaboration, they require better management. The impact on patients was limited at the time of our audit.

**68** We found that the Commission oversaw the implementation of the Directive in the Member States well (paragraphs ***23*** to ***28***), and supported the work of National Contact Points responsible for providing information for cross-border patients. It has recently developed a practical toolbox for the NCPs. However, EU patients still face challenges in accessing healthcare abroad and only a minority of potential patients are aware about their rights to seek cross border healthcare. The complexity of cross-border healthcare treatment pathways available for patients under the Cross-border Healthcare Directive and Social Security Coordination Regulation makes it difficult to provide patients with clear information. NCPs give limited information about ERNs on their websites (paragraphs ***29*** to ***32***).

## Recommendation 1 – Provide more support for National Contact Points

The Commission should:

(a) building on former actions, support the work of National Contact Points, including on how best to communicate the relationship between the Cross-border Healthcare Directive and the Social Security Coordination Regulation pathways,

(b) provide guidance on presenting information about European Reference Networks on the National Contact Points websites;

(c) follow up on the use by National Contact Points of the 2018 toolbox.

**Target implementation date: 2020**

**69** In 2018, the Commission adopted a new eHealth strategy without updating the current eHealth Action Plan. The 2018 eHealth strategy does not include an implementation plan committing to timelines for expected results and outputs (paragraphs ***34*** to ***37***).

**70** The work on cross-border exchanges of health data has resulted in the creation of interoperability standards. The Commission, in cooperation with the Member States, is building EU-wide infrastructure for these exchanges. The Commission did not estimate the likely numbers of users of the EU-wide eHealth Infrastructure before launching the project. The Commission's forecasts of the likely take-up of cross-border exchanges of health data were overoptimistic. There were delays in the deployment of the eHealth Infrastructure and cross-border health data exchanges via eHealth Infrastructure had not started at the time of our audit (paragraphs ***38*** to ***47***).

## Recommendation 2 – Better prepare for cross border exchanges of health data

The Commission should:

(a) assess the results achieved for cross-border exchanges of health data via EU-wide eHealth Infrastructure (for ePrescriptions and Electronic Patients Summaries);

**Target implementation date: 2021**

(b) in the light of this, assess the 2012 eHealth Action Plan and the implementation of the 2018 eHealth strategy, including whether these actions have provided cost-effective and timely solutions, and meaningful input to national healthcare systems.

**Target implementation date: 2021**

**71** The launch of the European Reference Networks is an ambitious innovation in cross-border healthcare cooperation, particularly as healthcare is a Member State competence. The Commission provided the ERNs set up with the Clinical Patient Management System to facilitate sharing of patient data. The ERNs were established in March 2017 and it is too early to assess their success in adding value to Member States efforts to provide better care to rare disease patients.

**72** We found that the Commission has not taken stock of its progress in the implementation of the EU rare disease strategy since 2014 (paragraphs ***49*** to ***51***). The process of establishing the ERNs and the Commission's on-going support for them was marked by shortcomings and the Commission did not set out a spending plan for the ERNs. The ERNs face significant challenges to ensure they are financially sustainable and are able to operate effectively within and across national healthcare systems. The Commission has therefore encouraged Member States to integrate ERNs into national healthcare systems (paragraphs ***52*** to ***62***). We also found that there were delays in launching the EU wide platform for rare disease registries (paragraphs ***63*** to ***65***).

## Recommendation 3 – Improve support to facilitate rare disease patients' access to healthcare

The Commission should:

(a) assess the results of the rare disease strategy (including the role of the European Reference Networks) and decide whether this strategy needs to be updated, adapted or replaced;

**Target implementation date: 2023**

(b) in consultation with the Member States set out ways forward to address the challenges faced by the European Reference Networks (including integration of the European Reference Networks into national healthcare systems, and patients' registries);

**Target implementation date: 2020**

(c) work towards a simpler structure for any future EU funding to the European Reference Networks and reduce their administrative burden.

**Target implementation date: 2022**

This Report was adopted by Chamber I, headed by Mr Nikolaos MILIONIS, Member of the Court of Auditors, in Luxembourg at its meeting of 10 April 2019.

For the Court of Auditors

Klaus-Heiner LEHNE

*President*

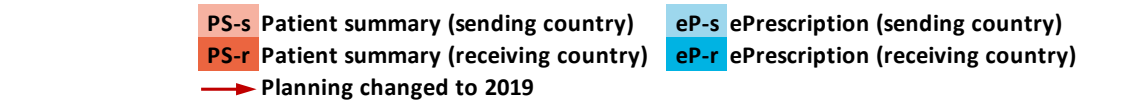
# Annexes

## Annex I – Comparison of patients' rights to cross-border healthcare under the Directive and the Regulation

| | DIRECTIVE | REGULATION |
|---|---|---|
| **Sector** | Public + Private | Public only |
| **Eligible treatments** | Treatments available under patients' own country's health-insurance | Treatments available under the other country's national health-insurance |
| **Prior authorisation** | Required under certain circumstances | Always required for planned care<br><br>Not required for emergency situations |
| **Costs covered** | Reimbursement up to the amount had the treatment been carried out in patients' home country | Complete funding (barring co-payment charges) |
| **Reimbursement of co-payment charges** | Up to the limit of the cost in the home country | Yes (under certain conditions) |
| **Method of payment** | Patients pay up-front and are reimbursed at a later time (reimbursement-system) | Between countries, no up-front payment from patients required (funding-system) |
| **Eligible countries** | All EU & EEA countries | All EU & EEA countries + Switzerland |

*Source:* ECA based on the website 'Healthcare beyond borders'.

# Annex II – State of play of planned deployment for cross-border health data exchanges in the EU




| Country | 2018 | 2019 | 2020 | 2021 |
|---|---|---|---|---|
| Finland | eP-s | eP-r | | |
| Estonia | eP-r | eP-s | PS-s PS-r | |
| Czechia | ~~PS-s~~ PS-r | | eP-s eP-r | |
| Luxembourg | PS-r | PS-s | eP-s | |
| Portugal | ~~PS-s PS-r eP-s eP-r~~ → | | | |
| Croatia | → ~~PS-r eP-s eP-r~~ | PS-s → | | |
| Malta | ~~PS-s PS-r~~ → | | | |
| Cyprus | | PS-s PS-r eP-s eP-r | | |
| Greece | | PS-r eP-s eP-r | PS-s | |
| Belgium | | PS-s | PS-r | |
| Sweden | | eP-s eP-r | | |
| Austria | | | PS-s PS-r eP-s eP-r | |
| Italy | | | PS-s PS-r eP-s eP-r | |
| Hungary | | | PS-s PS-r eP-s eP-r | |
| Ireland | | | PS-s eP-s | |
| Poland | | | eP-s eP-r | |
| Germany | | | PS-s PS-r | |
| France | | | PS-s PS-r | |
| Spain | | | PS-s PS-r | eP-s eP-r |
| Slovenia | | | | PS-s PS-r eP-s eP-r |
| Lithuania | | | | eP-s eP-r |
| Netherlands | | | | PS-r |

*Source:* 'Service Catalogue, Delivery and Overall Deployment – eHDSI – ePrescription and Patient Summary' available on eHDSI website[46].

[46] In November 2018, the eHealth Network granted permission to 'go live' in the cross-border exchanges of health data via eHDSI to four Member States: Finland can send ePrescriptions, while Estonia can receive them. Czechia and Luxembourg are now allowed to receive Electronic Patient Summaries from abroad, but no Member States can yet send them via eHDSI. Three Member States (Croatia, Malta and Portugal) plan to apply to 'go live' in the first quarter of 2019.

## Annex III – List of European Reference Networks

| ERN abbreviated name | ERN full name |
|---|---|
| Endo-ERN | ERN on endocrine conditions |
| ERKNet | ERN on kidney diseases |
| ERN BOND | ERN on rare bone disorders |
| ERN CRANIO | ERN on craniofacial anomalies and ENT disorders |
| EpiCARE | ERN on rare and complex epilepsies |
| ERN EURACAN | ERN on rare adult solid cancers |
| EuroBloodNet | ERN on rare haematological diseases |
| ERN eUROGEN | ERN on urogenital diseases and conditions |
| ERN EURO-NMD | ERN on neuromuscular diseases |
| ERN EYE | ERN on eye diseases |
| ERN Genturis | ERN on genetic tumour risk syndromes |
| ERN GUARD-Heart | ERN on rare and low prevalence complex diseases of the heart |
| ERN ERNICA | ERN on inherited and congenital abnormalities |
| ERN ITHACA | ERN on congenital malformations and rare intellectual disability |
| ERN LUNG | ERN on respiratory diseases |
| ERN TRANSPLANT-CHILD | ERN on transplantation in children |
| ERN PaedCan | ERN on paediatric cancer (haemato-oncology) |
| ERN RARE-LIVER | ERN on hepatological diseases |
| ERN ReCONNET | ERN on connective tissue and musculoskeletal diseases |
| ERN RITA | ERN on immunodeficiency, autoinflammatory and autoimmune diseases |
| ERN-RND | ERN on neurological diseases |
| ERN Skin | ERN on rare skin disorders |
| MetabERN | ERN on hereditary metabolic disorders |
| VASCERN | ERN on multisystemic vascular diseases |

# Acronyms and abbreviations

**AAR:** Annual Activity Report

**CEF:** Connecting Europe Facility

**CPMS:** Clinical Patient Management System

**DG SANTE:** Directorate-General for Health and Food Safety

**eHDSI:** eHealth Digital Service Infrastructure

**eHMSEG:** eHDSI Member States Expert Group

**epSOS:** Smart Open Service for European Patients

**ERN:** European Reference Network

**EUCERD:** European Union Committee of Experts on Rare Diseases

**HCP:** Healthcare Provider

**IAB:** Independent Assessment Body

**JRC:** European Commission's Directorate-General Joint Research Centre

**NCP:** National Contact Point

**NCPeH:** National Contact Point for eHealth

**RD:** Rare Disease

**TFEU:** Treaty on the Functioning of the EU

# Glossary

**Cross-border healthcare:** healthcare provided or prescribed outside the insured person's country of affiliation

**eHealth:** use of Information and Communication Technology in health products, services and processes combined with organisational change in healthcare systems and new skills. eHealth is the transfer of healthcare by electronic means

**Electronic Health Record (EHR):** a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes

**ePrescription:** a prescription for medicines or treatments, provided in electronic format with the use of software by a legally authorised health professional and the electronic transmission of prescription data to a pharmacy where the medicine can then be dispensed

**European Reference Networks (ERNs):** virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resources

**ERN Coordinator:** for each network, one member acts as coordinator. They facilitate cooperation between network's members. **Interoperability:** capacity to make use of and exchange data between different health systems in order to interconnect information

**Rare Disease (RD):** a disease or disorder is defined as rare in the EU when it affects fewer than 5 in 10 000 people

**REPLIES OF THE COMMISSION TO THE SPECIAL REPORT OF THE EUROPEAN COURT OF AUDITORS**

**"EU ACTIONS FOR CROSS-BORDER HEALTHCARE: SIGNIFICANT AMBITIONS BUT IMPROVED MANAGEMENT REQUIRED"**

## EXECUTIVE SUMMARY

I. The Directive 2011/24/EU on the application of patients' rights in cross-border healthcare is seen as a major development in EU health policy. It clarifies and codifies the rights to healthcare which derive from individual judgments of the European Court of Justice. Moreover, it introduced a number of significant flanking measures to enable patients' rights to cross-border healthcare to be applied in practice.

V. The EU actions in cross-border healthcare encompass innovative infrastructure solutions, supporting Member States in an area where they have the main competence and where the development of national infrastructure and use of services at Member State level is very different from one Member State to another.

VI. A robust framework is in place to monitor systematically the application of patients' rights in cross-border healthcare. The Commission works with the National Contact Points (NCPs) to support the continuous improvement of their information provision. Furthermore, it published recently the Guiding Principles for the practice of National Contact Points under the Cross-border Healthcare Directive and a National Contact Point toolbox containing a range of checklists and manuals to support a high quality, patient-oriented practice.

VII. E-prescriptions issued in Finland are now accepted in Estonia, with over 550 e-prescriptions being dispensed between end of January and the end of February 2019. The exchange of patient summaries could save lives of citizens travelling abroad by allowing doctors in the country of destination to access the medical history of the patient and avoid wrong medications, allergies etc. This is particularly relevant for countries with a large diaspora. When new cases will be added (images, laboratory results), exchanging this information may bring savings to the healthcare systems, by avoiding the repetition of tests.

Currently 2 million reimbursements are made every year for cross-border healthcare. There are 1.4 million cross-border workers and 17 million EU citizens are living in an EU Member State other than their country of citizenship.

The Commission has set up an inter-service task force, which monitors the implementation of the 2018 Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society.

VIII. In the last few years, the Commission developed a coherent approach in supporting the European Reference Networks (ERN) reflecting the innovative nature, the complexity and the political sensitiveness of the ERN Initiative. Acknowledging the pioneer work on rare disease and the innovative nature of the European Reference Networks, in 2017 the European Ombudsman, Emily O'Reilly, gave the first Prize of the Award for Good Administration to DG SANTE for its policy on rare diseases.

## INTRODUCTION

04. While the Directive offers the option for Member States to provide patients with an estimate of healthcare costs (a prior notification), it is not often used.

09. The eHDSI is open to all EU Member States and EEA countries and several Member States have also announced their intention to join the project.

10. The eHealth Digital Service Infrastructure (eHDSI) is the pioneering solution enabling the cross border exchange of health data between Member States. Once implemented in a Member State, the eHDSI becomes part of the national eHealth system, regulated in national legislation. The aim of the eHDSI is to empower patients with the access to their data within EU. The prerequisite to start exchanging data through the eHDSI is to have well established and functional national eHealth systems. Member States improvements of their national eHealth systems enable exchange of better quality data.

15. The number of panels created in CPMS between November 2017 and the end of February 2019 was 471 and continues to increase.

16. In addition to Italy other Member States such as France, Germany, Netherlands, Spain, Sweden, etc. are developing National Rare Diseases Plans.

## OBSERVATIONS

23. The Commission welcomes the European Court of Auditors' observation that it has monitored and enforced the transposition of the Directive and recognises the sustained effort committed over the years. The Commission will continue to assess Member States' compliance with the Directive as part of its conformity checks. Cooperation will also continue with the National Contact Points to improve the information provision to patients, including information on the European Reference Networks.

24. The Commission will continue to address the identified priorities – reimbursement conditions, the use of prior authorisation, administrative requirements and the charging of incoming patients. To achieve this, it will use the Cross-Border Health Expert Group, its bi-lateral structured dialogues with the Member States and, where necessary, infringement proceedings to achieve correct transposition of the Directive for the benefit of the European citizens.

26. The Commission agrees with the European Court of Auditors' observations and will continue to urge Member States to submit completed data sets on patient flows and patient mobility.

30. The Commission provided the National Contact Points with a toolbox which includes, *inter alia* manuals for patients, information on reimbursement rules and decision-making trees on the best legal pathway to receive healthcare in another EU country. This toolbox is publicly available on the Europa website.

The Commission acknowledges the importance of continuous and sustained guidance to National Contact Points on the complexity of the two instruments (the Social Security Coordination Regulations and the Directive) that offer two legal pathways to cross-border healthcare. In addition to the capacity-building workshop on 8 March 2018, the Commission published a National Contact Points toolbox in March 2019, including practical information for patients. The Commission will continue to provide NCPs with advice regarding the relationship between the Regulations and the Directive.

31. The Commission agrees that more in-depth information could be made available on the NCPs website in an accessible, and if possible, multilingual format. The Commission will discuss the matter with the National Contact Points.

32. The Commission considers that information on the European Reference Networks is of utmost importance for patients affected by rare and complex conditions and will work together with the National Contact Points to offer comprehensive information on the ERNs.

Common Commission reply to paragraphs 33 and 34:

The eHealth Digital Service Infrastructure is an innovative infrastructure solution, supporting Member States in an area where they have the main competence and where the development of national infrastructure and use of services at Member State level is very different from one Member State to another. The eHealth Digital Service Infrastructure has a solid governance structure in line with the requirements of the CEF programme for Digital Service Infrastructures and its progress and performance is monitored, on a quarterly basis, via a set of 11 key performance indicators. In addition, following an audit on CEF Telecom governance finalised in January 2019 by its Internal Audit Service, the Commission will better clarify some elements of its operational arrangements and further develop the set of result-oriented KPIs.

Almost half of the EU population has a European Health Insurance Card, and over 2 million request reimbursements yearly. In 2017, there were 17 million EU citizens living in an EU Member State other than their country of citizenship and 1.4 million cross-border workers were active in the EU. All of them represent potential users of eHealth Digital Service Infrastructure.

The exact number of e-prescriptions and patient summaries exchanged depends on the use of these services at Member State level, and a gradual, but significant development is expected (see Commission reply to paragraph 41).

34. The deliverables of the Communication are clearly spelled out in the text, although these are not accompanied by timelines.

Common Commission reply to paragraphs 35 and 36.

The Commission Communication included an update of the objectives of the eHealth Action plan and took up the relevant recommendations from its interim evaluation. In addition, due consideration was given to new opportunities (e.g. in the context of the digital single market and the adoption and application of the General Data Protection Regulation, Recommendation on a European Electronic Health Record exchange format) and to new challenges (e.g. cybersecurity threats)).

As regards the actions listed on the eHealth Action Plan 2012-2020, most of them have been delivered or taken forward in the Commission's Communication on enabling the digital transformation of health and care in the Digital Single Market.

The action plan is specific in terms of actions and timeline. The responsibilities for the plan's implementation stem from the tasks and missions of each Directorate-General. The actions were coordinated with the Member States, in the context of the e-health Network, and with wider stakeholders, such as the research community.

37. The Commission has set up an internal co-ordination mechanism (cross-DG Task Force) in order to coordinate and oversee the implementation of the Communication. The deliverables of the Communication are clearly spelled out in the text.

Before the Communication was adopted, an interim evaluation of the Action Plan on eHealth had been undertaken, and the Commission assessed to which extent its actions had been delivered, as set out in the Commission reply to paragraphs 35 and 36. The interim evaluation was overall positive, as most of the activities foreseen in the Action Plan had been delivered.

41. It is common practice for any business project to test its feasibility through a small scale "proof of concept" and then proceed with scaling-up the project to fit mass-deployment. The exchanges of test data implemented within the epSOS and EXPAND projects were sufficient to develop specifications and prove that the exchange of patient summaries and e-prescriptions is technically feasible. The validity of the epSOS project conclusions are confirmed by the fact that e-prescriptions issued in Finland are now accepted in Estonia (550 e-prescriptions being dispensed between end of January and the end of February 2019). This confirms that the exchange of test data within the ePSOS project, albeit limited, was sufficient to put down the basis for the successful deployment of a large-scale cross-border data exchange.

42. The Commission's 2014 assessment is corroborated by the successful going live in January 2019 of the eHDSI.

43. The epSOS final review stated that an impressive basis has been developed for the Legal, Semantic and Technological solutions necessary to exchange important patient data between the European countries.

The Commission concluded that epSOS had laid the foundations for cross-border exchange of patient information.

44. The cross-border exchange of electronic health data is based on voluntary cooperation among Member States (see Article 14(1) of the Cross-Border Health Care Directive (CBHD)). Joining eHealth Digital Service Infrastructure is voluntary and requires a certain level of digital readiness, as well as trust between parties.

An impact assessment was carried out in support of the provisions of the Directive, including the cross-border exchange of data, confirming the need for EU action in the area of cross-border health care.

The potential users include over 2 million EU citizens that request reimbursements yearly for cross border healthcare, 1.4 million cross-border workers active in the EU, 17 million EU citizens living in an EU Member State other than their country of citizenship and, eventually, the population having a European Health Insurance Card.

A gradual, but significant development is expected (see also Commission reply to paragraph 41).

45. In its public communication, the Commission used the timelines indicated by each Member State participating in the eHDSI[1].

Accurately estimating the time of completion of highly technological and innovative projects in an area where subsidiarity plays a major role is very difficult. Moreover, security of the exchange of

[1] Each Member State participating in the eHDSI received the funding from the CEF Telecom Programme to set up their National Contact Point for eHealth and start the cross border exchange of health data. The timeline of national implementation is part of a Grant Agreement signed by each Member State with the Commission.

sensitive patient data had to be ensured, while respecting the voluntary nature of the initiative and building trust among Member States.

46. The eHDSI is operational since January 2019 (see also Commission reply to paragraph 41).

47. Member States join the cross border exchange of health data according to the readiness of their national system to (1) retrieve the data from national infrastructure, and (2) display the data (received from other Member States) to the healthcare professionals.

Member States may choose to gradually deploy different services (sending and receiving e-prescriptions and patient summaries)[2].

Common Commission reply to paragraphs 48 and 49:

In the last few years, the Commission developed a coherent approach and a clear roadmap in supporting the ERNs reflecting the innovative nature, the complexity and the political sensitiveness of the ERN Initiative related i.a. to the fact that the provision and financing of healthcare is a Member States' competence and that it pertains to the Member States to decide how best to integrate the ERNs into their healthcare systems. The progress made by the Commission in developing the European Reference Networks notably influenced the decision by the European Ombudsman, Emily O'Reilly, to award the first Prize of the Award for Good Administration to DG SANTE for its policy on rare diseases. In particular, as far as the long term financing is concerned, in the next Multi-annual Financial Framework the Commission proposed to simplify the ERNs financial support.

49. Pursuant to Article 168(7) of the Treaty on the Functioning of the European Union[3], EU action in the field of public health must fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In this context, the Commission can focus on coordinating EU action in areas related to rare diseases and on improving patient access to diagnosis, information and care.

50. Advancing work on the definition, codification and registration of rare diseases has been consistently supported by the Commission via a series of projects and Joint Actions. This is an ongoing process that has made considerable progress in the five years following the implementation report of 2014 quoted by the European Court of Auditors. The Commission's endeavours are channelled through work with Member States, EU funding mechanisms and Joint Research Centre contributions.

---

[2] The four countries authorised to go-live by the eHealth Network in November 2018 plan to deploy more than one service (sending and receiving e-prescriptions are two different services). (i) Finland has started sending e-prescriptions and plans to start receiving them by the end of 2019. (ii) Estonia has started receiving e-prescriptions and plans to start sending them by the end of 2019. (iii) The Czech Republic is ready to both send and receive patient summaries and plans to start sending and receiving e-prescriptions by the end of 2020. (iv) Luxembourg is ready to receive patient summaries and plans to start sending them by the end of 2019. It also plans to start sending e-prescriptions by the end of 2020.

On 11 March, Croatia received a positive recommendation by the eHealth Member State Expert Group (eHMSEG) to go live with the exchange of e-prescritions (both sending and receiving) and patient summaries (receiving), once the auditors confirmed that the last pending corrective action has been successfully implemented. This recommendation has to be adopted by the eHealth Network in order to become effective.

[3] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12012E/TXT&from=EN

51. It is important to recall the innovative nature of the EU work on rare diseases, especially against the backdrop of the very limited EU's competencies in the public health policy area. Since 2009, the EU's efforts have focused on developing the various building blocks that make up the European response as described in the 2008 Commission Communication and 2009 Council Conclusion. This is still ongoing as can be illustrated by the recent launch of the European Platform on Rare Disease Registration in February 2019.

Taking stock of achievements, lessons learned, and persistent challenges, the Commission then plans to consult Member States and relevant stakeholders, and revise its rare disease strategy where appropriate and relevant[4].

52. The Commission has been developing a continuous monitoring and quality control system for the Network members. It has provided comprehensive proposals for the funding of the ERNs in the next Multi-annual Financial Framework and it is engaged in a dialogue with the Member States concerning the financial support that they should provide to the ERNs and their members. Moreover the Commission is supporting the Member States and the Networks in addressing the challenges that the Networks are facing.

53. The ERN initiative is innovative and complex, but also challenging and politically sensitive, especially concerning the integration of the ERNs in the healthcare systems of the Member States, taking into account that healthcare provision is a Member States' competence. The Commission has been supporting the Member States and the Networks in addressing this challenge as well as the others which are emerging in the first years of development of this complex initiative.

56. The Commission considers that the assessment was carried out in accordance with the Assessment Manual drafted in consultation with the Member States, and looked in detail of to the criteria and conditions that each ERN and each healthcare provider applying for membership had to fulfil. An explicit scoring system was included in the methodology and the outcomes signalled explicitly in the final reports.

57. The current legal framework already contains provisions related to the termination of Networks and loss of membership of the participant healthcare provider (see Articles 11 and 12 of the 2014 ERN Commission Implementing Decision) which might be eventually triggered by the outcomes of the monitoring exercise.

58. The Commission highlights that, while it cannot prejudge the final decision of the legislators, it has made concrete proposals for the smooth financing of the ERNs in the next Multi-annual Financial Framework.

59. In line with the spirit and the letter of Article 12 of the 2011 Cross-border Healthcare Directive, the ERN initiative is the primary responsibility of the Member States, which are "supported" in their endeavour by the Commission. Therefore, while the Commission provides financial support to the ERNs, it can legitimately expect that the Member States actively participate in the financing of this initiative. The Commission has therefore notably engaged in a dialogue with the Member States to encourage them, depending on the way their healthcare systems are organised and clinical

[4] Notably: 1) The conclusions of the Rare 2030 Pilot Project funded by the European Parliament aims to support future policy decisions, examine the feasibility of new approaches and propose policy recommendations (results expected by early 2021); 2) the evaluation of the Third Health Programme (expected by mid-2021); 3) the evaluation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (expected by the end of 2022); 4) the evaluation of the Horizon 2020 Framework Programme for Research and Innovation (expected date still to be confirmed).

procedures remunerated, to ensure their support to ERN Members whose healthcare professionals participate in virtual consultation panels.

61.

First indent: The total allocated budget from 2015 to 2018 for the development of e-health solutions for the ERNs from CEF budget is more than €12 million.

63. The European Platform on Rare Diseases Registration (EU RD Platform) was launched on the Rare Disease Day on 28 February 2019. The infrastructure and tools provided are open to all RD registries and make registries' data searchable and findable. It will facilitate epidemiological, clinical, translational, pharmacological studies and research, fostering knowledge generation on rare diseases.

The development of the EU RD Platform could not be achieved within the initially proposed timeframe due to the complexity and novelty of the project with its various stakeholders and unmet needs. The EU RD Platform has to be seen in its entirety, knowing that it is not one product, but the result of a combination of many individual components, each of which had to be developed separately and then integrated.

64. The scope of the EU RD Platform is different from the one of RD-Connect. RD-Connect focuses on genetic data and considers only patients having genetic data resulting from specific diagnostic methods (a minority). The EU RD Platform's Directory of Registries is an interactive tool addressed to ALL rare disease registries in Europe independent from the genetic data (the majority).

When mapping the needs for patient registration with all stakeholders (registries, national authorities, patients, regulators) neither RD-Connect, nor any other stakeholders reported that the need for a directory of registries was already covered by RD-Connect outputs. This indicated clearly that the need still existed and was not covered by RD-Connect.

65. The timing of the go-live of the JRC platform could not be planned with precision from the start due to the complexity of the project. Typical for infrastructure projects, the planning faced a number of unknown factors to conceive, develop and deploy practical solutions for the interaction of many hundreds of rare disease registries in the EU, with very different structures, purposes, and functionalities, to adapt to new data protection requirements and to transfer the central databases and coordinating activities of the two surveillance networks EUROCAT (European Surveillance of Congenital Anomalies) and SCPE (Surveillance of Cerebral Palsy in Europe) to the JRC.

Both DG SANTE and the JRC are committed to financially sustaining the platform.

## CONCLUSIONS AND RECOMMENDATIONS

67. eHealth DSI entered into its operational phase on 21 January 2019 when the first Member States enabled their citizens to make use of their health data in the cross border environment. Before that, eHealth DSI was still in the deployment phase, in which no real benefits could be realised. At the same time, good management of the project was proved by running the routine operations.

The ERNs have already carried out almost 500 virtual consultations and are considered a success by all stakeholders.

68. The Commission agrees with the European Court of Auditors that there remains a lack of awareness of the Directive’s benefits for EU citizens. Raising awareness requires cooperation

between all actors involved – National Contact Points, health authorities, health insurers, health providers and patient organisations – at local, regional and national level. At EU level, the Commission publicises the Directive and its benefits on the Europa website of the Directorate-General Health and Food Safety and on the website "YourEUROPE". The Commission will urge NCPs to provide information about the ERNs on their websites.

**Recommendation 1 – Provide more support for National Contact Points**

The Commission accepts recommendation 1(a).

The Commission will build on its actions to support the work of the National Contact Points (NCP) including advice regarding the different legal routes for cross-border healthcare and make the NCP toolbox available to the wider public. The toolbox includes useful decision-trees for planned cross-border treatment to guide patients to the best legal pathway (the Directive or the Regulations).

The Commission accepts recommendation 1(b).

Two Commission studies[5] provide evidence that the uptake of information on European Reference Networks on the NCPs' website increased over time. The Commission will provide guidance to the NCPs to encourage the provision of information on the European Reference Networks to all NCPs.

The Commission accepts recommendation 1(c).

The Commission has published the National Contact Point toolbox and will follow up on its use as part of the exchange of good practices in the NCP Sub-Group meeting organised by the Commission.

69. As stated in paragraphs 36 and 37, when the Communication was adopted, an interim evaluation of the Action Plan on eHealth had been undertaken, and the Commission considered to which extent its actions had been delivered (most of its actions have been delivered) and took its objectives forward in the Communication on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society.

With respect to the implementation of the Communication, the Commission has set up an internal co-ordination mechanism (cross-DG Task Force) in order to monitor and coordinate the implementation of the Communication.

70. See Commission reply under paragraphs 33 and 44.

**Recommendation 2 – Better prepare for cross border exchanges of health data**

The Commission accepts recommendation 2(a).

It will monitor and report the results achieved through the eHDSI governance structures. In order to provide the overall assessment, a critical mass of Member States is needed and this will be achieved, at the earliest, by 2023.

The Commission partially accepts recommendation 2(b).

[5] https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2018_crossborder_frep_en.pdf

The Commission will monitor and assess the eHealth Strategy and the eHealth Action Plan and will consider appropriate follow-up action. The focus of the assessment concerning cost-effectiveness and meaningful input to national healthcare systems will be only on the eHDSI, which is the major element of the EU funding. The assessment will build upon the outcome of the actions undertaken under 2(a) after 2023.

72. The ERN initiative is very innovative and complex, as well as politically sensitive notably because the provision of healthcare is a Member States' competence. The ERNs are financed under the Health Programme and CEF and the Commission has made comprehensive proposals to continue financing ERNs in the next Multi-annual Financial Framework. The Commission provides grants for the development of patient registries and finances a variety of support activities for the Networks such as the provision of logistic and secretarial support to the ERN Coordinators Group and its Working Groups, the development of taxonomy, of the templates for ERN documents, the support to the development of clinical guidelines, the mobility of healthcare professionals, etc. The Commission has also raised to the attention of Member States the issue of integration of ERNs in national healthcare systems.

Even if the launch of the European Platform on Rare Diseases Registration (EU RD Platform) was delayed for the reasons presented in paragraphs 63 and 65, the JRC organised three training sessions (February-March 2018) on the structure and functions of the Platform for users from the ERNs, thus preparing the implementation of the Platform with ERN registries.

**Recommendation 3 – Improve support to facilitate rare disease patients' access to healthcare**

The Commission accepts recommendation 3(a).

The Commission will assess the progress made as regards the implementation of the rare disease strategy building on the outcomes of several processes that are currently ongoing or foreseen.

Taking stock of achievements, lessons learned, and persistent challenges, the Commission then plans to consult Member States and relevant stakeholders, and revise its rare disease strategy where appropriate and relevant by early 2023.

The Commission accepts recommendation 3(b).

The Commission works closely with the Member States and the Networks in the ERN Board, in the ERN Coordinators Group and in various thematic working groups which focus on the different challenges faced by the networks in their first years of activities. The Commission is fully committed to supporting the Member States and the European Reference Networks.

The Commission accepts recommendation 3(c).

The Commission has made proposals to simplify the financing of the Networks within the future Multi-annual Financial Framework, but it cannot commit at this stage on the outcomes of the ongoing negotiations with the co-legislators concerning the future Multi-annual Financial Framework.

# Audit team

This ECA's special reports set out the results of its audits of EU policies and programmes, or of management-related topics from specific budgetary areas. The ECA selects and designs these audit tasks to achieve maximum impact by considering the risks to performance or compliance, the level of income or spending involved, forthcoming developments and political and public interest.

This performance audit was carried out by Audit Chamber I Sustainable use of natural resources, headed by ECA Member Nikolaos Milionis. The audit was led by ECA Member Janusz Wojciechowski, supported by Kinga Wiśniewska-Danek, Head of Private Office and Katarzyna Radecka-Moroz, Private Office Attaché; Colm Friel, Principal Manager; Joanna Kokot, Head of Task; Nicholas Edwards, Deputy Head of Task and Frédéric Soblet, Aris Konstantinidis, Anna Zalega, Michela Lanzutti, Jolanta Zemailaite, Auditors. Mark Smith provided linguistic support.

*From left to right:* Frédéric Soblet, Kinga Wiśniewska-Danek, Aris Konstantinidis, Janusz Wojciechowski, Colm Friel, Joanna Kokot, Nicholas Edwards, Jolanta Zemailaite.

| Event | Date |
|---|---|
| Adoption of Audit Planning Memorandum (APM) / Start of audit | 7.2.2018 |
| Official sending of draft report to Commission (or other auditee) | 21.2.2019 |
| Adoption of the final report after the adversarial procedure | 10.4.2019 |
| Commission's (or other auditee's) official replies received in all languages | 16.5.2019 |

PDF ISBN 978-92-847-1934-1 doi: 10.2865/280048 QJ-AB-19-005-EN-N

HTML ISBN 978-92-847-1903-7 doi: 10.2865/946816 QJ-AB-19-005-EN-Q

The 2011 Cross-border Healthcare Directive seeks to ensure EU patients' rights to access safe and high-quality healthcare, including across national borders within the EU. These rights are also intended to facilitate closer cooperation between Member States on eHealth and the treatment of rare diseases. We concluded that although EU actions in cross-border healthcare enhance Member States' collaboration, the benefits for patients were limited. We found that despite the progress made on providing EU citizens with information on cross-border healthcare, in some areas this information remains difficult to access. We identified weaknesses in the Commission's strategic planning and project management. We make recommendations focusing on the Commission's support for National Contact Points, the deployment of cross-border exchanges of health data, and EU's actions in the field of rare diseases.

EUROPEAN COURT OF AUDITORS

Publications Office

EUROPEAN COURT OF AUDITORS
12, rue Alcide De Gasperi
1615 Luxembourg
LUXEMBOURG

Tel. +352 4398-1

Enquiries: eca.europa.eu/en/Pages/ContactForm.aspx
Website: eca.europa.eu
Twitter: @EUAuditors