# EUROPEAN COURT OF AUDITORS

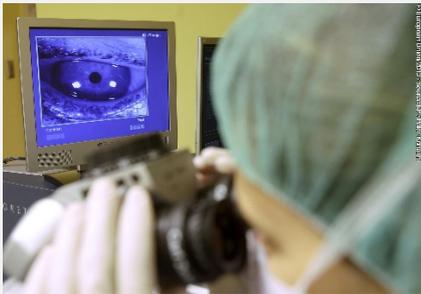CURIA RATIONUM

**Background paper**

# Cross-border healthcare in the EU

May 2018

Healthcare systems in Europe are under pressure because of an ageing population and budgetary constraints. Sometimes, the healthcare that citizens need can best be provided in another Member State than their country of residence, due to proximity, the specialised nature of care, or the lack of capacity to provide that care in their own country. Ensuring EU patients' rights to access safe and high-quality healthcare, including across national borders within the EU, and their right to be reimbursed for such healthcare is one of the goals of EU health policy and principles of the internal market. These rights are set out in the EU's 2011 Cross-border Healthcare Directive.

We are conducting an audit on whether implementation of the Directive to date has been effective, and whether cross-border healthcare is delivering benefits to patients. In particular, we will examine the Commission's monitoring and supervision of this implementation, the results achieved to date in delivering cross-border healthcare access, and the effectiveness of the EU funding framework and the action funded.

If you wish to contact the audit team, you may do so at the following email address: **ECA-cross-border-heathcare-audit@eca.europa.eu**
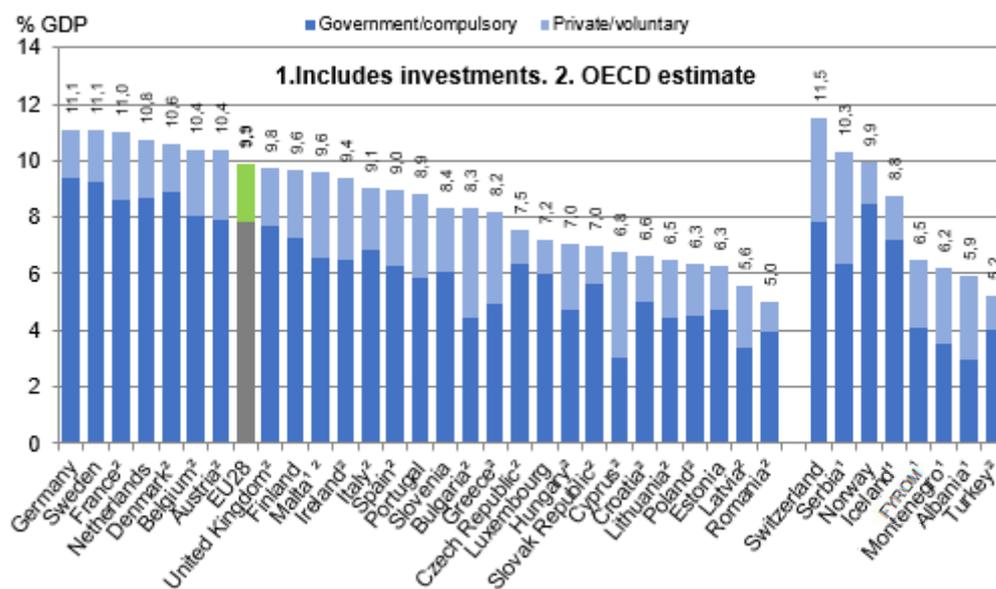
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# CROSS-BORDER HEALTHCARE

## The European health sector

The health sector is a vital component of the EU economy, representing 10 % of its GDP and 8 % of its total workforce (see *Figure 1*). It could account for as much as 12.6 % of EU's GDP by 2060[1].

## *Figure 1* – Health expenditure as a share of GDP, 2015 (or nearest year)



*Source:* OECD Health Statistics 2016; Eurostat Database; WHO, Global Health Expenditure Database.

Healthcare systems in Europe are under pressure because of an ageing population and budgetary constraints. In 2016, persons aged 65 or over had a 19.2 % share of the EU population, an increase of 2.4 % compared with 10 years earlier[2]. This share is projected to increase further. Against the backdrop of these common challenges facing Member States' healthcare systems, the Council of the European Union in 2011 emphasised "the need to join forces and enter into more coordinated EU-level cooperation in order to support Member States, when appropriate, in their efforts to ensure that their health systems meet future challenges"[3]. That same year, Directive 2011/24/EU on patients' rights in cross-border healthcare (the 'Cross-border Healthcare Directive') was adopted, providing for the first time an EU framework and set of rights for European citizens planning to seek care abroad.

**Why cross-border healthcare?**

From the patients' perspective, the ability to make a free and informed choice to access cross-border healthcare can improve healthcare outcomes. In some situations, the most accessible or appropriate care for patients is only available in a Member State other than their country of residence.

**Two priority areas – eHealth and rare disease treatment**

The Cross-border Healthcare Directive' has a number of objectives. In addition to providing an EU framework and set of rights to EU citizens seeking planned care abroad, the Directive is intended to facilitate closer cooperation in a number of areas of medicine and healthcare in which the EU aims to add value: notably *eHealth* and *rare disease treatment*.
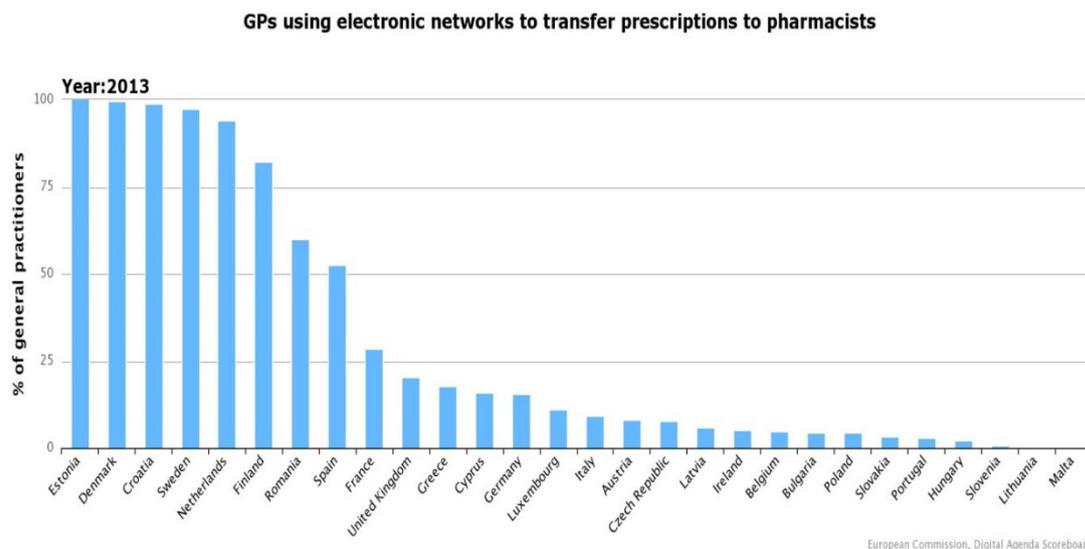
**eHealth**

eHealth refers to "the use of Information and Communication Technologies (ICT) in health products, services and processes, combined with organisational change in healthcare systems and new skills, in order to improve the health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health"[4]. It can make an important contribution to ensuring  the sustainability of health systems and forms an important part of the response to some of today's healthcare challenges. eHealth is a key part of the European Commission's Digital Single Market (DSM) strategy. The aims of cooperation at EU level are to develop common standards, improve interoperability of systems and help to reduce Member States' healthcare costs using eHealth solutions. Such cooperation can also encourage the development of a single, EU-wide eHealth market – part of a global growth market expected to grow globally by 14 % per annum up to 2021[5].

The Commission, together with Member States, is building an EU-wide eHealth Digital Service Infrastructure or eHDSI, aimed at allowing the exchange of limited health data – specifically ePrescriptions and patient summaries – across national borders. Member States can connect their health systems to the eHDSI through a dedicated national contact point for eHealth (NCPeH).

Member States are starting from different baselines in the field of eHealth. This is illustrated, for example, by the number of general practitioners (GPs) in each country using electronic networks to transfer prescriptions to pharmacists (see *__Figure 2__*).

*__Figure 2__* **– GPs using electronic networks to transfer prescriptions to pharmacists**



GPs using electronic networks to transfer prescriptions to pharmacists

*Source:* Studies committed by DG CNECT to monitor the adoption of eHealth technologies by General Practitioners: 2013.

**Rare diseases**

There are an estimated 5800 recognised rare diseases in the EU, affecting approximately 6-8 % of the population or between 27 and 36 million people. Given the small number of patients affected by each rare disease, and that relevant knowledge and expertise are scarce, the advantage to be gained from EU-wide cooperation is potentially high.

The aims of the EU's work in this area include increasing public awareness and understanding of rare diseases, ensuring that they are adequately coded and traceable in health information systems, developing national action plans on rare diseases and funding research and drug development. EU-wide cooperation can help to ensure that scarce knowledge and resources are pooled as efficiently as possible in order to tackle rare diseases effectively across the EU as a whole.

One way in which medical experts and national healthcare providers in different Member States cooperate in this field is through the recently established European Reference

Networks (ERNs). The aim of these multidisciplinary thematic networks is to facilitate the sharing of patient data and improve cooperation on complex or rare diseases and conditions that require highly specialised treatment and concentrated knowledge and resources. However, they pose many challenges as their operating principles and interaction with national healthcare systems and other EU programmes are still being defined, and it is still not clear how they will be financed in the long term.

## EU POLICY AND LEGAL FRAMEWORK FOR CROSS-BORDER HEALTHCARE

**Relevant EU policies and strategies**

*EU health policy*

EU health policy is implemented through multi-annual Health Programmes. There have been three such programmes to date, for the periods 2003-2007[6], 2008-2013 and 2014-2020 respectively.

The second and third of these programmes have provided support for cross-border healthcare actions, which may be aimed at facilitating the implementation, application, monitoring and review of cross-border healthcare legislation, or at developments in the area of eHealth.

*Digital Single Market strategy*

eHealth forms a critical part of the European Commission's Digital Single Market (DSM) strategy. Adopted in May 2015, the strategy's aim is to digitalise the free movement of goods, capital, services and labour, and boost growth and jobs in the EU. With reference to eHealth, this includes telemedicine (i.e. medical services based on interaction between doctors and patients through electronic media) and digital healthcare, and promoting interoperability and common standards within the EU.

The Commission's DSM strategy for eHealth is implemented through the 2012-2020 eHealth Action Plan[7], which has an explicit cross-border dimension. The Action Plan outlines the EU's vision for fostering widespread adoption of eHealth solutions throughout the EU and

addressing barriers, notably a lack of interoperability between Member States' eHealth systems, fragmented legal frameworks and regional inequalities.

*Rare diseases*

The Commission's 2008 Communication on rare diseases[8] and the 2009 Council Recommendation on an action in the field of rare diseases[9] provide the political and policy framework for the EU's actions in this area.

**Legal framework**

The main legal basis for EU cross-border healthcare is Directive 2011/24/EU on patients' rights in cross-border healthcare (the Cross-border Healthcare Directive, discussed above). Below is an overview of cross-border healthcare access under the Directive:

*Figure 3* **– Overview of cross-border healthcare access under the Cross-border Healthcare Directive**

| | |
|---|---|
| Sector | Public + Private |
| Eligible treatments | Treatments available under country's health-insurance |
| Prior authorization | Required under certain circumstances |
| Insurance may always refuse prior authorization, unless undue delay applies | True |
| Costs covered | Reimbursement up to the amount had the treatment been carried out in the home country |
| Method of payment | Patients pay up-front and are reimbursed at a later time (reimbursement-system) |
| Eligible countries | All EU & EEA countries |
| Malpractice & Liability | Possible under country of treatment's laws and regulations |

*Source*: ECA, based on 'Healthcare beyond borders' (https://www.crossborderhealthcare.org/en/legal-information)

To the extent that healthcare is intertwined with social security, Regulation (EU) 883/2004 on the coordination of social security systems (in the context of labour mobility) is also of relevance to cross-border healthcare. Member States have a duty to inform patients of their rights both under this Regulation and under the Cross-border Healthcare Directive[10].

## EU FUNDING FOR CROSS-BORDER HEALTHCARE

Funding for cross-border healthcare primarily comes from the second (2008-2013) and third (2014-2020) Health Programmes which, on average, provide a combined total of around 64 million euros in EU funding per year for health-related issues. The Health Programme supports "actions required by or contributing to the implementation of Union legislation in the field of […] cross-border healthcare"[11]. The types of action co-funded include cooperation projects at EU level, action jointly undertaken by Member State health authorities, action related to the functioning of NGOs and cooperation with international organisations.

Other EU funds, notably the Research Framework Programme (FP7 and CIP in 2007-2013 and Horizon 2020 for 2014-2020), the Connecting Europe Facility  and the Structural Funds, also provide funding for cross-border healthcare and eHealth actions, although the nature of activities and types of beneficiaries may differ from those under the Health Programme. eHealth projects managed by DG CNCET that are relevant for the implementation of the Cross-border Healthcare Directive are funded from the FP7 and H2020 spending programmes.

## STATE OF PLAY

### Some progress made but barriers remain

The Commission's 2015 evaluation of patients' use of the Directive's provision for cross-border healthcare highlighted areas for improvement, particularly in the information provided to EU citizens on their rights to cross-border healthcare and on the treatment and reimbursement procedures involved. Furthermore, a May 2015 Eurobarometer survey indicates that fewer than 20 % of citizens feel well informed about their cross-border healthcare rights.

**_Figure 4_ – Extent to which EU citizens feel well informed about their rights to cross-border healthcare and reimbursement**
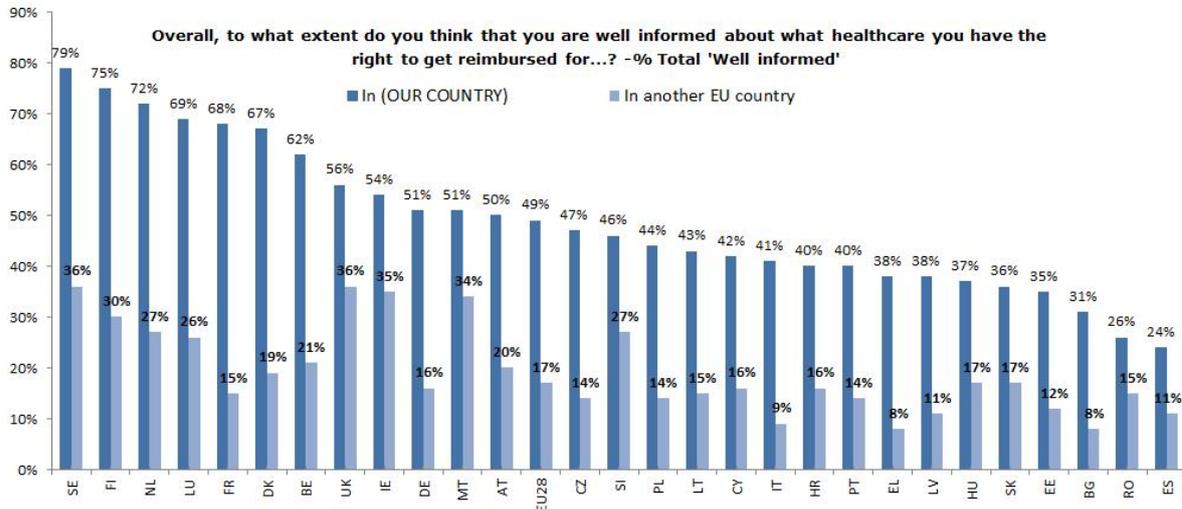


_Source:_ 2015 Eurobarometer survey results published in May 2015.

_eHealth_

The mid-term evaluation for the 2012-2020 eHealth action plan identified several barriers that need addressing[12]. eHealth is facing both general challenges related to the adoption of ICT and challenges specific to eHealth, namely:

  – complexity, e.g. managing dependencies between infrastructure, applications, information and integration.
  – governance, e.g. ensuring alignment between initiatives and overall organisation.
  – local conditions, e.g. balancing central and local motivation, priorities and funding.
  – stakeholder engagement, e.g. ensuring involvement and acceptance from managers, clinicians and IT staff.

A report on eHealth[13] prepared for the Commission in 2014 noted that many eHealth projects had been delayed or failed, either because of lack of long-term vision, lack of skills, unrealistic expectations or a lack of interoperability of systems and standards.

*Rare diseases*

A 2014 report by the Commission[14] on rare diseases found that its objectives in this area had largely been achieved and provided some indications of future direction. According to the Commission's website on rare diseases[15], there is no uniform accepted standard for data in rare disease registries, and current registries are estimated to cover only 20 % of rare diseases.

## ROLES AND RESPONSIBILITIES

**European Commission**

Within the Commission, responsibility for implementing the Cross-border Healthcare Directive lies primarily with the directorate general for health (DG SANTE), which is in charge of the strategic planning, monitoring and evaluation of the Health Programme. DG SANTE supports Member States in developing National Contact Points (NCPs) for cross-border healthcare, supports the development of ERNs and facilitates recognition of prescriptions across borders.

*Cooperation with other DGs and executive agencies*

The Consumers, Health and Food Executive Agency (CHAFEA) implements individual projects under the Health Programme. In the area of research, DG SANTE also cooperates with the Joint Research Council (JRC), and with the directorate general for research and development (DG RTD) on relevant funding opportunities. The JRC has, since 2013, been developing and maintaining the European platform on rare diseases registration under an administrative agreement with DG SANTE. The other relevant department within the Commission is the directorate general for communications networks, content and technology (DG CNECT), which is responsible for eHealth under its DSM strategy.

**Member States**

Member States are either responsible for providing access to the requested healthcare (Member State of treatment) or ensuring that the relevant costs are reimbursed (Member State of affiliation). Member State national healthcare services are responsible for setting

the criteria for citizens to receive healthcare in another Member State (including pre-approval procedure, list of eligible treatments, administrative requirements, and reimbursement arrangements). Each Member State is also represented in the eHealth network and on the Board of Member States for ERNs, which oversee the application of EU policy and help drive important voluntary cooperation on digital health and ERNs.

*National contact points*

All Member States must have an NCP to provide citizens with relevant information on their rights to cross-border healthcare and on the relevant procedures. NCPs provide foreign patients with information on healthcare providers, including on a specific provider's right to provide services. They also provide information on patients' rights, complaints procedures and mechanisms for seeking remedies under that Member State's law. This includes legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare.

## MAIN ISSUES IDENTIFIED WHEN PREPARING THE AUDIT

When preparing our audits, we carry out an issue analysis of the policy area or programmes that we intend to examine. Since these issues are identified before the audit work commences, they should not be regarded as audit observations, conclusions or recommendations.

In the course of our audit on cross-border healthcare in the EU, we will look at a number of areas related to the issues that have been identified. In particular, we will examine whether:

- the Commission effectively monitors and supports the implementation of EU cross-border healthcare legislation;

- the results achieved so far for the different aspects of cross-border healthcare access under Directive 2011/24/EU are in line with established objectives; and

- the EU funding framework in place and EU co-funded actions in the field of cross-border healthcare deliver results and facilitate patients' access to cross-border healthcare.

**ABOUT ECA SPECIAL REPORTS AND BACKGROUND PAPERS**

The ECA's special reports set out the results of its audits of EU policies and programmes or management topics related to specific budgetary areas.

Background papers provide information in relation to an ongoing audit task. They are based on preparatory work undertaken before the start of the audit and are intended as a source of information for those interested in the policy and/or programme being audited.

If you wish to contact the team in charge of this audit, please do so through the following e-mail address: **ECA-cross-border-healthcare-audit@eca.europa.eu.**

**1**   European Commission, 'Joint Report on Health Care and Long Term Health Care Systems and Fiscal Sustainability', ISSN 2443-8014 (online).

**2**   European Commission, EUROSTAT website: http://ec.europa.eu/eurostat/statistics-explained/index.php/Population_structure_and_ageing;

**3**   Council of the European Union, 'Council Conclusions: Towards modern, responsive and sustainable health systems', 3095th Council meeting. Employment, Social Policy, Health and Consumer Affairs. - Health issues. 6.6.2011.

**4**   European Commission eHealth Action Plan 2012-2020.

**5**   Mordor Intelligence, 'E-Health Market - Growth, Trends and Forecast (2017-2022)', October 2017

**6**   European Court of Auditors, Special Report No 2/2009: The European Union's public health programme 2003-2007: an effective way to improve European citizens' health?

**7**   European Commission eHealth Action Plan 2012-2020.

**8**   Commission Communication on rare diseases: Europe's Challenge, {SEC(2008)2713}.

**9**   Council Recommendation of 8 June 2009 on an action in the field of rare diseases, (2009/C 151/02).

**10**  Article 5 of Directive of the European Parliament and of the Council of 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p.45).

**11**  Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21.3.2014, p. 1–13).

**12**  "Interim evaluation of the eHealth Action Plan 2012-2020", study prepared for the European Commission DG Communications Networks, Content & Technology.

**13**  'Unlocking the ICT growth potential in Europe: Enabling people and businesses', study prepared for the European Commission DG Communications Networks, Content & Technology, DOI: 10.2759/38215 ISBN 978-92-79-34704-7.

**14**  Report from the Commission "Implementation report Health and Consumers on the Commission Communication on Rare Diseases: Europe's challenges and Council Recommendation of 8 June 2009 on an action in the field of rare diseases", COM (2014) 548 final.

**15**  European Commission, DG SANTE website: https://ec.europa.eu/health/rare_diseases/policy/registries_en, accessed 15.01.2018