

EUROPEAN COMMISSION HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation **Cross-border healthcare and tobacco control**

Minutes of Meeting: Cross-border Healthcare Expert Group 17 October 2019, 10:00-16:30 Chair: Mr Andrzej RYS (EC Director), Ms Thea EMMERLING (EC Head of Unit)

PARTICIPANTS:

- Present: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and Norway.
- Excused: Greece, Poland, the United Kingdom.

1. WELCOME AND INTRODUCTORY REMARKS

The Chair welcomed the participants and announced a number of minor changes to the agenda before it was duly accepted. The Chair introduced Caroline Hager, the new Team Leader responsible for the patient rights aspects of the Cross-border Healthcare Directive in DG SANTE, and informed the forum about the new Commissioner-designate for health, Stella Kyriakides, from Cyprus. The Chair explained the objectives of the meeting:

Objectives:

- Present and discuss the European Court of Auditors' "Special Report No 7/2019 on EU actions for cross-border healthcare" and follow-up action;
- Feedback on compliance with the Cross-Border Healthcare Directive 2011/24/EU as well as cases before the Court of Justice of the EU concerning cross-border healthcare issues;
- Present and discuss the preliminary results of the 2018 data collection exercise and agree improvements for the 2019 questionnaire;
- Consider the Commission machine translation tool;
- Exchange views on EU actions to support better implementation of the Cross-Border Healthcare Directive 2011/24/EU and identify areas for further cooperation;
- Consider the next steps for NCPs in respect of the Single Digital Gateway;
- Update from the Committee of the Regions on its forthcoming "Outlook Opinion" on regional cooperation on cross-border healthcare;
- "Healthcare in cross-border regions": Update on European initiatives.

2. IMPLEMENTATION OF THE DIRECTIVE 2011/24/EU

2.1 Present and discuss the European Court of Auditors' "Special Report No 7/2019 on EU actions for cross-border healthcare"

Presentation by the European Court of Auditors and exchange of views.

Joanna Kokot and Colm Friel, representatives of the European Court of Auditors, made a short presentation explaining the scope of the assessment and the approach adopted before giving an overview of the main observations and findings that fed into the report recommendations addressed to the Commission. The ECA representative explained that "Special Report No 7/2019 on EU actions for cross-border healthcare" is a performance audit that assesses EU actions for patients under the Cross-border Healthcare Directive from October 2017 to December 2018. The audit examined the effectiveness of the Commission's monitoring and supervision of the implementation of the Cross-Border Healthcare Directive, the results achieved and the effectiveness of the funding framework put in place. The Court found that the Commission has ensured the effective monitoring and enforcement of the Directive and recommends continued support for National Contact Points to improve information provision for patients. The Court cautioned that the high expectations for the exchange of patients' health data across borders have not been matched by results to date. The Court also signalled that while the European Reference Networks for rare and complex diseases are an ambitious innovation, their sustainability has not been demonstrated - the Networks need funding into the future as well as integration into the MSs' healthcare systems.

A number of MSs asked clarifying questions.

The Chair welcomed the Court's recommendations, which seek to improve the implementation of the Directive. The Chair stressed the importance of the Directive in protecting patients' rights in the EU and noted its power to trigger major innovations in cross-border healthcare through European cooperation (for example ERNs and eHealth).

The Chair also emphasised that both the ERNs and eHealth Digital Service Infrastructure are voluntary initiatives and the competence lies with MSs. The Chair thanked the MSs for their contributions to surveys prepared by the Court, noting in particular Denmark, Italy, Lithuania, Sweden and the Netherlands, who hosted study visits by the Court.

2.2 Actions to be taken to implement the European Court of Auditors' recommendations

Corina Vasilescu, Enrique Terol and Licinio Kustra Mano (DG SANTE) summarised the main points of the Commission's draft Action Plan – covering conformity checks and information to patients; European Reference Networks for rare, low-prevalence and complex diseases; and Digital health.

Conformity checks and information to patients

The auditors found that the Commission had monitored the transposition of the Directive into national law and its implementation by the Member States well. The Commission also was found to support the Member States in improving information on patients' rights in cross-border healthcare, but there were still some gaps. The gaps will be addressed by further cross-fertilisation of NCPs and ERNs. To this end, as agreed at the meeting of the Sub-Group of NCPs on 21 May 2019, the NCPs would inform patients about ERNs based on the ERNs' descriptions provided by the Commission. The Commission is also translating the Toolbox and Manual for Patients it has

developed into all EU languages and will publish this material in due course. The NCPs were invited to make full use of this material and include hyperlinks on their respective webpages.

European Reference Networks

The ERNs are a very innovative and ambitious project and a common endeavour of many players: healthcare professionals, patients associations, national authorities and the Commission.

There are now 24 ERN coordinators, more than 950 healthcare providers and thousands of professionals who are members of the networks, which are located in 300 hospitals across Member States' national healthcare systems. This work has been supported by the Member States, hospital management and the Commission services.

The ERNs system is now at a stage where it is facilitating the virtual exchange of healthcare advice for the treatment of hundreds of individual patient cases, the development of training and education actions, the production of clinical practice guidelines and leading to the development of research projects, as well as the setting up of registries.

The ERN initiative is innovative and complex but also challenging and politically sensitive, especially concerning the integration of the ERNs into the healthcare systems of Member States, taking into account that healthcare provision is a Member State competence.

Action by Member States to integrate and support the networks is required – namely, defining national patient pathways and referral systems to allow the clear interlinking of the national systems with each of the ERNs in a hub–spoke model.

ERN members need to be supported at hospital level and their work recognised as part of their tasks and their needs addressed by the national authorities and hospital managers, including IT and administrative support.

The capacity of the ERNs to innovate, generate knowledge and to provide solutions and support to the patients and the national healthcare systems depends on the commitment of the national authorities. There are already excellent examples of that commitment and support, however, this support is not the reality in all cases.

E-health

Access to health records across the EU can offer great benefits to European citizens. Better access to health data across borders will improve the quality and continuity of care offered to citizens. Several Member States have already started exchanging patient summaries and e-prescriptions through the eHealth Digital Service Infrastructure (eHDSI).

This year the first cross-border exchange of electronic patient data took place. Three Member States (FI, EE, HR) have begun to exchange ePrescriptions across borders. To date, more than 4,200 ePrescriptions have been dispensed. Three Member States have also begun exchanging electronic patient summaries (LU, CZ, HR). MT and PT are expected to begin such exchanges soon. It is hoped that 22 Member States will begin exchanging electronic patient data by mid-2022 and that soon all the Member States will join these exchanges.

To address the ECA recommendations, the Commission will work with Members States to develop the Key Performance Indicators, assess the effectiveness of the infrastructure and increase its uptake.

The Chair made the following conclusions in relation to three main areas discussed:

Conformity checks and information to patients

As agreed at the meeting of the Sub-Group of NCPs on 21 May 2019, the NCPs would inform patients about ERNs based on the ERNs' descriptions provided by the Commission.

The NCPs were invited to make full use of the Toolbox and Manual for Patients and include hyperlinks or simply use the material on their respective webpages.

European Reference Networks

Action by Member States to integrate and support the networks is required – namely, defining national patient pathways and referral systems to allow the clear interlinking of the national systems with each of the ERNs in a hub–spoke model.

The Chair asked for MSs' continued support for the ERNs and called on MSs to bring this message to colleagues and decision-makers in their respective capitals.

E-health

Any countries that have not already done so can still apply until **14 of November 2019** for funding under the CEF Telecom eHealth Call¹.

The Chair strongly encouraged the MSs to disseminate the information about the eHDSI to their respective citizens and healthcare professionals.

2.3 Council Conclusions on the ECA Report – Intervention by the Finnish Presidency

Pasi Mustonen, the Finnish Health Attaché, gave an update on developments in the area of cross-border healthcare during the Finnish Presidency of the Council of the European Union.

The Finnish Presidency has convened two meetings of the Working Party on Public Health (11/09, 11/10) to agree a set of Council Conclusions on the recent ECA Report. The draft Council Conclusions have been submitted to Coreper I for adoption at next week's EPSCO. The Council urges the Commission and Member States to continue the development of the Directive, including on digital health and ERNs, and assess whether the 2008 rare diseases strategy should be updated, adapted or replaced. Specifically, the Conclusions urge the Commission to continue its financial support for the ERNs. Welcomes regular reporting to the Council on the implementation of the Directive.

The Chair welcomed in particular the closing paragraph of the draft Council Conclusions, encouraging Member States to assist the Commission by providing information that is relevant for the preparation of the triennial reports, including on patient mobility and patient flows.

2.4 State of play: compliance with the Cross-Border Healthcare Directive 2011/24/EU

Balazs Lengyel (DG SANTE) presented an overview of the state of play in relation to compliance checks carried out by the Commission. The overview included a section on a number of cases before the European Court of Justice seeking preliminary rulings related to interpretations of the Cross-Border Healthcare Directive 2011/24/EU.

The Chair stressed that the Commission services will continue to work with the MSs in their efforts to enable the Directive to deliver fully on its potential for the benefit of all EU citizens.

¹ <u>https://ec.europa.eu/inea/en/connecting-europe-facility/cef-telecom/apply-funding/2019-ehealth</u>

3. PATIENTS' MOBILITY IN THE EU - PRESENTATION OF THE **2019** DATA COLLECTION EXERCISE

Isabelle Andoulsi, a representative from Health Connect Partners, presented 2018 data on the impact of the Directive. The contractor noted that data quality issues persist, as in other years, as not all Member States were in a position to provide data as requested.

A background document, "Member State Data on cross-border patient healthcare following Directive 2011/24/EU, Year 2018", was circulated in advance of the meeting.

A number of MSs asked clarifying questions. The point was made that patient mobility alone is not sufficient to measure the impact of the Directive.

DG SANTE noted that there is a new chapter in the patient mobility report where information on patient mobility numbers under the Directive and the Social Security Regulations will be compared. This information will be updated once the report on the Regulation has been agreed with the Administrative Commission on 24 October 2019. DG SANTE will participate in the Administrative Committee to draw attention to the patient mobility report and the importance of sharing data on cross-border healthcare.

The Chair thanked MSs that already submitted data and urged the remaining MSs to intensify their efforts to collect data and submit it by **8 November** as it is planned to publish the report before the end of the year. The Commission will continue to seek solutions with those Member States who are not in a position to reply to ensure a comprehensive picture of patient mobility in the EU.

Looking ahead, DG SANTE announced that it would like to start a reflection on how to further improve information on cross-border healthcare using existing data sources and possibly using new questions in the patient mobility questionnaire, as well as a new Eurobarometer survey, with a view to the Directive's evaluation in 2022/2023.

The Chair proposed to organise a dedicated meeting with experts on data and information on cross-border healthcare in spring 2020, before the launch of the next data collection exercise. Members of the Cross-Border Healthcare Expert Group will be invited. Further details will be circulated in 2020.

4. COMMISSION MACHINE TRANSLATION OF DOCUMENTS

Daniel Prou, a representative of DG Translation, made a short presentation, introducing the main features of the machine translation tool eTranslation, which is available in the 24 official EU languages as well as Icelandic and Norwegian. ETranslation is at the disposal of NCPs for cross-border healthcare and to MS representatives in the Expert Group for Cross-Border Healthcare.

The Chair noted that language differences remain a huge obstacle to cross-border cooperation – being an administrative burden to both patients and national administrations – and urged Member States to register with the platform and make maximum use of the eTranslation tool in their daily work.

5. TOWARDS BETTER IMPLEMENTATION OF THE CROSS-BORDER HEALTHCARE DIRECTIVE

Caroline Hager (DG SANTE) introduced the topic, talking through to a discussion paper, "Towards better implementation of the Cross-Border Healthcare Directive 2011/24/EU, EU cooperation: sharing good practices and exchanging information", circulated in advance of the meeting, which details EU actions to support implementation of the Directive in Member States. The paper included questions to the Cross-Border Expert Group to help frame the exchange of views.

To kick off the discussion, the Chair also invited MSs that do not have prior-authorisation measures in place, as well as those MSs who have a functioning prior-notification system, to share their experiences.

Many MSs made suggestions as to how to improve implementation, for example in the areas of prior-authorisation, information to patients via NCPs or campaigns, prior-notification, upfront payment, (regional) workshops involving a variety of stakeholders and sharing case studies in implementation and related challenges. For a successful use of cross-border rights, it is essential that a close cooperation between healthcare providers, National Contact Points and also health insurers (health funds) takes place. The task of NCPs is not only to inform about the entitlements arising from the Directive 2011/24/EU, but also about the entitlements arising from the Regulations on social security coordination.

One MS sought clarification on whether the Commission guidance note 246 from 2012^2 was still valid. DG SANTE confirmed that it was still valid and offered to circulate it to the Expert Group again in case of interest.

The Chair thanked the participants for the productive discussion and concluded that there is sufficient interest among Member States to share experience and best practice. A possible format could be a 1 ½-day workshop to be hosted in a MS.

DG SANTE noted the suggestions for a session at the workshop to present case studies of challenges encountered in implementing the Directive in practice. Also noted the wish for a best practice based approach. Funding for the workshops would be considered by the Commission.

² Guidance note of the Commission services on the relationship between Regulations (EC) Nos 883/2004 and 987/2009 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross border healthcare.

DG SANTE would be willing to facilitate and organise these exchanges in cooperation with the MSs, including workshops for NCPs.

6. SINGLE DIGITAL GATEWAY: NEXT STEPS FOR NCPS

Hans Dietrich Druener, a representative of DG GROW, made a short presentation on the Single Digital Gateway Regulation (Regulation 2018/1724), which entered into force last December. DG GROW explained that the SDG will have implications for many public assistance and information services across Europe, including the NCPs, which are listed as Assistance Services under Annex III of the Regulation. He noted the December 2020 target for the launch of the SDG.

The Chair concluded that based on the survey conducted among NCPs earlier this year, most NCPs appear to already be compliant with the requirements of the SDG. However, there remains room for improvement in two key areas: a) the need for a user feedback mechanism, which DG GROW is currently developing and b) the need to publish estimated or average wait times for responses to standard queries and more details about what users should expect. DG SANTE will circulate the results of the survey in due course.

7. REGIONAL COOPERATION ON CROSS-BORDER HEALTHCARE

- 7.1 Update on the "Outlook opinion" being drafted by the Committee of the Regions Dorota Tomalak, a representative from the European Committee of the Regions, gave a brief overview of the Committee's work on its "Outlook opinion" on the implementation and future perspectives for cross-border healthcare that is expected to be published in May-June 2020.
- 7.2 Update on the Thematic Network on "Healthcare in cross-border regions" supported by the DG SANTE Health Policy Platform Valentina Polylas and Julia Winkler, representatives from the European Regional & Local Authorities (EUREGHA) and the Health Across initiative, made a joint presentation. They informed the Expert Group about "Healthcare in cross-border regions", a theme of the 2019 Thematic Network cycle of the EU Health Policy Platform. Member States were invited to support the resultant Joint Statement on Healthcare in Cross-Border Regions³ via the campaign website.

8. CLOSING OF THE MEETING

The Chair summarised the outcomes and actions arising from the meeting, as follows:

³ <u>http://www.euregha.net/CrossBorderHealthcare/</u>

1. ECA Report and follow-up

- The Chair welcomed the Court's recommendations, which seek to improve the implementation of the Directive. The Chair stressed the importance of the Directive in protecting patients' rights in the EU and noted its power to trigger major innovations in cross-border healthcare through European cooperation (for example ERNs and eHealth).
- The Chair also emphasised that both the ERNs and eHealth Digital Service Infrastructure are voluntary initiatives and the competence lies with MSs. The Chair thanked the MSs for their contributions to surveys prepared by the Court, noting in particular Denmark, Italy, Lithuania, Sweden and the Netherlands, who hosted study visits by the Court.
- As agreed at the meeting of the Sub-Group of NCPs on 21 May 2019, the NCPs would inform patients about ERNs using the ERNs descriptions provided by the Commission.
- NCPs were invited to make full use of the Toolbox and Manual for Patients and include hyperlinks or draw on this material on their respective webpages.
- Action by Member States to integrate and support the networks is required namely, defining national patient pathways and referral systems to allow the clear interlinking of the national systems with each of the ERNs in a hub–spoke model.
- The Chair asked for MSs' continued support for the ERNs and called on MSs to bring this message to colleagues and decision-makers in their respective capitals.
- Member States who have not already done so have until **14 of November 2019** to apply for funding under the CEF Telecom eHealth Call.
- The Chair strongly encouraged the MSs to disseminate the information about the eHDSI to their respective citizens and healthcare professionals.
- The Chair stressed that the Commission services will continue to work with the MSs in their efforts to enable the Directive to deliver fully on its potential for the benefit of all EU citizens.

2. 2018 collection of data on patient mobility

- The Chair thanked MSs that have already submitted data and urged the remaining MSs to intensify their efforts to collect data and submit it by **8 November**. The Commission will continue to seek solutions with those Member States who are not in a position to reply to ensure a comprehensive picture of patient mobility in the EU.
- DG SANTE will start a reflection on how to further improve information on cross-border healthcare with a view to the Directive's evaluation in 2022/2023.
- The Chair welcomed in particular the closing paragraph of the draft Council Conclusions, encouraging Member States to assist the Commission by providing information that is

relevant for the preparation of the triennial reports, including on patient mobility and patient flows.

• It was agreed to organise a dedicated meeting with experts on data and information on cross-border healthcare in spring 2020, before the launch of the next data collection exercise. Members of the Cross-Border Healthcare Expert Group will be invited. Further details will be circulated in 2020.

3. Machine Translation

• The Chair noted that language differences remain a huge obstacle to cross-border cooperation – being an administrative burden to both patients and national administrations - and urged Member States to make maximum use of the eTranslation tool in their daily work.

4. EU actions to support better implementation

- The Chair noted that implementation issues were highlighted by the ECA, the European Parliament and the Commission's reports published last year on the operation of the Directive.
- The Chair concluded that there is sufficient interest among Member States to share experience and best practice and proposed the format of a 1 ¹/₂-day workshop to be hosted in a MS.
- DG SANTE noted the suggestions for a session at the workshop to present case studies of challenges encountered in implementing the Directive. Also noted the wish for a best practice based approach. Funding for the workshops would be considered by the Commission.
- DG SANTE would be willing to facilitate and organise these exchanges in cooperation with the MSs.
- DG SANTE will circulate Commission guidance note AC246/12 to the Expert Group.

5. Single Digital Gateway

- The Chair concluded that based on the survey conducted among NCPs earlier this year, most NCPs appear to already be compliant with the requirements of the SDG. However, there remains room for improvement in two key areas: a) the need for a user feedback mechanism, which DG GROW is currently developing and b) the need to publish estimated or average wait times for responses to standard queries and more details about what users should expect.
- DG SANTE will circulate the results of the survey in due course.

6. Regional Cooperation in Cross-Border Healthcare

- Participants were briefed about the work underway on the European Committee of the Regions "outlook opinion" on the implementation and future perspectives of cross-border healthcare, expected in May-June 2020.
- Member States were invited to support the resultant Joint Statement on Healthcare in Cross-Border Regions via the campaign website.

The Chair closed the meeting and thanked the participants and colleagues.

Annex I: List of participants

European Commission: DG SANTE B2

Andrzej Rys (Chair) Thea Emmerling Caroline Hager Balazs Lengyel Veronica Ann Miller Corina Vasilescu

Member States:

Austria	(Austrian Public Health Institute)
Belgium	(FPS Health, Institut national d'assurance maladie-invalidité)
Bulgaria	(Ministry of Health/Permanent Representation of Bulgaria to the EU)
Croatia	(Ministry of Health)
Cyprus	(Ministry of Health, Medical and Public Health Services)
Czech Republic	(Ministry of Health)
Denmark	(Ministry of Health)
Estonia	(Permanent Representation of Estonia to the EU)
Finland	(Ministry of Social Affairs and Health)
France	(Ministère de la sante)
Germany	(Deutsche Verbindungsstelle Krankenversicherung - Ausland)
Greece	Excused
Hungary	(Ministry of Human Capacities)
Ireland	(Department of Health, Health Service Executive)
Italy	(Ministry of Health)
Latvia	(National Health Service)
Lithuania	(Ministry of Health)

Luxembourg	(Permanent Representation of Luxembourg to the EU/ Ministry of Health, Caisse nationale de santé)
Malta	(Ministry of Health – Office of the Chief Medical Officer)
Poland	Excused
Portugal	(Administração Central do Sistema de Saúde, I.P.)
Romania	(National Health Insurance House)
Slovakia	(Ministry of Health)
Slovenia	(Ministry of Health)
Spain	(Ministry of Health, Consumer Affairs and Social Welfare)
Sweden	(National Board of Health and Welfare)
The Netherlands	(Ministry of Health, Welfare and Sport)
United Kingdom	(Excused)
Norway (observer)	(Ministry of Health and Care Services)