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DRAFT REPORT

on the implementation of the Cross-Border Healthcare Directive
(2018/2108(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Ivo Belet

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EXPLANATORY STATEMENT - SUMMARY OF FACTS AND FINDINGS

Procedure and sources

On 16 April 2018, the rapporteur was entrusted with the task of preparing an implementation report on the Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

The present report intends to analyse the current shortcomings in the implementation of the Directive and to make recommendations for the improvement of the Directive. The rapporteur therefore has organized meetings with stakeholders (see annex).

The rapporteur also invited stakeholders for a public hearing in the European Parliament on 17 October 2018.

Origin, structure and purpose of the Directive

According to Article 168(1) of the Treaty on the Functioning of the European Union (TFEU), in the definition and implementation of all Union policies and activities, a high level of human health protection is to be ensured whilst the organization, management, financing and delivery of healthcare remains the responsibility of the EU Member States.

Case law over the years has acknowledged that patients have, under specific conditions, the right to access healthcare in other Member States than their own.

The main purpose of the Directive is to originate an EU framework and set of rights to ensure the access of EU citizens to care abroad, with the intention to facilitate closer cooperation in a number of areas of medicine and healthcare such as eHealth and rare disease treatment.

The rights provided under the Directive exist in parallel to similar benefits provided under Regulation (EC) No 883/2004 on the coordination of social security systems. The Directive applies without prejudice to the Regulation. In practice, planned and unplanned care may often be provided more favourably under the Regulation. Accordingly, patients will choose to receive care in another Member State under the provisions of the Regulation rather than the Directive, because up-front payments and reimbursement claims afterwards are not necessary for unplanned care.

Following the logic of the cost-neutrality to national health systems of cross-border treatment of the Directive, it only covers the costs up to the level of the treatment in the home Member State; while the Regulation covers patient costs in full.

Nevertheless, particular aspects of healthcare abroad have improved significantly following the Directive. The Regulation only covers healthcare provided by public or contracted providers, while the Directive covers all healthcare providers in the EU. Moreover, the Directive should facilitate easier planned care abroad because in comparison to cross-border healthcare under the Regulation, prior authorisation is rather an exception than an obligation for planned care.

Implementation

As foreseen in the Directive, the transposition deadline was 25 October 2013. On the grounds of late or incomplete implementation, infringement procedures were launched against 26 Member States. Currently, all Member States notified their complete transposition measures.

The second phase of the compliance assessment by the European Commission is currently still ongoing. The main goal of the Commission is to assess whether all national legal acts and other measures comply with the Directive. In total, more than five hundred national measures were notified to the Commission. As a result of the own-initiative investigations gathering information for proper compliance, currently one infringement case remains open.

Funding

Funding for cross-border healthcare mainly comes from the second (2008-2013) and the third (2014-2020) Health Programmes which foresee a combined total of approximately 64 million euros per year for health-related issues. The Commission proposes that the funding continues under the European Social Fund Plus (ESF+) which will have, among its operational objectives, to support the implementation of Union legislation in the area of cross-border healthcare.

Next to this, the previous (FP7 & CIP) and the current (Horizon 2020) Research Framework Programmes, the European Regional Development Fund, the Cohesion Fund and InvestEU Fund also provide means for cross-border healthcare and eHealth projects.

Patient Mobility

Cross-border patient mobility is an important policy issue. Even though the levels of patient mobility currently are still relatively low, for certain groups of patients, due to rare diseases or due to geographical proximity of healthcare services, cross-border healthcare is the most appropriate and accessible care. The cross-border patient mobility brings along certain issues such as the continuity of care and the exchange of information between the health professionals on different sides of a border. Next to this, there are also logistical and administrative barriers, which can unintendedly affect the cross-border care for patients negatively.

Flows of patients travelling for healthcare after receiving prior authorisation is the most intense from France to Spain. Where authorisation was not required, the greatest flow was from France to Germany. Looking at the direction of patient flow, one significant trend that clearly emerges is that most mobility is across shared borders. There is however one significant exception, which is the number of patients travelling from Norway to Spain.

The Commission has identified four areas, which have the greatest potential to act as barriers to patients if left unaddressed: systems of reimbursement, use of prior authorisation, administrative requirements and charging of incoming patients.

Although the Member States are obliged, under Article 7 of the Directive, to notify the Commission of any decision to introduce limitations and some Member States have transposed in ways that could be considered as limiting, the Commission has received no specific notifications from the Member States.

Information to patients: National Contact Points

The Directive has a large potential to improve and facilitate patients' access to cross-border

healthcare and most importantly ensure the best quality of care for all patients. Nevertheless, for the Directive to succeed it is crucial that patients, health care professionals and other stakeholders are well informed about the Directive in all its aspects. Unfortunately, this is currently not the case.

The May 2015 Eurobarometer survey indicates that fewer than 20% of citizens feel well informed about their cross-border healthcare rights.

As foreseen in Article 6 of the Directive, each Member State has at least one National Contact Point (NCP) to provide patients and health professionals with information concerning their rights regarding a cross-border healthcare service or product.

Across the 29 NCPs in Europe, Norway and other EEA countries providing data, 74589 enquiries were made in 2017, but most Member States received fewer than 1,000 requests. The number of enquiries differs strongly between the different NCPs. Overall, patients are not aware of the existence of their national NCP. A broad and lasting information-campaign on NCP's and on patients' rights with regard cross-border care is vital.

It shows that in-depth information on patients' rights is generally lacking on the NCPs websites. Insight into what to do in case of undue delay, information on complaint procedures and settlement of dispute, as well as information on the duration to process reimbursement or prior authorisation requests is rather scarce.

European Reference Networks

In accordance with Article 12 of the Directive, the European Commission supports the Member States in the development of European Reference Networks (ERN) between healthcare providers and centres of expertise in the Member States.

On 1 March 2017, the first 24 European Reference Networks officially started their activities, based on the framework provided by the European Commission, driven by the involved healthcare providers and national health authorities. They aim to tackle complex or rare diseases, which require specialised treatment and knowledge. In total, the ERNs bring together more than 900 highly specialised healthcare units located in more than 300 hospitals across the EU, Norway and the EEA countries.

Given there are 5800 recognised rare diseases in the EU affecting approximately 6 - 8% of all European citizens only a small number of patients are affected by each rare disease. In combination with the scarcity of the relevant knowledge and expertise, EU-wide cooperation has a high added value potential.

eHealth

The objective of eHealth is to work towards sustainable economic and social benefits of European eHealth systems and services and interoperable applications, to achieve a high level of trust and security, to improve the continuity of care and to ensure access to safe and high-quality healthcare.

Maximizing the potential of eHealth in the EU enables health professionals to share patients' summaries and data across borders. The transferability of data will facilitate cross-border

healthcare with less barriers but is also crucial for further research, especially in the field of rare diseases.

Cross-border regional cooperation

Cross-border regions represent 40% of the territory of the EU and more than 1 in 3 Europeans live in a border region. In total, there are 37 cross border urban areas in Europe.

Cross-border healthcare initiatives in border regions have proven their worth over the years. The similarity of factors such as the geographical context, habits, culture, language and the political and administrative constellation have a large impact on the sustainability of the cooperation.

Brexit

Yearly an estimate of 1000 UK citizens are reimbursed for treatment in accordance with the Directive. France, Poland and Latvia are among the most popular destinations for treatment. In addition to the above number, the UK treats an estimate of 1500 EU patients under the Directive. Because not all Member States are able to present relevant patient mobility data to the Commission, in practice mobility to the UK is slightly larger than estimated. Next to this, around 40 UK National Health Service Hospitals are involved in the ERNs that have been established under the Directive.

MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on the implementation of the Cross-Border Healthcare Directive (2018/2108(INI))

The European Parliament,

– having regard to 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[1],

– having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168 thereof,

– having regard to Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems[2],

– having regard to Council Conclusions of 6 June 2011 on moving towards modern, responsive and sustainable health systems[3],

– having regard to the multi-annual health programmes for the periods 2003-2008[4], 2008-2013[5] and 2014-2020[6] respectively,

– having regard to the Commission's reports of 4 September 2015 and 21 September 2018 on the operation of the Cross-Border Healthcare Directive (COM(2015)0421, COM(2018)0651),

– having regard to the Commission's report of 18 July 2018 on Member State Data on cross-border patient healthcare in the year 2016[7],

– having regard to the Commission Implementing Decision No 2011/890/EU of 22 December 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth[8],

– having regard to the Commission communication of 6 May 2015 on a Digital Single Market Strategy for Europe (COM(2015)0192),

– having regard to the 2012-2020 eHealth Action Plan, in particular the explicit cross-border dimension (COM(2012)0736),

– having regard to the Commission's mid-term evaluation of the 2012-2020 eHealth

[1] OJ L 88, 4.4.2011, p. 45.
[2] OJ L 166, 30.4.2004, p. 1.
[3] OJ C 202, 8.7.2011, p. 10.
[4] Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), OJ L 271, 9.10.2002, p. 1.
[5] Decision No 1350/2207/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-2013), OJ L 301, 20.11.2007, p. 3.
[6] 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.
[7] https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2016_msdata_en.pdf
[8] OJ L 344, 28.12.2011, p. 48.

Action Plan (COM(2017)0586),

– having regard to the Commission communication of 11 November 2008 on rare diseases (COM(2008)0679) and the Council recommendation of 8 June 2009 on an action in the field of rare diseases[1],

– having regard to the Commission's implementation report of 5 September 2014 on its communication on rare diseases (COM(2014)0548),

– having regard to the Court of Auditors' background paper on cross-border healthcare in the EU of May 2018[2],

– having regard to the Commission communication of 20 September 2017 on boosting growth and cohesion in EU border regions (COM(2017)0534),

– having regard to the Interinstitutional Proclamation on the European Pillar of Social Rights[3],

– having regard to Rule 52 of its Rules of Procedure, as well as Article 1(1)(e) of, and Annex 3 to, the decision of the Conference of Presidents of 12 December 2002 on the procedure for granting authorisation to draw up own-initiative reports,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on the Internal Market and Consumer Protection (A8-0000/2018),

A. whereas health systems in the EU are crucial for ensuring a high level of social protection, social cohesion and social justice;

B. whereas Directive 2011/24/EU respects the freedom of each Member State to make the appropriate healthcare decisions and does not interfere with or undermine the fundamental ethical choices of the Member States;

C. whereas healthcare systems in the EU are facing challenges due to an ageing population and budgetary constraints;

D. whereas the healthcare that citizens need may sometimes be best provided in another Member State, on account of proximity, the specialised nature of care or a lack of capacity in their own Member State;

E. whereas the health sector is a vital part of the EU economy, amounting to 10 % of its GDP – a figure that could rise to 12.6 % by 2060;

F. whereas the directive provides a clear legal basis for European cooperation and collaboration with regard to health technology assessment (HTA), eHealth, rare diseases and the safety and quality standards of healthcare services and products;

[1] OJ C 151, 3.7.2009, p. 7.
[2] https://www.eca.europa.eu/Lists/ECADocuments/BP_CBH/BP_Cross-border_healthcare_EN.pdf
[3] OJ C 428, 13.12.2017, p. 10.

G. whereas the number of patients availing themselves of their right to cross-border care, as provided for under the directive, is growing, albeit very slowly;

H. whereas patient mobility in the EU remains relatively low and has not had a significant budgetary impact on the sustainability of the national health systems;

I. whereas the Member States are responsible for providing access to the healthcare that people require and for ensuring that the relevant costs are reimbursed; whereas the Member States' national healthcare services are responsible for setting the criteria permitting citizens to receive healthcare in another Member State;

J. whereas the role of the national contact points (NCPs) is to ensure that patients receive the correct information to make an informed decision;

K. whereas the efficiency and outreach of the NCPs depends on the support that they receive from both the EU and the Member States;

L. whereas there are large variations between the various NCPs with regard to the functioning, visibility and allocation of resources;

M. whereas the directive will only be effective if patients, healthcare professionals and other stakeholders are well informed about it;

N. whereas patients and healthcare professionals are still encountering a large information gap regarding patients' rights under the directive;

O. whereas there is considerable room for improvement in the reimbursement procedures in a number of Member States;

P. whereas six Member States and Norway currently have no prior authorisation systems in place at all, giving patients the freedom to choose and reducing administrative burdens;

Q. whereas there are a number of bilateral agreements between neighbouring Member States and regions that could serve as a basis for excellent best practices to further develop EU-wide cross-border healthcare;

Implementation

1. Welcomes the actions taken by the Commission to assess whether Member States have transposed the directive correctly;

2. Invites the Commission to proceed with its triennial evaluation reports on the operation of the directive and to submit them to Parliament and the Council accordingly;

3. Reminds the Member States of their commitment to provide the Commission with assistance and all the requisite information at their disposal, for the purposes of carrying out its assessment and preparing the aforesaid reports;

4. Stresses that the Member States should transpose the directive correctly in order to ensure the highest level of quality and secure easily accessible cross-border healthcare

for patients;

Funding

5. Expresses serious concern about the proposed reduction in funding for the health programme; reiterates its call for the health programme to be restored as a robust stand-alone programme with increased funding in the next multiannual financial framework (MFF) (2021-2027), in order to implement the UN Sustainable Development Goals (SDGs) on public health, health systems and environment-related problems, and ensure an ambitious health policy with a focus on cross-border challenges, including, in particular, a considerable increase in common EU efforts in the fight against cancer, the prevention of chronic and rare diseases, combating anti-microbial resistance and ensuring easier access to cross-border healthcare;

Patient mobility

6. Notes that the reasons for low patient mobility are threefold: i) some Member States were quite late implementing the directive; ii) citizens' awareness about their general rights to reimbursement is extremely low and iii) Member States have transposed the directive in ways that could be construed as limiting cross-border healthcare;

7. Asks the Commission to continue the structured dialogues with Member States, providing greater clarity regarding prior authorisation requirements;

8. Reminds the Member States that any limitation on the application of the rules on reimbursement for cross-border healthcare should be necessary and proportionate and should not give rise to arbitrary discrimination or unjustified obstacles to the free movement of patients and services;

9. Urges the Member States to notify the Commission of any decision to introduce limitations regarding reimbursement of costs under Article 7(9) of the directive;

10. Regrets the fact that some Member States grant lower levels of reimbursement for cross-border healthcare supplied by private or non-contracted healthcare providers on their own territories than for that supplied by public or contracted healthcare providers;

11. Asks the Commission and the Member States to work together to assess, realign and drastically simplify reimbursement procedures for patients receiving cross-border care, and to install a one-stop-shop front office;

12. Calls on the Commission to ensure that the rules regarding reimbursement under Article 7(1) and Article 4(1) also apply to health services provided remotely (telemedicine);

Border regions

13. Encourages the Member States and border regions to deepen cross-border healthcare cooperation, in an efficient and financially sustainable manner, in order to secure the best possible care for patients; asks the Commission to support and stimulate a structural exchange of best practices among border regions;

14. Welcomes the Commission's proposal to enhance the cohesion between border regions by addressing some of the legal and administrative barriers that they face through the creation of an EU cross-border mechanism;

Information for patients

15. Calls on the Commission and the Member States to invest further in the development of highly accessible and clearly visible NCPs which provide user-friendly information for patients and health professionals;

16. Recommends that the Commission develop guidelines on the functioning of the NCPs and further facilitate and improve the structural exchange of information and practices between them;

17. Calls on the Member States to provide sufficient funding for their NCPs to be able to develop comprehensive information, and asks the Commission to intensify cooperation between the NCPs across the Union;

18. Asks the Commission to clarify, for the benefit of national experts and by means of information campaigns, the complexity of the current legal situation deriving from the interaction between the directive and the regulations governing social security coordination;

19. Asks the Commission to organise, in conjunction with the competent national authorities, NCPs, patient organisations and networks of healthcare professionals, information campaigns designed to foster structural awareness of patients' rights under the directive;

Rare diseases and European Reference Networks (ERNs)

20. Stresses the importance of EU-wide cooperation in ensuring the efficient pooling of knowledge and resources to tackle rare diseases effectively across the EU;

21. Encourages the steps already taken to increase public awareness and understanding of rare diseases and to increase funding for R&D;

22. Proposes that the Commission should open a fresh call for the development of new ERNs and should continue to support the development and scaling up of the ERN model;

23. Regrets the uncertainty surrounding the operating principles of the ERNs and their interaction with national healthcare systems and other EU programmes; asks the Commission, therefore, to support the Member States and ERNs in establishing clear and transparent rules for patient referral and to reach an agreement on the form of support to be provided by the Member States to the ERNs;

24. Urges the Commission to implement an action plan for the further development and financing of the ERNs, via the European Joint Programme on Rare Diseases;

Mutual recognition of (e-)prescriptions

25. Regrets the difficulties faced by patients in securing access to and reimbursement for medicines in other Member States, owing to differing availabilities and rules across the EU;

26. Suggests that prescriptions issued by ERN-linked centres of expertise should be accepted for reimbursement in all Member States; calls on the Commission to take a legislative initiative in this regard;

27. Welcomes the support from the Connecting Europe Facility (CEF) as part of efforts to ensure that current pilot projects on the exchange of e-prescriptions and patient summaries are successfully developed and pave the way for other Member States to follow by 2020;

EHealth

28 Acknowledges that eHealth can help to ensure that health systems are sustainable and can be an important part of the EU's response to the healthcare challenges of today;

29. Welcomes the creation of the EU-wide eHealth Digital Service Infrastructure (eHDSI), which will foster the cross-border exchange of health data, specifically e-prescriptions and patient summaries;

30. Urges the Member States to take swift action to connect their health systems to the eHDSI through a dedicated NCP for eHealth, and asks the Commission to facilitate this process;

Brexit

31. Asks the Commission to negotiate a solid agreement with post-Brexit UK on health, devoting specific attention to cross-border rights for patients and the functioning of the ERNs;

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32. Calls on the Member States to implement, properly and in full cooperation with the Commission, all provisions of the directive;

33. Instructs its President to forward this resolution to the Council and the Commission.

ANNEX: LIST OF ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

The following list is drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the report, until the adoption thereof in committee:

Entity and/or person
BEUC:
Jelena Malinina
Francesca Cattarin
European Patients Forum:
Kaisa Immonen
Kostas Aligiannis
Christelijke Mutualiteit:
Michael Callens
Bernard Debbaut
Agnès Chapelle
International Association of Mutual Benefit Societies
Corinna Hartrampf
Department eHealth of the Dutch Ministry of Health:
Marcel Floor
European Hospital and Healthcare Federation:
Pascal Garel
European Court of Auditors:
Janusz Wojciechowski
Kinga Wisniewska-Danek
Nicholas Edwards
Colm Friel
Joanna Kokot
European Commission, DG SANTE:
Thea Emmerling
Balasz Lengyel
Brian Kilgallen
Antti Maunu
Corina Vasilescu
Andrzej Jan Rys
Marie-Sophie Wenzel
Lim Roger