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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 (TFEU), 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 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)[3],

– having regard to Council Conclusions of 6 June 2011 on moving towards modern, responsive and sustainable health systems[4],

– having regard to the multi-annual health programmes for the periods 2003-2008[5], 2008-2013[6] and 2014-2020[7] 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 communication of 25 April 2018 on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM(2018)0233),

– having regard to the Commission's report of 18 July 2018 on Member State Data on cross-border patient healthcare in the year 2016[8],

– having regard to the Commission Implementing Decision No 2011/890/EU of 22

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[1] OJ L 88, 4.4.2011, p. 45.
[2] OJ L 166, 30.4.2004, p. 1.
[3] OJ L 119, 4.5.2016, p. 1.
[4] OJ C 202, 8.7.2011, p. 10.
[5] 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.
[6] 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.
[7] 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.
[8] https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2016_msdata_en.pdf

December 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth[1],

– 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 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[2] ,

– 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 Recommendations on Rare Disease European Reference Networks of the EU Committee of Experts on Rare Diseases (EUCERD) of 31 January 2013 and the addendum thereto of 10 June 2015,

– having regard to the Court of Auditors' background paper on cross-border healthcare in the EU of May 2018[3],

– 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[4],

– 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 (A8-0046/2019),

A. whereas affordable-to-all health systems in the EU and its Member States are crucial for ensuring a high level of public health, social protection, social cohesion and social justice, by preserving and guaranteeing universal access, and whereas quality of life for patients is recognised as an important component of healthcare cost-efficiency assessment;

[1] OJ L 344, 28.12.2011, p. 48.
[2] OJ C 151, 3.7.2009, p. 7.
[3] https://www.eca.europa.eu/Lists/ECADocuments/BP_CBH/BP_Cross-border_healthcare_EN.pdf
[4] OJ C 428, 13.12.2017, p. 10.

B. whereas Directive 2011/24/EU (hereinafter 'the directive'), in accordance with Article 168(7) TFEU, 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 relevant authorities within the Member States; whereas there are differences in the respective services provided by the Member States as well as in the way they are funded; whereas the directive provides other healthcare options to European citizens in addition to those available in their own country;

C. whereas health can be regarded as a fundamental right under Articles 2 (on the right to life) and 35 (on healthcare) of the Charter of Fundamental Rights of the European Union;

D. whereas healthcare systems in the EU are facing challenges due to an ageing population, budgetary constraints, the increasing incidence of chronic and rare diseases, difficulties in ensuring basic healthcare in rural areas and the high prices of medicines; whereas Member States are responsible for developing, keeping and exchanging across borders information on an updated catalogue of medicine shortages to ensure the availability of essential medicines;

E. whereas the healthcare that citizens need may sometimes be best provided in another Member State, on account of proximity, ease of access, the specialised nature of care or a lack of capacity, such as a shortage of essential medicines, in their own Member State;

F. whereas the results of the report on the operation of the directive show that in 2015, not all Member States implemented the directive completely or correctly;

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

H. whereas, pursuant to Article 20 of the directive, the Commission has the obligation to present an implementation report on the directive's operation every three years; whereas the Commission should constantly assess and regularly present information on patient flows, on the administrative, social and financial dimensions of patient mobility and on the functioning of the European Reference Networks (ERNs) and national contact points;

I. whereas, according to the Commission report of 21 September 2018 on the operation of the directive, it remains difficult for citizens to find out how they can use their rights in terms of cross-border healthcare; whereas further clarity and transparency is needed on the conditions under which healthcare providers operate in order to secure safe patient mobility;

J. whereas the Commission communication on e-health of 25 April 2018 notes that health and care systems require reforms and innovative solutions in order to become more resilient, accessible and effective; whereas therefore the use of new technologies and digital tools should be strengthened to improve the quality and sustainability of healthcare services;

K. 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;

L. whereas EU citizens have the right to access specialised care in their own Member State; whereas, however, the number of patients availing themselves of their right to cross-border care, as provided for under the directive, including preventive medical tests, scans and health checks, is only growing very slowly;

M. whereas vaccination programmes are not covered by the directive, even though they count among the EU's most effective policies, and bearing in mind the difficulties people in certain Member States encounter in accessing them;

N. whereas not all Member States were able to supply data or information regarding patients travelling abroad, and whereas data collection is not always comparable from one Member State to another;

O. whereas 83 % of people surveyed in a recent Commission consultation endorsed the disclosure of medical data for the purposes of conducting research and improving patients' health conditions[1]; whereas any future integration of health systems must, from a digital point of view, guarantee that the health systems and patients are the ultimate custodians and managers of the information concerned, so as to guarantee fairness, sustainability and safety for patients;

P. whereas patient mobility in the EU covered by the scope of the directive remains relatively low, and has not had a significant budgetary impact on the sustainability of the national health systems;

Q. whereas the Member States are responsible for providing access to the healthcare that people require and for ensuring that all 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; whereas in a considerable number of Member States, the obstacles that patients encounter when dealing with health systems remain significant; whereas administrative burdens could create delays to reimbursements; whereas this only deepens the fragmentation of access to services, and should therefore be improved through coordination between Member States;

R. whereas the European Health Insurance Card (EHIC) is regulated by the regulation on the coordination of social security systems, and its implementation varies widely across the Member States; whereas a uniform implementation of the EHIC and greater coordination between the Member States is essential for reducing the existing administrative burdens and for guaranteeing swift, discrimination-free reimbursement for patients, while guaranteeing freedom of movement for EU citizens;

S. whereas patients still encounter practical and legal difficulties when using medical prescriptions across Member States;

T. whereas the role of the national contact points (NCPs) is to ensure that patients receive

[1] Commission synopsis report on its consultation entitled 'Transformation Health and Care in the Digital Single Market', 2018, https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018_consultation_dsm_en.pdf

the correct information to make an informed decision;

U. whereas NCPs are not yet sufficiently well known to the public, which has an impact on their effectiveness; whereas the efficiency and outreach of the NCPs depend on the support that they receive from both the EU and the Member States, on communication channels, the exchange of good practices and information, including contact information, and guidelines for patient referral;

V. whereas there are large variations between the various NCPs with regard to the functioning, accessibility, visibility and allocation of resources, in terms of both quality and quantity;

W. whereas according to a Eurobarometer Survey from May 2015[1], patients are not sufficiently informed of their cross-border healthcare rights, with fewer than 20 % of citizens feeling well informed;

X. whereas cross-border healthcare will only be effective if patients, caregivers, healthcare professionals and other stakeholders are well informed about it and the rules governing it are readily available and generally accessible;

Y. whereas patients, caregivers and healthcare professionals are still encountering a large information gap regarding patients' rights in general, and especially those under the directive;

Z. whereas healthcare professionals deal with some highly sensitive patient issues, which require clear and comprehensible communication; whereas language barriers could hinder the transfer of information between healthcare professionals and their patients;

AA. whereas there is considerable room for improving and simplifying the reimbursement procedures in a number of Member States, particularly with regard to prescriptions, orphan drugs, pharmaceutically compounded medicinal products and follow-up therapy and procedures;

AB. 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;

AC. 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. Notes the benefits of the directive in clarifying the rules on cross-border healthcare and in ensuring access to safe and high-quality cross-border healthcare in the Union, as well as for achieving patient mobility in accordance with the case-law of the Court of

[1] Special Eurobarometer 425: Patients' rights in cross-border healthcare in the European Union.

Justice; expresses disappointment that a significant number of Member States have not effectively implemented the requirements for guaranteeing patients' rights; urges Member States therefore to ensure its proper implementation, guaranteeing a high level of public health protection that contributes to the improvement of citizens' health, while respecting the principle of the free movement of persons within the internal market;

3. 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; highlights the importance of collecting information, for statistical purposes, about patients travelling abroad for treatment and of analysing the reasons why patients move between countries; calls on the Commission, furthermore, to publish, where feasible and on an annual basis, breakdowns of the services provided and total amounts reimbursed by each Member State as cross-border healthcare provision;

4. Invites the Commission to factor patient quality of life and care outcomes into its evaluation of the cost-efficiency of the implementation of the directive;

5. 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;

6. Invites the Commission to establish guidelines for implementation, especially on those areas where the directive and the regulation on the coordination of social security systems interact, and to ensure better coordination, in that regard, amongst all the relevant stakeholders within the institutions;

7. Stresses that the Member States should transpose the directive correctly in order to ensure high-quality and accessible cross-border healthcare for patients, in full compliance with the implementation deadlines laid down in the legislation; recognises that specific improvements can be made with regard to access to prescribed medicines and continuity of treatment; calls on the Commission to explore the possibility of expanding the scope of the directive to include vaccination programmes;

8. Notes with satisfaction the positive impact of initiatives such as the EHIC, which is issued free of charge and allows anyone who is insured by or covered by a statutory social security scheme to receive medical treatment in another Member State free or at a reduced cost; stresses the importance of successful cooperation between institutions in order to avoid misuse of the EHIC;

9. Stresses the need to ensure clarity and transparency regarding the conditions under which healthcare providers operate; underlines the importance of healthcare providers and professionals having professional civil liability insurance, as provided for in the directive as well as in Directive 2005/36/EC, in order to improve the quality of health services and increase patient protection;

Funding

10. Points out that the funding of cross-border healthcare is a matter for the Member States, which reimburse costs in accordance with the relevant regulations; points out, furthermore, that the Commission supports the cooperation referred to in Chapter IV of

the directive via health programmes;

11. Expresses serious concern, in this regard, 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, early detection and management of chronic and rare diseases, including genetic and pandemic diseases and rare cancers, in combating anti-microbial resistance and in ensuring easier access to cross-border healthcare;

12. Stresses the importance of the European Social Fund, the European Structural and Investment Fund for health and the European Regional Development Fund, including the Interreg Programme, for improving health services and reducing health inequalities between regions and social groups across Member States; requests that structural and cohesion funds also be used to improve and facilitate cross-border healthcare in the next MFF;

Patient mobility

13. Notes that the reasons for low patient mobility are fourfold: i) some Member States were quite late implementing the directive; ii) citizens' awareness about their general rights to reimbursement is extremely low, iii) certain barriers limiting cross-border healthcare, such as administrative burdens, have been erected by some Member States, and iv) information on patients seeking healthcare in another Member State on the basis of the directive is missing or incomplete;

14. Notes that certain prior authorisation systems appear to be unduly burdensome and/or restrictive with regard to the number of applications each year; asks the Commission to continue the structured dialogues with Member States, providing greater clarity regarding prior authorisation requirements and the associated conditions for reimbursement;

15. Asks the Commission to develop guidelines for the Member States in order to enable people, should prior authorisation be established, to compare treatment abroad with that available in their own Member State, with cost effectivity for patients as the guiding principle;

16. Reminds the Member States that any limitation on the application of the directive, such as prior authorisation requirements or limitations on reimbursement, should be necessary and proportionate and not give rise to arbitrary or social discrimination, must not put up unjustified obstacles to the free movement of patients and services, nor should it place an excessive burden on national public health systems; calls on Member States to take into consideration the difficulties faced by low-income patients who have to pay for cross-border treatment in advance; notes that prior authorisation systems are intended to allow for Member State planning and protect patients from treatments that raise serious and specific concerns about the quality or safety of care;

17. Notes with concern that in some Member States insurance companies have discriminated arbitrarily or created unjustified obstacles to the free movement of patients and services, with adverse financial consequences for patients;

18. 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, giving their reasons for doing so;

19. Regrets the fact that some Member States on occasion grant lower levels of reimbursement for cross-border healthcare supplied by private or non-contracted healthcare providers on their own territories than for cross-border healthcare supplied by public or contracted healthcare providers; considers that reimbursement for private healthcare at the same level as public healthcare should be guaranteed, provided that the quality and safety of care can be ensured;

20. Asks the Commission and the Member States to work together to assess, realign and simplify reimbursement procedures for patients receiving cross-border care, including by clarifying the reimbursement of follow-up care and procedures, and to set up coordinating one-stop-shop front offices at the relevant healthcare insurers;

21. Regrets the fact that application of the directive with regard to telemedicine – health services provided remotely – has led to a certain lack of clarity concerning reimbursement schemes, as some Member States do reimburse or provide consultation with general or specialised practitioners at a distance, while others do not; calls on the Commission to support the uptake of the reimbursement rules, in accordance with Articles 7(1) and 4(1), so that they also apply to telemedicine, where appropriate; encourages the Member States to align their approaches to the reimbursement of telemedicine;

Border regions

22. Encourages the Member States and border regions to deepen cross-border healthcare cooperation, in an efficient and financially sustainable manner, including by providing accessible, sufficient and understandable information, 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; encourages the Member States to use these best practices to also improve healthcare in other regions;

23. 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

24. Recalls the essential role of NCPs in providing information to patients and helping them to make an informed decision about seeking healthcare abroad in the EU; calls on the Commission and the Member States to invest further in the development and promotion of accessible and clearly visible NCPs and eHealth platforms for patients, which should provide user-friendly, digitally accessible and barrier-free information for patients and health professionals in multiple languages;

25. Recommends that the Commission, in conjunction with patient organisations, develop guidelines on the functioning of the NCPs in order to further facilitate and significantly improve the ways in which they systematically exchange information and practices, with the aim of producing harmonised, simplified and patient-friendly procedures, forms or manuals, and establishing a link between NCPs and the sources of information and expertise available in the Member States;

26. 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 among the NCPs across the Union;

27. Stresses the potential of eHealth to improve patients' access to information on the possibilities of cross-border healthcare and on their rights under the directive;

28. Calls on the Member States to urge healthcare providers and hospitals to supply patients, in advance, with an accurate and up-to-date estimate of the cost of treatment abroad, including medicine, honoraria, overnight stays and supplementary fees;

29. 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 regulation on social security coordination;

30. Asks the Commission to organise, in conjunction with the competent national authorities, NCPs, ERNs, patient organisations and networks of healthcare professionals, comprehensive public information campaigns, including by tapping into new digital opportunities, which should be designed to foster structural awareness of patients' rights and obligations under the directive;

31. Calls on the Commission to encourage the Member States to make information easily accessible on the procedures through which patients can file complaints in cases where their rights under the directive have not been respected or have even been violated;

32. Recommends that the Commission develop guidelines on the type of information the NCPs should be providing, especially the list of treatments which are or are not subject to prior authorisation, the criteria applied and the procedures in force;

33. Calls on the Commission and the Member States to assess the need to identify the reasons for granting access to cross-border healthcare in a way that guarantees free movement, but without healthcare being an end in itself as long as the organisation of health systems is a national competence;

34. Encourages the Commission to promote increased cooperation between Member States' authorities in general, and not only through the NCPs, and to assess further the benefits of existing initiatives for cooperation, especially in cross-border regions, guaranteeing access to safe, high quality and efficient healthcare for citizens;

Rare diseases, rare cancers and European Reference Networks (ERNs)

35. Stresses the importance of EU-wide cooperation in ensuring the efficient pooling of knowledge, information and resources to tackle rare and chronic diseases, including rare

cancers, effectively across the EU; encourages the Commission, in that regard, to support the setting up of specialised centres for rare diseases in the EU, which should be fully integrated into the ERNs;

36. Recommends building on the steps already taken to increase public awareness and understanding of rare diseases and rare cancers and to increase funding for R&D; asks the Commission to further guarantee access to information, medicine and medical treatment for patients with rare diseases throughout the EU, and to strive for improved access to early and accurate diagnosis; urges the Commission to address the low registration rate of rare diseases and to further develop and promote common standards for sharing and exchanging data in rare disease registries;

37. Stresses the critical need to improve patient adherence models, which should be based on the most reliable findings from meta-analyses and large-scale empirical studies, and should reflect the realities of medical practice and offer recommendations for making patients more dedicated to their treatment, particularly when it comes to the management of chronic diseases – a key barometer for measuring the efficiency and effectiveness of healthcare systems;

38. Underlines the importance and added value of EU-wide mobility of healthcare professionals, during both their education and professional careers, and of their particular role in improving knowledge and expertise on rare diseases;

39. Proposes that the Commission should open a fresh call for the development of new ERNs and continue to support the development and scaling up of the ERN model, in order to overcome geographical differences and gaps in expertise; stresses, however, that any extension of ERNs must not undermine the operation of existing ERNs during their initial phase;

40. 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;

41. Urges the Commission to implement an action plan, through the European Joint Programme on Rare Diseases, for the further sustainable development and financing of the ERNs and the patient networks supporting them; encourages the Member States to support the healthcare providers within the ERNs and to integrate ERNs into their healthcare systems, adapting their legal and regulatory frameworks and referring to the ERNs in their national plans on rare diseases and on cancer;

Mutual recognition of (e-)prescriptions

42. Regrets the difficulties faced by patients, especially those in border areas, in securing access to and reimbursement for medicines in other Member States, owing to differing availabilities and administrative rules across the EU; calls on the Member States and their respective health authorities to address the legal and practical issues that are hindering the mutual recognition of medical prescriptions across the EU, and urges the Commission to take supportive action in this regard;

43. 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;

44. Calls on the Commission to draw up an action plan to systematically address excessively high medicine prices and the great disparities in them between the various Member States;

45. Calls on the Commission to take steps to ensure that prescriptions issued by ERN-linked centres of expertise are accepted for reimbursement in all Member States;

46. Welcomes the support from the Connecting Europe Facility (CEF) as part of efforts to successfully develop current pilot projects on the exchange of e-prescriptions and patient summaries and pave the way for other Member States to follow by 2020; insists that this support be continued in the next MFF;

EHealth

47. Acknowledges that eHealth can help to ensure that health systems are sustainable, by reducing certain costs, and can be an important part of the EU's response to the healthcare challenges of today; emphasises that the interoperability of eHealth should be made a priority, in order to improve global patient records and continuity of care, while guaranteeing patient privacy; considers that special attention should be devoted to granting all patients, not least elderly and disabled persons, easy access to care; suggests, in this regard, that the Member States take steps to invest in citizens' digital literacy and to scale up new solutions for the ageing population, while using all means at their disposal to ensure that exclusion through digitalisation shall be prevented;

48. 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;

49. Invites the Member States to take swift action to connect their health systems to the eHDSI through a dedicated NCP for eHealth, in line with their own risk assessments, and asks the Commission to facilitate this process;

50. Calls on the Commission to address the digital health needs in the Member States as a matter of priority; welcomes the Commission's support for putting sustained financial resources towards ensuring strong national digital health strategies and creating a suitable framework for common actions at EU level in order to prevent efforts from being duplicated and ensure the exchange of best practices for a more widespread use of digital technology in the Member States;

51. Asks the Member States to further intensify cooperation across Europe between their health authorities, in order to connect eHealth data and personal records with ePrescription tools, so as to enable health care professionals to deliver personalised and well-informed care to their patients and foster cooperation among doctors, while fully respecting EU data protection legislation in this regard; calls on the Commission to take action to facilitate such endeavours;

52. Calls on the Member States to swiftly implement the General Data Protection Regulation (GDPR) in order to safeguard patient data used in eHealth applications and underlines the importance, with particular regard to health, of monitoring the implementation of Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions in the internal market[1]; stresses the need to enable citizens to access and use their own health data, in accordance with the principles laid down in the GDPR;

Brexit

53. 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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54. Welcomes the intention of the European Court of Auditors to conduct an audit on the effectiveness of the implementation of the directive, and to examine in particular 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 as regards the action funded;

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

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

[1] OJ L 257, 28.8.2014, p. 73.

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

23.11.2018

OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur for opinion: Maria Grapini

(*) Associated committee – Rule 54 of the Rules of Procedure

SUGGESTIONS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions into its motion for a resolution:

– having regard to Articles 114 and 168 of the Treaty on the Functioning of the European Union (TFEU),

– 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 report from the Commission of 21 September 2018 on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COM(2018)0651),

– having regard to the Commission communication of 25 April 2018 on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM(2018)0233),

A. whereas, pursuant to Article 20 of Directive 2011/24/EU, the Commission has the obligation to present an implementation report on the operation of that directive every three years; whereas the Commission should constantly assess and regularly present information on patient flows, on the administrative, social and financial dimensions of patient mobility and on the functioning of the European reference networks and national

[1] OJ L 88, 4.4.2011, p. 45.

contact points;

B. whereas on 21 September 2018 the Commission presented a report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, showing that a large number of Member States have not properly implemented the Directive; whereas the obstacles placed in the way of patients by health systems are significant and further contribute to the fragmentation of access to healthcare services;

C. whereas, according to a 2015 Eurobarometer survey, fewer than 20 % of citizens were aware of their rights regarding cross-border healthcare; whereas there has been little change in the level of awareness since 2015, as demonstrated by the slow increase in the number of citizens travelling to receive care;

D. whereas, according to the Commission report of 21 September 2018 on the operation of Directive 2011/24/EU, it remains difficult for citizens to find out how they can use their rights in terms of cross-border healthcare; whereas further clarity and transparency is needed on the conditions under which healthcare providers operate in order to secure safe patient mobility;

E. whereas the Commission communication on e-health of 25 April 2018 notes that health and care systems require reforms and innovative solutions in order to become more resilient, accessible and effective; whereas therefore the use of new technologies and digital tools should be strengthened to improve the quality and sustainability of healthcare services;

1. Notes the benefits of Directive 2011/24/EU in clarifying the rules on cross-border healthcare and in ensuring access to safe and high-quality cross-border healthcare in the Union, as well as for achieving patient mobility in accordance with the case-law of the Court of Justice; expresses disappointment that a significant number of Member States have not effectively implemented the requirements for guaranteeing patients' rights; urges Member States therefore to ensure its proper implementation, guaranteeing a high level of public health protection that contributes to the improvement of citizens' health, while respecting the principle of the free movement of persons within the internal market;

2. Stresses the need to ensure clarity and transparency regarding the conditions under which healthcare providers operate; underlines the importance of healthcare providers and professionals having professional civil liability insurance, as provided for in Directives 2005/36/EC and 2011/24/EU, in order to improve the quality of health services and to increase patient protection;

3. Calls on the Commission and the Member States to put in place or to enhance an appropriate complaint mechanism for patients seeking treatment abroad, should their rights not have been respected;

4. Calls on Member States to make the reimbursement of costs for cross-border healthcare much simpler and to avoid undue delays or unnecessary and disproportionate limitations; encourages national authorities not to apply burdensome requirements such as the provision of unnecessary additional documents accompanied by certified translations;

5. Believes it is essential for the smooth functioning of the internal market to address future challenges, and underlines that digitalisation could bring added value to the implementation of the Directive; encourages the Commission and the Member States to focus on developments in the field of digital healthcare and to look into new initiatives, such as electronic invoices, electronic prescription or interoperable and properly functioning eHealth solutions, that could ensure smooth patient mobility, while guaranteeing effective personal data protection through appropriate security and privacy requirements; urges the Commission and the Member States to address remaining issues concerning the mutual recognition of medical prescriptions between Member States, as well as the lack of clarity concerning the reimbursement of telemedicine in which medical consultations are provided from a distance;

6. Underlines that citizens, and in particular patients, as well as healthcare professionals providing services abroad, either experience difficulties in finding and understanding information on the applicable rules and procedures in other Member States, or are unaware of their rights; stresses the importance of the availability of comprehensive, easily accessible and user-friendly information to patients about their rights and the procedures, costs and reimbursement rates in cross-border healthcare within the framework of Directive 2011/24/EU;

7. Calls on the Commission and the Member States to take measures to increase patients' awareness about their rights, and in particular to inform patients, in cooperation with patient organisations, on the complex practical and legal aspects of medical information in an easily understandable way, including by developing guidelines on step-by-step procedures for using cross-border healthcare services and by providing standardised templates for all types of forms required in cross-border healthcare;

8. Highlights in this regard the key role of National Contact Points (NCPs) in providing information to patients and professionals on their rights, and on procedures, costs and reimbursements, in order to help them take well-informed decisions on whether to seek treatment, or whether to provide a service, at home or abroad and thus save time and costs; recognises the importance of providing detailed information on complaint procedures and the settlement of disputes by electronic means through the NCPs; calls therefore for the allocation of appropriate resources in order to ensure the proper functioning of the NCPs and to promote regular exchange of information between them;

9. Encourages the Commission to promote increased cooperation between Member States' authorities in general, and not only through the NCPs, and to assess further the benefits of existing initiatives for cooperation, especially in cross-border regions, guaranteeing access to safe, high quality and efficient healthcare for citizens;

10. Notes with satisfaction the positive impact of initiatives such as the European Health Insurance Card (EHIC), which is issued free of charge and allows anyone who is insured by or covered by a statutory social security scheme to receive medical treatment in another Member State free or at a reduced cost; stresses the importance of successful cooperation between institutions in order to avoid misuse of the EHIC;

11. Regrets that patient mobility for planned healthcare, and especially specialised care, in other Member States remains low due to the lack of clarity for patients in a number of Member States as regards treatments subject to prior authorisation and involving an

‘overnight stay’ and ‘highly specialised care’; urges Member States to clarify and simplify the regimes for prior authorisation and recalls that any system of prior authorisation must be non-discriminatory, justified and proportionate to the objective pursued, and may not constitute an unjustified obstacle to the free movement of patients, leading to patients suffering from health inequalities between different Member States being unable to access much-needed specialist treatment in other Member States;

12. Highlights the importance of relying on comparable data for monitoring the implementation of the Directive; notes that the collection of data varies significantly from one Member State to another; calls on the Commission to establish and make publicly available benchmarks and key indicators for the quality of healthcare and patient mobility in order to allow for better comparisons between Member States;

13. Welcomes the intention of the European Court of Auditors to conduct an audit on the effectiveness of the implementation of the Directive, and to examine in particular 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 as regards the action funded;

14. Points out that, pursuant to Article 20 of Directive 2011/24/EU, the Commission is obliged to draw up a report on the operation of this Directive every three years; urges the Commission, however, to constantly monitor the performance and the efficiency of healthcare systems, including by undertaking a mapping exercise of patients’ rights across the Union, in order to support the implementation and enforcement of these rights, and to report regularly to Parliament thereon.

INFORMATION ON ADOPTION IN COMMITTEE ASKED FOR OPINION

Date adopted	22.11.2018
Result of final vote	+: 27 –: 2 0: 1
Members present for the final vote	Carlos Coelho, Sergio Gaetano Cofferati, Daniel Dalton, Nicola Danti, Dennis de Jong, Evelyne Gebhardt, Maria Grapini, Robert Jarosław Iwaszkiewicz, Liisa Jaakonsaari, Philippe Juvin, Antonio López-Istúriz White, Morten Løkkegaard, Eva Maydell, Virginie Rozière, Christel Schaldemose, Olga Sehnalová, Jasenko Selimovic, Ivan Štefanec, Catherine Stihler, Anneleen Van Bossuyt, Marco Zullo
Substitutes present for the final vote	Julia Reda, Adam Szejnfeld, Sabine Verheyen
Substitutes under Rule 200(2) present for the final vote	Salvatore Cicu, Mady Delvaux, Czesław Hoc, Jean Lambert, Juan Fernando López Aguilar, Anne-Marie Mineur

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

27	+
ALDE	Morten Løkkegaard, Jasenko Selimovic
ECR	Daniel Dalton, Czesław Hoc, Anneleen Van Bossuyt
EFDD	Marco Zullo
PPE	Salvatore Cicu, Carlos Coelho, Philippe Juvin, Antonio López-Istúriz White, Eva Maydell, Ivan Štefanec, Adam Szejnfeld, Sabine Verheyen
S&D	Sergio Gaetano Cofferati, Nicola Danti, Mady Delvaux, Evelyne Gebhardt, Maria Grapini, Liisa Jaakonsaari, Juan Fernando López Aguilar, Virginie Rozière, Christel Schaldemose, Olga Sehnalová, Catherine Stihler
Verts/ALE	Jean Lambert, Julia Reda

2	-
GUE/NGL	Anne-Marie Mineur, Dennis de Jong

1	0
EFDD	Robert Jarosław Iwaszkiewicz

Key to symbols:
+ : in favour
- : against
0 : abstention

INFORMATION ON ADOPTION IN COMMITTEE RESPONSIBLE

Date adopted	22.1.2019
Result of final vote	+: 55 –: 0 0: 3
Members present for the final vote	Margrete Auken, Pilar Ayuso, Catherine Bearder, Ivo Belet, Simona Bonafè, Biljana Borzan, Paul Brannen, Soledad Cabezón Ruiz, Nessa Childers, Birgit Collin-Langen, Miriam Dalli, Seb Dance, Angélique Delahaye, Mark Demesmaeker, Stefan Eck, Bas Eickhout, José Inácio Faria, Karl-Heinz Florenz, Francesc Gambús, Elisabetta Gardini, Arne Gericke, Jens Gieseke, Julie Girling, Sylvie Goddyn, Françoise Grossetête, Jytte Guteland, Anneli Jäätteenmäki, Jean-François Jalkh, Benedek Jávor, Kateřina Konečná, Urszula Krupa, Peter Liese, Valentinas Mazuronis, Susanne Melior, Miroslav Mikolášik, Rory Palmer, Gilles Pargneaux, Bolesław G. Piecha, Pavel Poc, John Procter, Frédérique Ries, Daciana Octavia Sârbu, Annie Schreijer-Pierik, Ivica Tolić, Nils Torvalds, Adina-Ioana Vălean, Jadwiga Wiśniewska, Damiano Zoffoli
Substitutes present for the final vote	Nikos Androulakis, Cristian-Silviu Buşoi, Christophe Hansen, Martin Häusling, Anja Hazekamp, Jan Huitema, Tilly Metz, Bart Staes, Tiemo Wölken
Substitutes under Rule 200(2) present for the final vote	Olle Ludvigsson

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

55	+
ALDE :	Catherine Bearder, Jan Huitema, Anneli Jäätteenmäki, Valentinas Mazuronis, Frédérique Ries, Nils Torvalds
ECR:	Mark Demesmaeker, Arne Gericke, Urszula Krupa, Bolesław G. Piecha, Jadwiga Wiśniewska
GUE/NGL :	Stefan Eck, Anja Hazekamp, Kateřina Konečná
PPE:	Pilar Ayuso, Ivo Belet, Cristian Silviu Buşoi, Birgit Collin Langen, Angélique Delahaye, José Inácio Faria, Karl Heinz Florenz, Francesc Gambús, Elisabetta Gardini, Jens Gieseke, Julie Girling, Françoise Grossetête, Christophe Hansen, Peter Liese, Miroslav Mikolášik, Annie Schreijer Pierik, Ivica Tolić, Adina Ioana Vălean
S&D:	Nikos Androulakis, Simona Bonafè, Biljana Borzan, Paul Brannen, Soledad Cabezón Ruiz, Nessa Childers, Miriam Dalli, Seb Dance, Jytte Guteland, Olle Ludvigsson, Susanne Melior, Rory Palmer, Gilles Pargneaux, Pavel Poc, Daciana Octavia Sârbu, Tiemo Wölken, Damiano Zoffoli
VERTS/ALE:	Margrete Auken, Bas Eickhout, Martin Häusling, Benedek Jávor, Tilly Metz, Bart Staes

0	-

3	0
ECR:	John Procter
EFDD :	Sylvie Goddyn
ENF :	Jean-François Jalkh

Key to symbols:
+ : in favour
- : against
0 : abstention