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Session III

The cross-border healthcare Directive: Stocktaking two years after transposition

Discussion paper

The Directive 2011/24/EU on the application of patients' rights in cross-border healthcare¹ ("the Directive") is undoubtedly one of the most important pieces of EU legislation from the patient perspective. Its real added value will however depend on its effective application by national authorities.

Nearly two years after the Directive was due to be transposed into national legislation by the 28 Member States, the Luxembourg Presidency considers it timely to raise a more focused discussion on selected topics that are core to the application of the Directive. It is important to use the momentum created by the Commission implementation report of the Directive², adopted on 4 September 2015, to explore the positive elements of the Directive as well as its challenges.

The Commission report captures the current state of play of transposition with particular emphasis on the use of prior authorization, the level of patient mobility, reimbursement practices, patient flows, information to patients and cross-border cooperation. One of the key findings is that only small numbers of patients from EU Member States have experienced cross-border treatment under the Directive, in particular as concerns planned treatment abroad requiring prior-authorization. While reasons for these small numbers are manifold, a major explanation lies in the absence of patients' awareness of their rights to reimbursement for cross-border healthcare and their very low awareness of the existence of National Contact Points (NCPs).

The Presidency would like to actively encourage Ministers of Health to draw on the experience gained in implementing the Directive and to engage into a debate on the positive outcomes and on possible areas for action at national and EU level in order to further enhance the application of the Directive. A particular focus will be put on the provision of information to patients and cross-border collaboration in border regions.

Provision of information to patients

One of the main objectives of the Directive is to enable patients to make an informed choice and thus to contribute to patient empowerment. The Directive contains a number of provisions relating to patient information based on the principle that "*appropriate information on all essential aspects of cross-border healthcare is necessary to enable patients to exercise their*



*rights on cross-border healthcare in practice*³”. Articles 4 to 6 of the Directive define the responsibilities of Member States as well as those incumbent on NCPs as regards the provision of information to patients seeking to receive healthcare abroad. Article 4(2)(b) requires Member States to oblige healthcare providers to provide patients with a certain amount of information (for example, on treatment options and prices) to enable them to make an informed choice.

Since 2013, a central EU NCP portal, providing for a central overview of all NCP websites across the different Member States, is at the disposal of EU citizens looking for information on cross-border healthcare.⁴ The Commission network of NCPs, which met in February and September 2014, allows national authorities to exchange on the different issues surrounding the provision of information to EU citizens on cross-border healthcare and the most efficient ways to deliver such information, including on safety and quality, and how to best communicate on the totality of cross-border healthcare rights.

The issues of patient information and of better cooperation between NCPs have also been addressed by several recent studies carried out on behalf or with the active support of the Commission (see Annex). The 2014 special Eurobarometer survey on awareness of patient rights showed that most Europeans are not well-informed about what healthcare they have the right to be reimbursed for in another Member State (78% of respondents) or even in their own country (49% of respondents). Around 10% were aware of the existence of NCPs providing information about cross-border healthcare inside the EU and only a minority among those had ever contacted one.

The Commission and Member States carried out a first data collection exercise for the calendar year 2014 to assist in the preparation of the report on the operation of the Directive. Further data collection on requests for prior-authorisation, reimbursement and patient flows is planned only for the calendar year 2017 in support of the report which the Commission is due to present by October 2018 according to Art. 20(1) of the Directive. A yearly reporting exercise on such data would prove very helpful for patient groups.

Further work is needed to ensure sound information for the benefit of all citizens within the EU on their rights to healthcare in another Member State to raise awareness of entitlements to cross-border care and to provide information on how to uphold them in practice.

Cross-border cooperation

Article 10(3) of the Directive requires Member States to facilitate cooperation in cross-border healthcare provision at regional and local level and provides that the Commission shall encourage Member States, particularly neighboring countries, to conclude agreements among themselves. Recital 51 of the Directive further notes that the Commission “(...) may, in accordance with Article 168(2) of the Treaty on the functioning of the European Union, take, in close contact with the Member States, any useful initiative to facilitate and promote such (cross-border) cooperation (...), particularly by identifying major obstacles to collaboration



between healthcare providers in border regions, and by making recommendations and disseminating information and best practices on how to overcome such obstacles.”There are many potential benefits of cross-border cooperation, notably greater choice for patients, improved education and training for healthcare providers, better mobility for both patients and professionals, reduced waiting lists, enhanced quality and efficiency and quicker response to medical emergencies in geographical proximity. Access to efficient cross-border cooperation remains however hampered by many obstacles such as legal and regulatory incompatibilities, the lack of continuity of care and the absence of a legal basis for entities engaged in cross-border activities.

The Commission has initiated a certain amount of work in relation to cross-border collaboration (see Annex). Most recently, the opinion of the Expert Panel on Effective Ways of Investing in Health (EXPH) on cross-border cooperation, adopted on 3 August 2015, put forward a number of suggestions for action in order to improve cooperation on cross-border healthcare provision, some of which are taken up in the Commission report. The progress report furthermore underlines the potential of cooperation between Member States in terms of benefits for health systems across the EU and stresses the need to identify those EU activities and best practices which will help to put into place efficient cross-border cooperation.

As of today, there are areas of ongoing activities between some Member States which have a positive impact on cross-border cooperation, but many projects suffer from a lack of experience in the initial phase. Taking into account the increased mobility of patients and healthcare providers as well as of health systems’ interconnection, better cooperation between the various actors involved is needed, especially in areas where health systems across the EU face similar challenges, so as to ensure effective, high-quality and sustainable health services.

Against this overall background, Ministers/Heads of Delegations are invited to consider the following questions in preparation for discussion:

Question 1: Based on your experiences regarding the implementation of the Directive, how do you assess both, the positive elements and the challenges identified in the Commission report? Are there any further issues that need to be addressed?

Question 2: What action should be taken at national and EU level to raise the awareness of EU citizens of their rights in the field of cross-border healthcare? What kind of information do patients need and how should it be provided? Do you think that a greater involvement of patients’ organisations, or measures such as the development of a quality assurance mechanism for NCPs or guidance on information to patients on safety and quality could help achieving this aim?

Question 3: What are the specific areas where greater cross-border cooperation could make a difference to patient access? How could cross-border collaboration in border regions be further



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promoted? To which extent do you consider the following initiatives useful: mapping of existing projects across Member States to build up a comprehensive picture of cross-border cooperation in the EU, exchange of best practices, identification of border areas where greater cross-border collaboration might be of interest?



ANNEX

Work on patient information carried out by or on behalf of the Commission

- Study on a best practice based approach to National Contact Point websites with recommendations to Member States and the Commission on how to provide the appropriate information on various essential aspects of cross-border healthcare through NCPs⁵
- Evaluative study published in August 2014 on the impact of information on patients' choice within the context of the Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare⁶
- A series of conferences organised between 2013 and 2015, at the request of the Commission, by the European Patients' Forum (EPF)
- 2014 special Eurobarometer survey on awareness of patient rights⁷
- Opinion of the expert panel on effective ways of investing in health on cross-border cooperation⁸
- Evaluative study published in May 2015 on the operation of the Directive 2011/24/EU containing *inter alia* a review of NCP websites⁹

Work on cross-border cooperation carried out by or on behalf of the Commission

- Study on "Hospitals and Borders"¹⁰, carried out in 2013 by the European Observatory as part of the Evaluating Care Across Borders (ECAB) research project
- Commission funded a report by the European Critical Care Foundation on opportunities, challenges and recommendations on improving cross-border access to treatment for coronary heart diseases¹¹
- Study on effective cross-border cooperation in high cost capital investments in health to be published by March 2016 which will identify examples of cost intensive devices where resource pooling could be desirable and present a proposal for a cross-border cooperation mechanism for pooling resources for high-cost investment
- Opinion of the expert panel on effective ways of investing in health on cross-border cooperation (see footnote 7)



¹ OJ L88/45, 4.4.2011, see: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2011.088.01.0045.01.ENG .

² Commission Report on the operation of the Directive 2011/24/EU on the application of the patients' rights in cross-border healthcare, 4.9.2015, COM (2015) 421

³ Recital 48 of Directive 2011/24/UE.

⁴ See: http://europa.eu/youreurope/citizens/health/planned-healthcare/get-more-info/index_ex.htm#! .

⁵ Feasibility study, 17.10.2012, see:
http://ec.europa.eu/health/cross_border_care/docs/pwc_national_contact_points_website_en.pdf .

⁶ Ipsos and London Economics have been mandated by the Executive Agency for Consumers, Health and Food (CHAFEA), acting on behalf of the DG SANCO, to undertake this study; see:
http://ec.europa.eu/health/cross_border_care/docs/cbhc_information_patientschoice_en.pdf .

⁷ Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, May 2015, see:
http://ec.europa.eu/public_opinion/archives/ebs/ebs_425_en.pdf .

⁸ See: http://ec.europa.eu/health/expert_panel/opinions/docs/009_crossborder_cooperation_en.pdf .

⁹ See: <http://ec.europa.eu/digital-agenda/en/news/final-report-evaluative-study-cross-border-healthcare-directive> .

¹⁰ Hospitals and Borders, Seven case studies on cross-border collaboration and health system interactions, see
http://www.euro.who.int/_data/assets/pdf_file/0019/233515/e96935.pdf .

¹¹ Improving access to treatment for coronary heart diseases: overcoming barriers, addressing inequalities - Improving cross-border access to early primary angioplasty in the EU opportunities, challenges and recommendations, see
http://euroccf.org/Documents/Cross-border_PPCI_report_ECCF_FINAL.pdf .