

Informal meeting of Health Ministers

14th – 15th of April 2019
Bucharest, Romania



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Background to the Informal Meeting of Health Ministers under the Romanian Presidency to the EU Council

Challenge 1: Patient Mobility - Directive 2011/24/EU on the application of patient rights in cross-border healthcare: Taking stock on implementation in the EU

Every year millions of European citizens travel to another EU Member State safe in the knowledge they can access healthcare when abroad. The Directive 2011/24/EU works together with the EU Regulations on Social Security Coordination, including the European Health Insurance Card¹, by reaffirming the principle of free movement of people and guaranteeing patients' rights to receiving safe and high-quality crossborder healthcare under certain conditions. While Member States remain responsible for healthcare systems on their own territory, the Directive has encouraged them to strengthen cross-border cooperation in healthcare and to put in place legal frameworks facilitating it in the fields of eHealth, e-prescriptions, health technology assessment, rare diseases and complex diseases (with the establishment of 24 European Reference Networks). There has been a steady increase in patient mobility since the Directive's transposition deadline in 2013, mostly driven by geographical and cultural proximity of healthcare across borders. However, patient mobility remains low with around 200 000 requests for reimbursement in 20 Member States in 2017².

Member States could benefit from sharing experience on the implementation of the Directive to enable EU citizens reap the benefits of cross-border healthcare and to explore how cross-border collaboration can benefit health systems in terms of greater efficiency, particularly in border regions. Based on their experience, Member States could reflect collaboratively on actions to improve the Directive's effectiveness, taking into account the findings of the European Commission report on the Directive's implementation³ and the European Parliament resolution of February 2019.

Improving Access to Cross-Border Healthcare

Crucial for improving access to planned cross-border healthcare is clear accessible information. The availability of adequate information and guidance can reduce the administrative burden of repetitive requests and unnecessary administrative procedures arising from the prior authorisation and reimbursement process. The Commission and European Parliament reports on the Directive's implementation identify a number of areas where improving information and increasing transparency of the reimbursement process could better guide and inform patients seeking cross-border healthcare:

- Patients may be required, in certain circumstances, to request prior authorisation from their national health insurance provider in order to receive reimbursement for medical treatment

¹ Regulations (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

² Ibid. Data on patient mobility see pp 6-8

³ Report from the Commission to the European Parliament and the Council on the Directive 2011/24/EU on the application of patients rights in cross-border healthcare, COM (2018) 651 final of 21st September 2019



abroad. National Contact Points (NCPs) play an important role in making publicly available, as required by the Directive⁴, those medical treatments subject to prior authorisation to guide a patient's decision to seek healthcare abroad. The circumstances in which a prior authorisation is required, taking into account the principle of necessity and proportionality, could be considered together with the administrative cost in the application of this procedure. Six Member States and Norway have no prior authorisation system in place, leaving the patient the freedom to choose and removing an administrative burden.

- Some Member States have introduced a system of prior notification for patients as part of the national reimbursement mechanism under the Directive. The patient receives a written confirmation of the costs to be reimbursed before the treatment abroad. Yet this option remains underused by Member States.
- Fewer than 20% of citizens feel well informed about their cross-border healthcare rights⁵. Large information gaps persist. Raising awareness of the Directive and its benefits remains a challenge. The National Contact Points (NCPs) are operational in all Member States providing information to help patients make an informed decision on healthcare in another Member State. Nonetheless, further action may be necessary to promote the NCPs and to enhance the provision of accessible and where feasible, multi-lingual information. The NCP toolbox produced by the Commission in response to the Council's request during the Luxembourg Presidency is welcome in this regard as is the Commission's useful guidance on the Directive's complex link with the Social Security Coordination Regulation 883/2004.
- Promoting the benefits of the Directive and enhancing awareness requires cooperation between the actors involved in the Directive's implementation – NCPs, health authorities, health insurers, health providers and patient organisations at local, regional and national level.

Taking into account all the above, the Presidency proposes the following questions for guiding the ministerial debate:

Question 1: What is in your view the biggest challenge to implementation of the Directive on patients' rights in cross-border healthcare? And how to improve patients' awareness of their rights and the transparency of the reimbursement process?

Question 2: How could cross-border collaboration, particularly in cross-border regions, be further promoted?

⁴ Article 8 (7) of Directive 2011/24/EU

⁵ Eurobarometer 2015



Challenge 2: Proposal of the Romanian presidency to have a focused discussion on how to further enhance the Integration of ERNs into the healthcare systems of the Member States

The ERNs are in their initial deployment phase and are now facing the logical challenges of being operative and functional. They will really be able to bring benefits to patients suffering from rare and low prevalence complex diseases across the EU only once they will be linked in a clear and stable way to the healthcare systems of the Member States. These challenges shall be addressed in close cooperation between all actors and especially with the Member States, as they are the key leaders of the process.

It is important to use the momentum and address this fundamental issue before the enlargement process of the Networks is launched and explore the Member States' positions and engage into a debate on the benefits/potentials of the ERNs in order to further enhance the integration process.

As regards patients suffering from rare diseases, they are very often children. Therefore, even if the ERNs support all age categories, a lot of cases referred to ERNs concern minors. Moreover, as per their competences, some ERNs are dedicated specifically to minors (European Reference Network on Paediatric cancer (haemato-oncology) - ERN PaedCan; European Reference Network on Transplantation in Children - ERN Transplant-child etc).

The ERNs implementation is considered a success by all the involved actors (Member States healthcare providers, hospital managers, patients and scientific associations), nevertheless, they are phasing several challenges, the major and most urgent of which is the integration of the ERNs into the healthcare systems of the Member States.

Integration of the ERNs into the healthcare systems of the Member States refers to a set of policies and procedures that the Member States need to put in place to embed/link the ERNs into their healthcare systems in order for ERNs to realise their full potential. This requires a substantial investment from the Member States.

To address these challenges in October 2017, the Board of Member States has set up a specific Working Group on Integration with the objective to support Member States in the integration process. The intervention areas identified by the Working Group are the following:

1. **Adapting the legal and regulatory framework to reflect the existence of the Networks.** This may imply for instance setting rules for the selection and endorsement of healthcare providers applying for membership of existing Networks.
2. **Defining patient pathways for rare or low prevalence complex diseases and conditions covered by the 24 Networks** - this means defining the way the patient moves from one healthcare provider to more specialised ones – is an essential instrument for defining the best patient care and in consequence improve outcome.
3. **Setting up procedures for the referral of patients to the ERNs** - ERNs are not directly accessible to individual patients. Therefore, it is essential that patients are “referred” to the relevant ERN by the right healthcare professional. Formal referral systems, depending on the organisation of the patient pathways in the Member States as well as on medical considerations, need to be put in



place to enable timely access to ERNs by patients from all Member States including those that do not yet have a member in a Network.

4. **Providing support to ERN Members and Coordinators** - Member States should actively participate in this initiative providing in particular support to the ERN members (i) for the participation of their staff in ERN virtual panels (depending on the way clinical procedures are reimbursed) and (ii) for the increase flow of patients that the ERN members could attract. They should also support the ERN Coordinators.
5. **Providing information on ERNs** - A good communication strategy targeting healthcare providers and patients is essential to avoid that lack of information becomes an access barrier. The information provided should cover in particular the existence and the role of the ERNs, as well the patient's pathways for each type of rare disease and the referral procedures for each ERN.
6. **Ensuring geographical and clinical coverage of ERNs** - Not all ERNs have at least one member per country (the number of "represented" Member States varies between 8 and 19 across the ERNs). To ensure access to all European citizens, the geographical and clinical coverage of the Networks need to be expanded. The Member States which are not represented may consider to designate "Affiliated Partners" and/or prepare for a new call for membership.

In order to respond to the challenge rare disease strategies may need to be updated.

Against this background, we invite Ministers to consider the following questions for discussion:

Question 1: What could Member States do in order to support the integration of ERNs in the national healthcare systems? Are there additional issues that need to be addressed (in addition to the ones identified by the "working group on integration")?

Question 2: What should be the role of rare disease strategies for the integration of ERNs in national healthcare systems?

Question 3: How to best support the access of vulnerable groups, such as minors, to rare disease diagnose and treatment ADVICE through the existing ERNs?