



5th European Conference on Rare Diseases ECRD Krakow



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Proposal for a Directive on Patients' rights in cross-border healthcare

*OPENING THE DOOR TO BETTER
HEALTHCARE ACROSS EUROPE*

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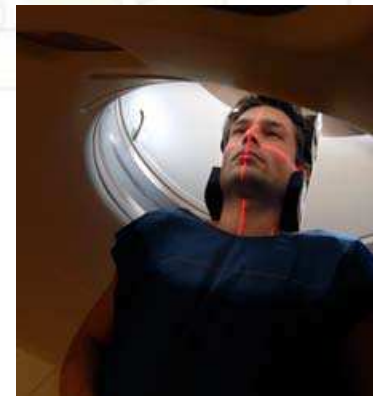
The 3 Aims of this initiative



1. Help patients to exercise their right to reimbursement for health treatment in any EU country ('cross-border healthcare')

2. Provide assurance about safety and quality of cross-border healthcare

3. Foster cooperation between health systems, to improve healthcare for all



1. Helping patients to access cross-border healthcare

■ Rules differ regarding the type of care:

- For non - hospital care
- For hospital care

■ Clear rules on reimbursement

■ Information available to patients

■ Procedural guarantees

2. Ensuring Safer & Better Quality cross-border healthcare by clarifying responsibilities

- **MS of treatment is responsible for assuring:**
 - Quality & safety of care (standards)
 - Information & assistance to patients
 - Providing mechanisms to seek redress & compensation for harm
 - protection of privacy & personal data
 - equitable treatment of patients from home country & from other Member States.

Arrangements should be transparent ;
monitoring systems in place

Safeguards to ensure fair and equitable system for health authorities



■ **TARIFF OF REIMBURSEMENT:**

- ✓ They pay out NO MORE than they would have for the same or similar treatment at home
- ✓ They pay out ONLY for treatment they would pay for at home

- **The RULES of the HOME SYSTEM apply for people going abroad: eg gp gatekeeper**
- **If there is a risk to their system, they can introduce prior authorisation for HOSPITAL CARE**

3. Fostering cooperation between healthcare systems to improve healthcare for all

- **eHealth**
- **European Reference Networks**
- **Health Technology Assessment**
- **Recognition of prescriptions**





European Reference Networks - ERN (Article 13)

- Commission supports MS in the development of ERN through:
 - ❖ Providing clarity on the definition of an ERN
 - ❖ Facilitating the exchange of information & expertise in relation to the establishment of networks & their evaluation
- Very important for Rare Diseases



European Reference Networks - ERN

- **Commission Communication COM (2008) 679/2 to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on Rare diseases: Europe's challenges creating an integrated approach for the EU action in the field of rare diseases. **Adopted 11th November 2008.****

Improving universal access to high-quality healthcare for rare diseases, in particular through development of national/regional centres of expertise and establishing EU reference networks (Point 5.1)



European Reference Networks - ERN

- **Council Recommendation on a European action in the field of rare diseases recommending actions at national level to implement the EU action (e.g. National Plans for Rare Diseases).**

Adopted 8th June 2009.

- **Identify appropriate centres of expertise throughout their national territory by the end of 2013, and consider supporting their creation.**
- **Foster the participation of centres of expertise in European reference networks respecting the national competences and rules with regard to their authorisation or recognition**
- **Organise healthcare pathways for patients suffering from rare diseases through the establishment of cooperation with relevant experts and exchange of professionals and expertise within the country or from abroad when necessary.**
- **Include, in their plans or strategies, the necessary conditions for the diffusion and mobility of expertise and knowledge in order to facilitate the treatment of patients in their proximity. 16. Encourage centres of expertise to be based on a multidisciplinary approach to care when addressing rare diseases.**



European Reference Networks - ERN

Some suggested criteria by the EU Task Force on Rare Diseases to be fulfilled by the European reference networks are:

- **Sufficient activity and capacity to provide relevant services and maintain quality of the services provided**
- **Capacity to provide expert advice, diagnosis or confirmation of diagnosis, to produce and adhere to good practice guidelines and to implement outcome measures and quality control**
- **Demonstration of a multi-disciplinary approach;**
- **High level of expertise and experience documented through publications, grants or honorific positions, teaching and training activities**
- **Strong contribution to research**
- **Involvement in epidemiological surveillance, such as registries**
- **Close links and collaboration with other expert centres at national and international level and capacity to network**
- **Close links and collaboration with patients associations where they exist.**
- **Appropriate arrangements for referrals of patients from other Member States established within a framework.**
- **Appropriate capacities to diagnose, to follow-up and manage patients with evidence of good outcomes so far as applicable.**



European Reference Networks - ERN

To develop European Networks of Centres of Reference for Rare Diseases it's a priority in the Health Programme. 10 Projects have been selected as ERN pilot project for funding between 2006 and 2009:

- European Centres of Reference Network for Cystic Fibrosis with the Klinikum der Johann Wolfgang Goethe-Universität (DE) as Project Leader,
- European Network of Centres of Reference for Dysmorphology with The University of Manchester (UK) as Project Leader,
- Patient Associations and Alpha1 International Registry with the Stichting Alpha1 International Registry (NL) as Project Leader,
- European Porphyria Network: providing better healthcare for patients and their families with the Assistance Publique - Hôpitaux de Paris (FR) as Project Leader,
- Establishment of a European Network of Rare Bleeding Disorders, with the Università degli Studi di Milano (IT) as Project Leader.
- European network of paediatric Hodgkin's lymphoma – European-wide organisation of quality controlled treatment with the University of Leipzig (D) as Project Leader.
- European Network of Reference for Rare Paediatric Neurological Diseases (NEUROPED) with the European Network for Research on Alternating Hemiplegia (AT) as Project Leader.
- A reference network for Langerhans cell histiocytosis and associated syndrome in EU with Assistance Publique Hôpitaux de Paris (FR) as Project Leader.
- Improving Health Care and Social Support for Patients and Family affected by Severe Genodermatoses – TogetherAgainstGenodermatoses (TAG) with Fondation René Touraine (FR) as Project Leader.
- European Reference Network of expert centres in rare anaemias (ENERCA 3) with Hospital Clínic de Barcelona (ES) as Project Leader.

Situation of the political process

- **Adoption** of the Proposed Directive by the **College**: 2 July 2008
- Text in Co-decision procedure
- **EP** – Vote in 1st reading: 23 April 2009
- **Work in Council**: 3 Presidencies; failure to find a political agreement on 1 December 2009

The position of the EP

- 1st reading: 23 April 2009
- EP very positive on the text
- EP reinforced patients' rights
(no prior authorisation)

The Commission position on the latest SE compromise text

- Prepared to accept the compromise to allow the process to move forward
- However, text not fully satisfactory to us:
 - ✓ Very restrictive system of prior authorisation
 - ✓ Weak eHealth provision

The Swedish Presidency

- Strenuous efforts to reach a political agreement at EPSCO
- Council narrowly failed to reach a political agreement at EPSCO
- Blocking minority

The Spanish Presidency

- The political commitment of the Minister (1 December 2009)
- New Spanish Proposal
- Informal Council: 22/04
- Discussions resumed in Council: 26/04

Possible Next Steps

- Crucial month of **May**
- Council ('EPSCO'): **8 June**
- Start of second reading: **July?**
- End of second reading: **end 2010**
or **mid-2011?**



Europe for Patients



THANK YOU !