European Haemophilia Consortium
Office of the National Member Organisations

EHC Stakeholders Round Table

The Implications of the EU Cross-Border Healthcare Directive for People with Haemophilia

Meeting Report

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The 18th European Haemophilia Consortium (EHC) Stakeholders Round Table focused on the topic of ***'The Implications of the EU Cross-Border Healthcare Directive for People with Haemophilia'.***

The Round Table was co-chaired by ***Nessa Childers MEP*** *and* ***Rebecca Taylor MEP****, who both introduced and concluded the event. It featured presentations from the* ***European Commission's Policy Officer for Healthcare Systems, Annika Nowak,*** *the clinician Professor* ***Cedric Hermans****, and patient representatives* ***Chris James*** *and* ***Radoslaw Kaczmarek****.*

The EU Cross-Border Healthcare Directive provides a ***legal framework*** *for people who wish to* ***obtain healthcare under Article 56 of the Treaty of the Functioning of the European Union.*** *The Directive also covers* ***prior authorisation for patients, common EU standards of treatment and continuity of care, an enhanced role for medical insurance and new pricing mechanisms, new rights for ex-pats*** *and* ***mechanisms for reimbursement.***

Participants at the March Round Table explored how these ***new patient rights might affect people with haemophilia*** *across Europe, both within and outside of the EU. They also discussed the* ***implications of this EU Directive on the health systems in individual countries*** *as well as more generally on* ***European rare disease policies in the future****.*

The Round Table provided an excellent opportunity for MEPs, European Commission officials, industry, insurance providers, patients and other stakeholders to express their thoughts on the current transposition of the Directive into domestic legislation. It was a ***timely conversation****, given that Member States are currently debating the same issues internally, in anticipation of their* ***October 25th 2013 deadline to fully implement the Directive into national law.***

- **Welcome and Introduction – Rebecca Taylor MEP as a Co-Chair**

Rebecca Taylor MEP opened the Round Table by explaining that the discussions would focus not only on rights for EU citizens, but also on **the impact the Directive would have on patients outside the EU wishing to seek healthcare treatment in EU Member States**, for example in areas such as **rehabilitation**, **surgical procedures** and **specialised healthcare services**.

Ms Taylor MEP said that a thorough analysis of the Directive's text, **including its legal basis and the 'political background' of topics addressed, shows that the legislation goes far beyond its original scope and may actually have a greater impact on several healthcare-policy concepts than was originally intended.** As a result, its implementation is of great importance to the haemophilia community.

She also said that the Directive itself **could be seen as a groundbreaking piece of legislation** that could have a **tremendous impact on the evolution of Member State healthcare competences** and the development of further legislative and policy initiatives within the EU going forward.

Ms Taylor MEP said she expected to hear discussions about the fact that patients seeking healthcare requiring an overnight hospital stay would need so-called "**prior-authorisation" before they go abroad for treatment**. Indeed, given the Directive is currently being implemented, **local GPs and clinicians in Member States may not be aware of the new rights enshrined in the legislation, potentially leaving people with haemophilia** with the task of explaining to their GP the new patient rights within the Directive. She further outlined three scenarios whereby a system of "prior-authorisation" can be established in a particular Cross-Border Healthcare patient case:

1) For **healthcare that involves overnight hospital stay** of at least one night;
2) For **highly specialised** and **cost-intensive healthcare**; and
3) In **serious and specific cases relating to the quality or safety of the care provided abroad**.

In these three cases, Ms Taylor MEP said, **patients may need to ask for permission in advance from their national health authority in charge of reimbursement and, given that this could impact upon the treatment that people with haemophilia receive, it is something that the participants of the Round Table should take into consideration.**

Lastly, Ms Taylor MEP encouraged participants to take into consideration the pre-existing arrangements that many countries within Europe have with regards to cross-border healthcare. **Some Member States may have already established procedures in place for "prior-authorisation"** given that **some cross-border healthcare arrangements already exist between countries**, with the most important 'borders' being the UK/Ireland; Netherlands/Germany; Netherlands/Belgium; Belgium/Germany; Germany/Poland; France/Belgium; France/Italy; Germany/Austria; Hungary/Austria; and Austria/Italy.

- **European Commission: History of the EU Cross-Border Healthcare Directive**
  – Annika Nowak, Policy Officer, Healthcare Systems, European Commission

Annika Nowak began her presentation by discussing the history of the EU Directive, dating from the 1970's and unplanned healthcare needs that were discussed at that time.

Ms Nowak explained how the authorisation of the E112/ S2 procedures could not be refused where 'undue delay' applied. Under these procedures, payment is dealt with between Member State health systems.

She said that the **European Court of Justice jurisprudence between 1997-2006** outlined that **if a patient is entitled to a treatment at home, then he or she is entitled to reimbursement for that treatment abroad**. However, the reimbursement is up to the cost of that treatment in the patients 'home' Member State.

She added that for some treatments, **such as treatment requiring a hospital stay**, Member State health systems **could require a patient to seek 'prior authorisation'**.

Ms Nowak also discussed the different provisions within the Directive, including **National Contact Points** and **provisions relating to rare diseases**.

For example, in relation to rare diseases, **patients must seek a specialist view and receive prior authorisation before going abroad for treatment**. She also mentioned awareness raising of **EU level diagnostic tools and that rare disease patients would benefit from political encouragement for their case in their 'home' Member State** given that in this area there were no legal obligations for Member States here.

Ms Nowak **said that many or most specialised services within the rare diseases area were likely to be subject to prior authorisation by Member States and that greater information would be available across the EU for rare disease patients in terms of their entitlements, the quality and safety standards of healthcare and the different treatments offered**.

Lastly, she outlined the other areas of cross-border healthcare cooperation within the EU Directive. These included **recognition of prescriptions**, **European Reference Networks**, **Health Technology Assessment** and **ehealth**.

- **Cross-Border Healthcare and People with Haemophilia: An EHC Perspective**
  - Chris James, EHC Steering Committee Member, CEO UK Haemophilia Society

Chris James opened his presentation by saying that haemophilia health service provision in Europe varied greatly but was **generally good within EU Member States**.

He also pointed out that in the medium to longer term, **access to haemophilia treatments would be improved through the bi-lateral healthcare agreements between European countries** that either already exist or would likely be made in the future.

He said that people with haemophilia often need access to expensive healthcare products, whilst there are **pressures on Member State Health Departments to reduce financial costs**. This raises a dilemma in the application of EU Cross-Border Directive patient rights in Member States, he said.

Mr James then spoke about the **potential benefits of the EU Directive for people with haemophilia and other rare bleeding disorders**. He comments that **from an EHC perspective, he did not expect a lot of cross-border movement in terms of haemophilia care within the EU in the coming years**. An exception to this might be patients from poorer countries with a lack of access to treatment and care, he said.

Rather, he commented that the Directive could enable patients with other rare bleeding disorders to make use of EU centres of excellence abroad. In fact, he said that **the European population as a whole could provide a critical mass to drive improvements in the area of other rare bleeding disorders**.

Both for haemophilia care and other rare bleeding disorders, Mr James **called for both more information and better access to that information to give patients more clarity about their rights**. He also said the Directive offered an **opportunity for European clinicians to drive improvements** and opportunities to develop expertise in new treatments.

- ## Cross-Border Healthcare and the Patient: A Case Study from Europe
  – Radoslaw Kaczmarek, EHC Steering Committee Member

Radoslaw Kaczmarek opened his presentation by suggesting that **the EU Directive might provide a few good opportunities.** For example, it could be used as **an advocacy tool to improve standards of haemophilia care within Europe.** It could also be used to **standardise Health Technology Assessments** within the EU.

However, Mr Kaczmarek also pointed out that the EU Directive affords Member States **a high degree of freedom in the transposition of the legislation into their national laws** and he shared his concerns that this would enable EU governments to protect their health financing systems.

He gave the example of how Poland is implementing the EU Directive. He said that on February 8th, the Polish Ministry of Health published amendments to its existing healthcare legislation that suggest that they will implement the legislation in a limited form. He pointed out that **Polish healthcare providers set different prices for their services**, with the **National Health Fund only paying the patient the average price paid to Polish healthcare providers in general**, dependent on the patient's region of residence.

Protective measures available to Member States, he said, **included a partial requirement for prior authorisation before a patient goes for treatment, reimbursement only for treatments included in the essential benefits basket of the patient's country of affiliation, and reimbursement only to the maximum financial amount that the treatment would cost in the country of affiliation**. Therefore, Mr Kaczmarek shared his concern that the potential benefits of this Directive could be muted in the course of their implementation into national law.

- **Cross-Border Healthcare: A Clinicians Perspective**
  – Professor Cedric Hermans, UCLouvain

Professor Cedric Hermans began his presentation by **discussing some of the characteristics of the 210 patients with haemophilia A or B that his service treats in St Luc University Hospital in Belgium**.

Professor Hermans presented eight medical cases of patients from Europe from the last 10 years. He said that for each case, his service provided treatment through **a different legislative vehicle**; **the EU Cross-Border Directive was only one of these vehicles.**

Professor Hermans commented that for most of the patients he received in his service, there was little objective information available on the treatment they had received prior to coming to Belgium. He suggested that **when patients of EU-countries seek treatment abroad, they should either have their medical records with them or the possibility to contact their haemophilia specialist at home**. They should also be aware of the **differences in treatment**. Professor Hermans pointed out that according to the EU Directive, they should **only seek treatment in Centres of Excellence**.

Professor Hermans observed that the **implications for the patient of having limited information available when treating haemophilia abroad are unknown**, and concluded that this **should be formally researched.**

- **The Cross-Border Healthcare Directive in the Republic of Ireland**
  – Nessa Childers MEP

Nessa Childers MEP **welcomed the EU Directive and the potential opportunities** when patients of EU-countries seek for treatment abroad they should carry with them either their medical records or the possibility to contact the specialist in haemophilia. And they should be aware of the differences in treatment. According to the EU-directive they should seek only help at the Centres of Excellence.
ple, she **warned that the application of the Directive and its provisions should not damage the existing right or access to care of people within Member States** where patients were seeking treatment. She also said that the EU Directive **should not supersede the existing rights currently guaranteed on the co-ordination of social security systems in Member States.**

Ms Childers MEP reminded participants of **the wide diversity of availability of haemophilia care and treatment in Europe** and pointed out that **the Directive does not aim to create an entitlement to reimbursement of the cost of haemophilia healthcare in other Member States** if such healthcare is not already included in the benefits provided for by the legislation of the Member State of affiliation.

As an MEP, Ms Childers said that she wondered about the Directive's impact on the regular supply of factor concentrates in various Member States. For example, **currently, per capita Factor VIII use in the EU countries varies from 0.51 IU in Romania to 8.56 IU per capita in Sweden**, she said. This is a 17-fold difference. **The system with prior authorisation is important especially in relation to highly specialised cross-border intensive healthcare**.

Focusing on rare diseses, she said that **the Directive refers to rare diseases as being those with a prevalence threshold of five affected persons per 10,000 persons or 1:2,000 individuals**. Haemophilia is a **well characterised relatively common rare disease** within the EU, she said, and she called for more information to be shared with haemophilia patients about the EU Directive.

Ms Childers MEP concluded that she **hoped that the Directive would shine a spotlight on conditions and treatment in different Member States** and may lead to an improvement in the minimum standard of care in many countries within Europe. **Currently, many European countries use less than 2 IU per capita of Factor VIII. The level of 2 IU per capita is a minimum standard for survival as set by the European Directorate for the Quality of Medicines and HealthCare (EDQM**), she said.

- **The Disparity of Haemophilia Care in Europe and the Cross-Border Healthcare Directive – Rebecca Taylor MEP**

Rebecca Taylor MEP began her presentation by **outlining a short history of the EU Directive from an MEP perspective**. She spoke about the **European Court of Justice cases (1998-2007), the European Commission Communication on Patient Mobility (April, 2004), the John Bowis MEP European Parliament Report on Patient Mobility (December, 2004)** and the **EU Services Directive (December, 2006).**

She then went on to speak about **patient informed choice in the EU Directive** as well as **disparities in haemophilia healthcare treatments within the EU**. She said that Healthcare Technology Assessment co-operation **could enable Member States to assess treatments more efficiently** if they can learn from the experience of other European countries.

Ms Taylor MEP concluded by saying that **European haemophilia treatment centres could benefit from involvement in European Reference Networks, an important part of the EU Directive**.

- **Wrap-Up and Conclusions - Nessa Childers MEP as Co-Chair**

Nessa Childers MEP, as co-chair of the Round Table, concluded the event by **reiterating that the new EU Cross-Border Healthcare Directive was currently being transposed into national law in each of the EU Member States and that its full impact would not be felt for some time**.

Ms Childers MEP said that it was **crucial to discuss its potential impact on people with haemophilia** and to **think through the benefits and opportunities the Directive may bring in the short, medium and long terms.**

She warned that the Directive **should not result in patients being encouraged to seek treatment outside of their own EU countries if that treatment was available at home.** She reminded participants that the Directive **is not a substitute for adequate care and treatment in the 'home' country**.

Ms Childers MEP also reiterated that **the Directive respects and is without prejudice to the freedom for each Member State to decide what type of healthcare it considers appropriate**. She underlined that Member States may limit the application of the Directive for reasons related to the quality and safety of the healthcare provided in their country.

- ## Recommendations

Given that the deadline for the implementation of the EU Directive is October 25th 2013, its full impact on haemophilia treatment within Europe has yet to be fully understood. In the meantime, the EHC's recommendations are:

1. **When haemophilia patients travel abroad for treatment under the EU Directive, they should only be referred to recognised centres of excellence: European Haemophilia Comprehensive Care Centres or other recognised Haemophilia Treatment Centres. These referrals could be based on the official network of Haemophilia Treatment Centres currently being developed by EUHANET.**

2. **The implementation of the EU Directive by Member States should by no means detract from the continued prioritisation and establishment of comprehensive care centres nationally.**

3. **The implementation of the EU Directive by Member States should by no means detract national authorities from continuing to prioritise the highest standards of haemophilia care and treatment in their countries.**

4. **The EU Commission and Member States should provide clearer information to haemophilia and other patients on their rights under the EU Directive before their national implementation deadline.**

5. **The EU Commission and other stakeholders should consider monitoring and analysing the cross-border movement of people with haemophilia.**

6. **Member States should pay due attention to rare diseases when implementing the Directive in their national laws.**

7. **Future reviews of this Directive should include an examination of the cross-border movements of haemophilia patients seeking treatment in different EU countries.**

The next EHC Round Table will take place on June 24th 2013 at the Royal Windsor Hotel in Brussels. The topic will be "Access to new therapies: opportunities, challenges and barriers".

All presentations mentioned in this report are available at the following link:
http://www.ehc.eu/round-table-of-stake-holders/last-round-table.html