Update on the Directive on Patients’ Right to Cross Border Healthcare

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Two main legislations

- **Regulation 883/2004 (E111/E112)**
  - Prior authorisation to access care in a different country than country of affiliation: always required
  - When OK: actual costs reimbursed

- **Now Directive 2011/24**
  - Prior authorisation not needed if disease on the « list »
  - When on the list, reimbursement on the basis of their cost in country of affiliation
A long list of ECJ judgments

- Decker 1995
- Kohll 1996
- Vanbraekekel 1998
- Müller-Faurel 1999
- Geraets-Smits-Peerboms 2001
- Leichtle 2002
- Inizan 2003
- Idryma Koinonikon Asfaliseon 2003
- Watts 2004
- Elchinov 2010

All judgments systematically in favour of the patients under the EU Treaty principle of free movements of good, services and people.
Focus on ECJ judgement 2001, Geraets-Smits & Peerbooms

- 10/12/1996: Mr Peerbooms into a coma following a road accident
- 22/02/1997: taken to hospital in the Netherlands, then transferred in a vegetative state to the University Clinic in Innsbruck, Austria
- The Innsbruck clinic gave Mr Peerbooms special intensive therapy using neuro-stimulation
- 20/06/1997: Mr Peerbooms came out of his coma and left the Innsbruck clinic
- Back to the Netherlands: reimbursement denied – neuro-stimulation not part of the “Dutch care basket”

**Judgment:**
- authorisation to purchase treatment in other Member State cannot be refused where it appears that the treatment concerned is sufficiently tried and tested by international medical science
- authorisation cannot be refused if treatment can be obtained in country of residence but only with long delays
The Elchinov case (2010)

- Mr Elchinov, Bulgarian, eye cancer.
- 9/03/2007: asks for E112 to NZOK to obtain advanced treatment in Berlin (attachment of radioactive applicators, proton therapy)
- Admitted in Berlin on 15/03/2007 given his state of health
- 18/04/2007: authorisation refused, since that treatment was not one of the benefits provided for by the Bulgarian legislation and reimbursed by NZOK
- On the list: enucleation only
The Elchinov case (2)

- Appeal as an expert confirmed the advanced treatment was not yet available in Bulgaria
- 13/08/2007: Court in Sofia cancelled the NZOK decision (found that treatment did not exist in Bulgaria, but corresponded to medical services 136 and 258 in the list of medical treatments)
- NZOK appealed to Supreme Administrative Court

► Court of Justice of the European Union
ECJ Judgment

- **authorisation cannot be refused:**
  - If
    - where the list of benefits does not expressly and precisely specify the treatment method applied
    - but defines types of treatment reimbursed
    - it is established that the treatment method in question corresponds to types of treatment included in that list, and
  - if
    - no alternative treatment which is equally effective can be given without undue delay in the Member State on whose territory the insured person resides
In the case of Elchinov

- If Bulgarian list says:
  - Type of treatment covered: « For eye cancer: radiological or surgical treatment »
- Then reimbursement of proton-therapy as provided in Berlin cannot be refused

- If Bulgarian list says:
  - Type of treatment covered: « For eye cancer, enucleation only »
- Then reimbursement of proton-therapy as provided in Berlin can be refused
  
  only the cost that is equivalent to the cost of enucleation to be reimbursed (?)
- For planed care (not for emergencies or accidents)
- For free, given by patients’ health insurance
  - Letter explaining the medical need
  - Prior authorisation (expert)
- Valid for one year
- Provides access to care under the conditions in the country of care
  - The healthcare system of the country of care pays the hospital (not all costs)
  - Part of costs: payment by the patient, and then reimbursement by his/her health insurance
Why E112 not satisfying

- **Arbitrary** (prior authorisation, expert)
- For well established care (hardly applicable to rare diseases)
- Case by case basis (paperwork, delays)
- Needs to be repeated every time a patient travels to the country of care
- Partial payment by patient (who is then reimbursed but after long delays) than can be costly
Each Member State defines the list of diseases for which prior authorisation is not required.

If patient has one disease in the list: patient can go to a different country for diagnosis, exam or treatment.

If up-front payment: patient reimbursed but on the basis of the cost of same type of care in country of affiliation.

Information Point
Authorisation needed if:

- Healthcare requiring planning for high quality treatment
  - Involves overnight hospital for at least one night
  - Requires highly specialised and cost-intensive infrastructure or equipment
  - Presents risk for the patient or the population
- Specific case for rare diseases (article 13)
Article 13 : Rare Diseases

- Commission and MS aiming to:
  - make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;
  - make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.
Example: patient lives in Italy and goes to Czech Republic, disease on list

- E112 and prior authorisation required
- Cost of care in Czech Rep.: 30 000 €
- Cost in Italy: 26 000 €
- Advanced payment by patient: 3 000 €*
- Remaining costs 27 000 € paid by Czech healthcare system to hospital
- Health insurance Italy reimburses 3 000 € to patient
- Cost for patient: 0 €  
  * Sometimes 0 €

- Directive: no prior authorisation
- Cost of care in Czech Rep.: 30 000 €
- Cost in Italy: 26 000 €
- Advanced payment by patient: 30 000 €*
- Health insurance in Italy reimburses 26 000 € to patient
- Cost for patient: 4 000 €  
  * or 0 €, depending of which Member State
Care provided in country of care can include:
  – Consultation
  – Examination
  – Surgery
  – Treatment, including medicines*

And this is not restricted to diagnosis

* Concept of basket of care: if country of affiliation limits the amount of pills per prescription to 1 month treatment, then only one month treatment will be reimbursed, even if prescription in country of care is for 3 months. In this case: prescription of 1 month, renewable, not 3 months
Is there a domestic price and a different price for foreigners?

- The price should be the same

- Article 4.4
  - “Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable medical situation, or that they charge a price calculated according to objective, non-discriminatory criteria if there is no comparable price for domestic patients.”
Reimbursement of « other costs »

Recital 34 and article 7.4:

– “Member States are free, for example, to reimburse extra costs, such as accommodation and travel costs, or extra costs incurred by persons with disabilities even where those costs are not reimbursed in the case of healthcare provided in their territory”.
Information on cross border care

Recital 48:

– “Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice.

– For cross-border healthcare, one of the mechanisms for providing such information (in any EU language) is to establish national contact points within each Member State”.
Complaints & Liability

Article 4.2 (c):

– “Transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive”
Reimbursement of main costs

Article 7.4:

– “Where the full cost of cross-border healthcare exceeds the level of costs that would have been assumed had the healthcare been provided in its territory the Member State of affiliation may nevertheless decide to reimburse the full cost.”
Which healthcare is subject to prior-authorisation?

Article 8.7:

“The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive, as well as all relevant information on the system of prior authorisation.”
Recital 21

- Inflows of patients may create a demand exceeding the capacities existing in a Member State for a given treatment. In such exceptional cases, the Member State should retain the possibility to remedy the situation on the grounds of public health.
Thank you.
Recital 16

- For the purpose of reimbursing the costs of cross-border healthcare, this Directive should cover not only the situation where the patient is provided with healthcare in a Member State other than the Member State of affiliation, but also the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service.

- The definition of cross-border healthcare should cover both the situation in which a patient purchases such medicinal products and medical devices in a Member State other than the Member State of affiliation and the situation in which the patient purchases such medicinal products and medical devices in another Member State than that in which the prescription was issued.
Patients should enjoy a guarantee of assumption of the costs of that healthcare at least at the level as would be provided for the same healthcare, had it been provided in the Member State of affiliation. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevent any significant effect on the financing of the national healthcare systems.
Eurordis follow-up of the Directive elaboration

- Analysis of ECJ jurisprudence by staff
  - + internship student in law
- Our position (EPAC, BOD)
  - No prior authorisation
  - No pre-payment
  - No regression compared to ECJ rulings

- EURAPDIS proposes amendments (Prior authorisation, except for RD): accepted

- 02/2011: adopted!
- MS opposed to exception for RD
- Prior Authorisation will de facto remain
- Obligation for patients to pay up-front
- MS opposed to the participation of stakeholders in HTA

- EURAPDIS response to public consultation: Position Paper
- No prior authorisation
- No pre-payment
- No regression compared to ECJ rulings

- EP 02/02/09
- Suppression of exception for RD
- blocking minority of Spa, Hun, Pol, Por, Gre and Rom
- Cost of pensioners from northern EU who retire in southern EU

- EP 26/02/09
- Suppression of exception for RD
- Blocking minority of Spa, Hun, Pol, Por, Gre and Rom
- Cost of pensioners from northern EU who retire in southern EU

- EP 24/04/09
- PSE abstained
- Red line crossed: Art. 152 of Treaty, not only Art. 95
- If no Prior Authorisation = Health no longer a national competence
- Exception for RD: back!
- (PermRep UK)