The Directive on Patients' Rights and Challenges for Implementation

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Structure

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Overview of ECJ Rulings I

- Directive 1408/71 (new 883/2004):
  - *EU citizens have a right to emergency treatment (EHIC)*
  - *Planned treatment with prior authorization (E112)*

- ECJ cases go beyond these possibilities

- 1998: Kohll-Decker rulings: Luxemburg, orthodontic treatment in Germany (Kohll) and spectacles from Belgium (Decker):

  Planned ambulatory care EU wide, home tariff reimbursed

- 2001: Vanbraekel / Smits-Peerbooms: Belgium/Netherlands, orthopedic treatment in France (waiting time) / Parkinson treatment in Austria

  Reimbursement for inpatient care, prior-authorization, medical necessity

Overview ECJ Rulings II

- 2003: Müller-Fauré / Van Riet: Netherlands

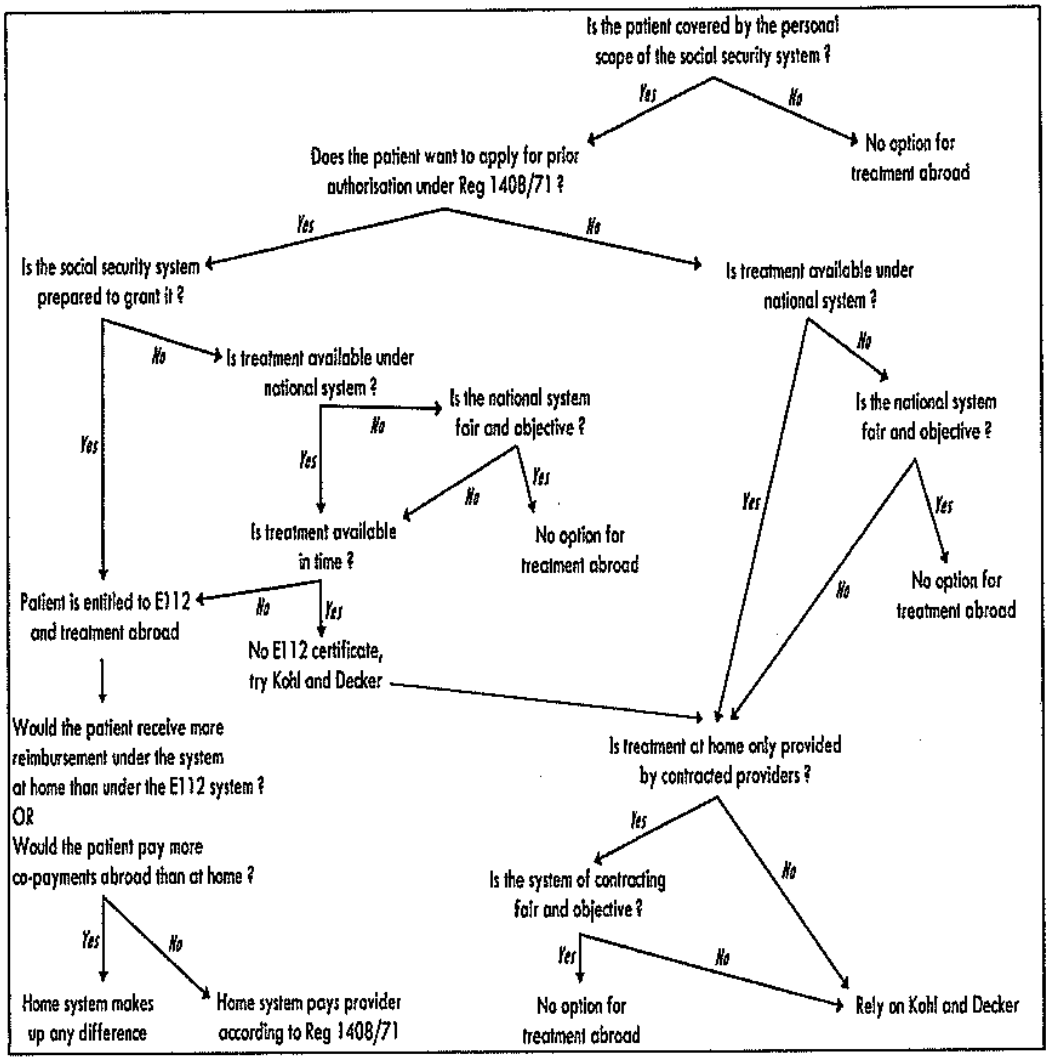
  Confirmation of Prior authorization for hospital treatment

- 2006: Watts: UK, hip replacement in France

  "Undue Delay" and application to NHS systems

- General concerns of Member States and potential impact :
  - potential loss of national control over patients / definition of illness
  - non discrimination of healthcare providers (quality)
  - Lack of definition (medical necessity, undue delay, inpatient/outpatient care)
  - Lack of information
  - Financial problems: viability of national control mechanisms

The system of the Rulings and Regulation 1408/71 (883/2004)



- Source: Nickless(2002), p. 78

Necessity of a Codification

- Various forms of implementation and non-implementation of ECJ rulings
- Negotiations of the Directive proved to be quite difficult, took several years
- Failed attempt of insertion in “Bolkestein” Directive (2005/2006)
- Member State views differed considerably:

  Belgium, Netherlands and Sweden in favour

  Eastern countries and smaller states against

  Many Member States for clarification of definition (EU-wide vs. national)
- Need to create legal certainty for Member States and patients

The Directive on Patients' Rights

- 2007: First proposal, withdrawn by Commission
- 2008: New Directive proposal
- 2009: Failure of negotiations
- 2011: Passing of Directive 2011/24/EU

- *Result*:
- Directive of 21 pages, with 64 recitals trying to clarify the aims and limits of the Directive
- Chapter 1: General Provisions
- **Chapter 2: Responsibilities of Member States**
- **Chapter 3: Reimbursement of Costs**
- Chapter 4: Cooperation in Healthcare
- Chapter 5: Implementing Provisions:

Key Points of the Directive I

- ***Overall, the Directive codifies the rulings and thus clarifies their application in all Member States***
  - ***delineation hospital / ambulatory care***
  - ***Obligation for objective and clear prior authorization procedure***
  - ***Criteria for refusal of prior authorization***
- ***Chapter 1: General Provisions***
- Definition of healthcare, Member State of affiliation, Member State of treatment

Key Points of the Directive I ct'd

- **Chapter 2: Responsibilities of Member States**
- **Information and contact points**

- National Contact Points must provide information

- The Member State of treatment must inform foreign patients about quality standards applied to providers (Art. 4.2°)

- Providers must inform patients with all "relevant information" to make an informed choice

- Providers are not obliged to give more information to foreign patients than they do nationally (Art. 4.2°b)

Challenges for Implementation I

- ***Information points and content of information***
  - One the most difficult issues for implementation of the Directive
  - Large difference between MS regarding available information
  - Fragmentation of nationally available data
  - Where? (central or regional; existing or new institution)
  - What kind of information? Translation issues?
  - How much information? Liability?
  - Adequacy of information for patients
  - Objectivity of information by providers (“informed choice”)?

Key Points of the Directive II

- ***Chapter 3: Reimbursement of Cross-border healthcare***
- Member State of affiliation must reimburse costs for cross-border treatment if the treatment is among the benefits at home (without prejudice to Regulation 883/2004) (Art. 7.7°), exception: hospital treatment
- But MS of affiliation may impose the same conditions and formalities as for the healthcare on its own territory
- Limits: overriding goals of general interest (planning, waste of resources)
- Member States must ensure that providers apply same tariffs for foreign patients as for home patients (Art. 4.4°) and provide clear invoices (Art. 4.2°)

Challenges for Implementation II

- **Reimbursement requirements**
- How to issue a bill to a foreign insurance fund?
- Reimbursement also available to private providers: inequality for those who stay at home?
- What kind of invoices would be acceptable?
- (Hidden) Supplements by private providers? Creative billing?
- Problematic calculation of costs for some hospital treatments (inclusion of tax financed costs / infrastructure…)

Key Points of the Directive III

- ***Chapter 3: Prior authorization procedures***
- Treatment in another MS that is subject to prior authorization (Art. 8), list of treatments must be made publicly available
- Includes also treatment
  - that needs an overnight stay (hospital) or
  - involves cost-intensive medical infrastructure or
  - Involves a risk for the patient or the population
  - Provided by a provider who gives rise to quality concerns
- Refusal possible: treatment possible at home (medically justifiable), concerns on standards/quality
- Art. 9: Procedure must be objective and non-discriminatory, individual

Challenges for Implementation III

- ***Prior authorization procedure***
- Who should check quality and security abroad?
- How to check quality abroad of a provider?

Further elements of the Directive…

- ***Dual existence with Regulation 883/2004***
  - Test still necessary if Regulation or Directive applies
- ***Obligation of Member State cooperation***
- ***Inflow control is possible (measures must be proportionate and necessary)***
- ***Creation of European Reference Networks***
- ***Acceptance of Prescriptions***

Practical impact

- ***Practical Simulation of the Implementation in Nov. 2011, organized by OSE, EHMA and AIM in Brussels***
- ***Results (Baeten, Jelfs 2012):***
- Patients will most probably always apply for prior authorization to be on the “safe side”
- Rules on quality and safety checks might not be applied
- Burden of proof for invoices will be on the patient (providers don’t want to adapt their bills to foreign insurers)
- Patients rather expect advice than “information” / Insurers reluctant on information regarding quality abroad

Conclusion

- ***Directive codifies ECJ rulings and clarifies several points:***
  - Duties of Member States
  - Criteria for authorization procedure
  - Difference between ambulatory care and hospital/inpatient care etc.
  - Criteria for control on reimbursement, inflow control
- ***Adds new aspects***
  - Information rights
  - Duty of Cooperation between States
- ***Implementation issues remain significant (information, reimbursement requirements)***
- ***Impact for patients ? Impact for systems?***