



Building a Framework for Cross-Border Healthcare in the European Union: Background and Future Perspectives

**Expert Seminar on the Draft Patients' Rights Directive
Brussels, 29 September 2010**

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Defining concepts and principles

- Health tourism
- Medical travel
- Patient mobility
- Cross-border care

- Territoriality principle
- Subsidiarity principle
- Free movement principle

- *The freedom to provide services includes the freedom for persons to receive medical treatment in another Member State (cf. Luisi and Carbone 1984)*
- *Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices (art. 35 Charter of fundamental rights of the EU)*
- *Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them (art. 168.7 Treaty on the Functioning of the European Union)*

Cross-border care and social security coordination (Regulations 883/04 and 987/09)

Modernised
coordination
since 1 May 2010



- People becoming «patients» when abroad (occasional care)
 - Care becoming necessary on medical grounds during a temporary stay taking into account nature of the benefits and expected length of stay
 - Incl. chronic care while abroad (e.g. LT residents)
- Patients crossing for care (planned care)
 - Convenience (proximity, familiarity)
 - Dissatisfaction with or deficiencies in home state system
 - Guided by external (f)actors (health tourism, attractive prices, internet, referral, contract)
- Limitations
 - Many practical problems (distinction between planned and occasional care, application limited to public/contracted providers, acceptance of the EHI card, additional payments if tariffs are higher in home state, etc.)
 - Member States generally maintain restrictive authorisation policies

Prior authorisation
required - E112

Modernised social security coordination (Regulations 883/04 and 987/09)

- Previously: Regulation 3/58 and 1408/71
- Basic principles of social security coordination
 - Statutory cover for healthcare outside the state of affiliation (insurance) under certain conditions according to the legislation of the state of stay (treatment) « *as if the person was insured there* » at the expense of the former
 - Refund by the competent state on the basis of actual cost, except if agreed otherwise (waiver, claim compensation, etc.) or on the basis of fixed amounts (for pensioners and family members residing outside the competent state)
- Key elements of modernisation
 - Extension to 3rd country nationals (2003)
 - Introduction of the European health insurance card (EHIC) (2004)
 - Temporary stay: « immediate » → « necessary » care
 - Extended rights for pensioners and frontier workers
 - Prior authorisation: undue delay (medically justifiable time limits)
 - Electronic exchange of social security information (EESSI)
 - Reinforced duty of information to citizens about rights

« From Kohll & Decker to Watts ... » (ECJ 1998-2010))

- C-120/95 (*Decker*) and C-158/96 (*Kohll*)
- C-368/98 (*Vanbraekef*)
- C-157/99 (*Geraets-Smits and Peerbooms*)
- C-385/99 (*Müller-Fauré and Van Riet*)
- C-326/00 (*Ioannidis*)
- C-56/01 (*Inizan*)
- C-496/01 (*Commission/France*)
- C-08/02 (*Leichtle*)
- C-145/03 (*Keller*)
- C-372/04 (*Watts*)
- C-466/04 (*Acereda Herrera*)
- C-444/05 (*Stamatelaki*)
- C-211/08 (*Commission/Spain*)



Treaty-based procedure (ECJ)

- Right to seek treatment in another Member State and claim reimbursement as if care was delivered in Member State of affiliation (irrespective of the type of system which subsequently will reimburse the costs).
- Prior authorisation prevents or deters patients to purchase health care abroad (Art. 56 TFEU - ex-49 ECT)
- Prior authorisation can only be justified for hospital care (subject to planning)
 - can not be used arbitrarily. It must be based on objective, non-discriminatory criteria, known in advance.
 - can not be refused if the same or equally effective treatment is statutorily covered in the state of affiliation and can not be obtained there in a contracted establishment within medically justifiable time-limits (undue delay) in the light of the patient's particular condition and clinical needs (Smits-Peerbooms; Van Riet; Watts)



Free movement of services and E112

- **Prior authorisation under Art. 20 Reg. 883/04 is consistent with article 56-57 TFEU:** it grants more beneficial rights to cross-border patients which they would otherwise not have (i.e. cover according to the legislation of the state of treatment) (Inizan)
- If coverage under Reg. 883/04 for patients who have been authorised to get treatment in another Member State turns out to be lower than reimbursement at home, an **additional reimbursement** covering the difference must be granted (as it could discourage people from applying for authorisation, hence restricting the free movement of services) (Vanbraeckel)
 - If hospital treatment is provided free of charge, any user charge for the patient should be additionally covered, up to the difference between the cost, objectively quantified, of the equivalent treatment in the home state and the amount reimbursed pursuant to the legislation of the treatment state, with the total amount invoiced for the treatment received in the host Member State as a maximum (Watts).
 - This does **not** apply to unscheduled « EHIC » care during a temporary stay (Commission/Spain 2010)

The « Vanbraeckel supplement »

**MS of
affiliation**

€2800
(reimbursement)

€3500
(reimbursement)



**MS of
treatment**

€4000 (cost)

€4000 (cost)

€3200
(reimbursement)

€3200
(reimbursement)

€800 (user charge)

€800 (user charge)

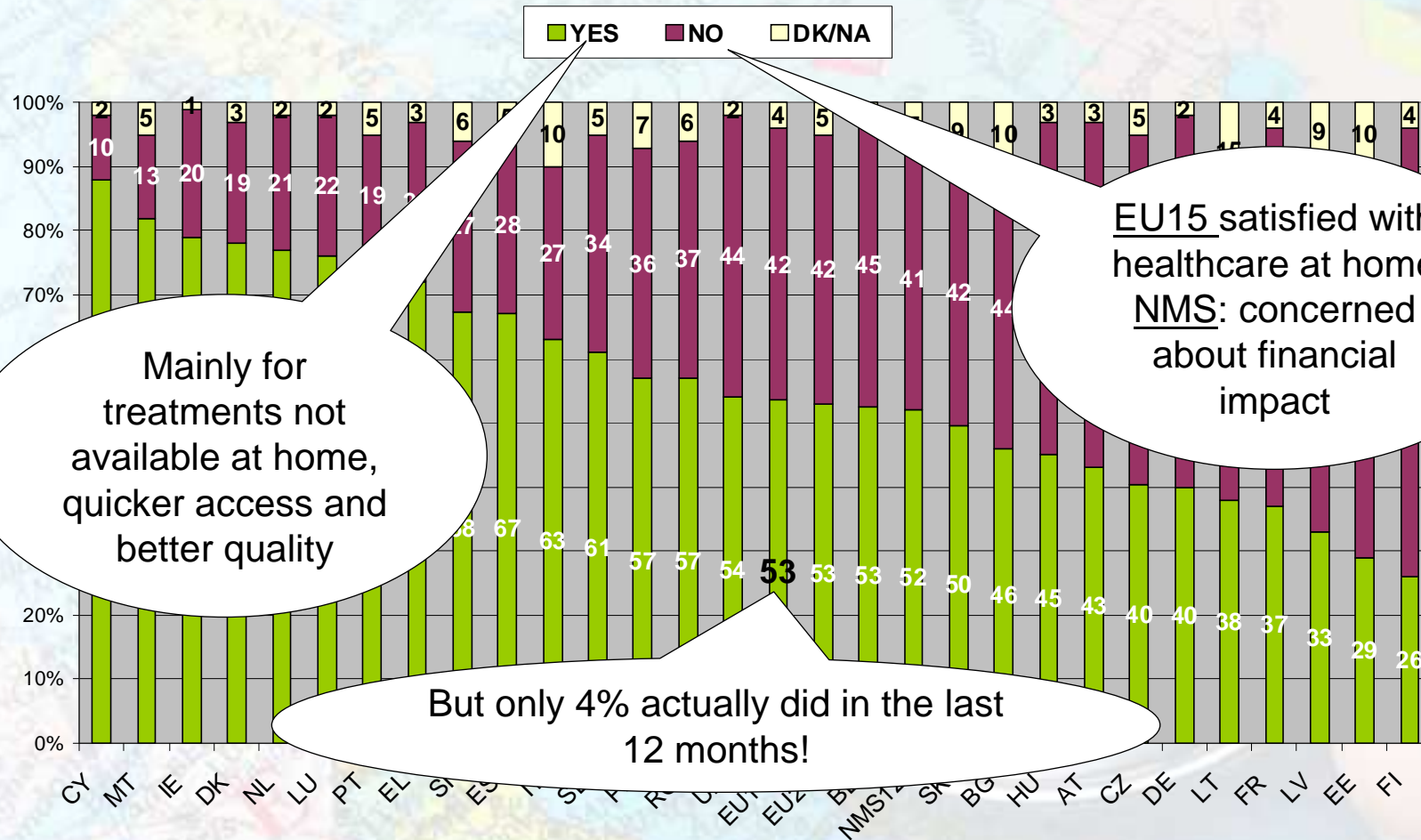
- **€300 (additional)**

Free movement of citizens	Free movement of services
<ul style="list-style-type: none"> • Art. 48 TFEU - Regulations 883/04 & 987/09 	<ul style="list-style-type: none"> • Art. 114 TFEU - Draft Directive
<ul style="list-style-type: none"> • <u>Reimbursement as if care was delivered to an insured person of the MoT*</u> <ul style="list-style-type: none"> – Additional compensation payment for pre-authorized care if reimbursement level in MoA** is higher (Vanbraekel, Watts) – Formalities and conditions of MoT* apply 	<ul style="list-style-type: none"> • <u>Reimbursement as if care was delivered to an insured person in the MoA**</u> <ul style="list-style-type: none"> – Can not be higher than real payment – Obligation to develop a calculation mechanism – Formalities and conditions of MoA** apply for as long as they are necessary, proportional and non discriminatory
<ul style="list-style-type: none"> • Statutory coverage of cross-border treatment by MoA** subject to conditions <ul style="list-style-type: none"> – Care becoming medically necessary during a temporary stay in MoT* – Care which is part of the statutory benefit package in MoA** but cannot be delivered there within medically justifiable time-limits (undue delay) 	<ul style="list-style-type: none"> • Statutory coverage of cross-border treatment by MoA** NOT subject to prior authorisation, except for <ul style="list-style-type: none"> – care subject to planning involving overnight hospital stay or highly specialised and cost intensive infrastructure or equipment – Treatment with particular risk for patient or population or concerns over quality and safety
<ul style="list-style-type: none"> • Priority if conditions for prior authorisation are met • MoA** allowed to widen conditions for prior authorisation to other situations 	<p>* MoT = Member State of treatment ** MoA = Member State of affiliation</p>

What do we (already) know...?

- Cost of cross-border care is marginal but on the rise
- Detailed and consistent data are lacking
- Patient mobility routes
 - Traditional (social security) coordination route
 - Treaty-based route (based on the ECJ jurisprudence)
 - Contractual route
 - Private patient route
- Need to re-establish coherence and clarity in the entitlements to cross-border care
- Court rulings have indeed had an effect on Member States (tackling domestic problems)
- Debate has changed: not only reimbursement, also broader conditions

Would you be willing to travel to another EU country to receive medical treatment?



Mainly for treatments not available at home, quicker access and better quality

EU15 satisfied with healthcare at home
NMS: concerned about financial impact

But only 4% actually did in the last 12 months!

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Different responses by the Member States

- Complete denial
- Fear for reaction of domestic contracted as well as non-contracted providers Avoiding litigation and reimbursing without legal ground
- Easening authorisation policies
- Addressing national deficiencies (e.g. waiting lists)
- Slight and progressive adaptation
- Reforming the system (e.g. optional reimbursement system)
- Cross-border contracting (e.g. border regions)

Milestones in the more than 10 years debate on free movement of health services

- | | | | |
|------|---|------|--|
| 1998 | First rulings Kohll & Decker | 2006 | Commission draft Regulation implementing Reg. 883/04
<u>Exclusion of health services from the Services Directive</u>
Watts ruling |
| 2001 | Smits-Peerbooms rulings | | |
| 2002 | Revision of the sickness benefits chapter of Reg. 1408/71 on social security coordination | | |
| 2003 | Müller-Fauré/van Riet ruling
Report on the application of internal market rules to health services
High level reflection process on patient mobility and healthcare developments in the EU | | Council Statement on common values and principles in EU health systems |
| 2004 | Commission proposal on services in the internal market
Creation of the high level group on health services and medical care
Adoption of Reg. 883/04 on social security coordination
Introduction of the European Health Insurance Card | 2007 | EP report on the impact of the exclusion of health services from the Services Directive
Consultation process on Community action on health services |
| 2005 | EP Report on patient mobility | 2008 | Adoption of the new proposal by the College of Commissioners |
| | | 2009 | Adoption of implementing Reg. 987/09 on social security coordination
First reading in EP |
| | | 2010 | Council adopts common position
Second reading in EP |

Proposal for a Directive on the application of patients' rights in cross-border healthcare

3 Sections

1. Defining the responsibilities of respective Member States (*information, quality, rights*)
2. Rules on reimbursement of care in other Member State
3. Cooperation between Member States

Legislative process

- Proposal by the Commission (*July 2008*)
- European Parliament first reading (*April 2009*)
- Council: Common position (*June 2010*)
 - following discussion under Presidencies of France (*2008*), Czech Republic (*2009*), Sweden (*2009*), Spain (*2010*)
- European Parliament: Draft report second reading (*8 Sept. 2010*)
- Commission position on Council position (*20 Sept. 2010*)

Legislative process: expected next steps

- European Parliament ENVI Committee, second reading (28 Oct.)
- Trilogy EP, Council, Commission, European Parliament
- European Parliament: plenary vote in second reading (17 jan 2011)

Comparison of the 3 texts

- Scope
- Legal basis
- Responsibilities of Member States
- Rules on reimbursement of care
- Cooperation on health care
- Comitology procedure

Comparing positions

Commission	EP first reading	Council
<ul style="list-style-type: none"> •Perspective of the provider and consumer •Internal market, free movement, free choice 	<p>Perspective of (mobile) Patient :</p> <ul style="list-style-type: none"> •Limit the financial burden for patients •Information provision 	<ul style="list-style-type: none"> •Perspective of healthcare system, management, financial viability, quality control •Patients who stay at home
<ul style="list-style-type: none"> •Harmonisation, compulsory cooperation 		<ul style="list-style-type: none"> •Subsidiarity, no harmonisation •Voluntary cooperation and exchange

Scope

Commission	EP first reading	Council
Health care •services	<i>Also: medical products</i>	<i>Also: medical products</i>
	<i>Not: Organ transplantation</i>	<i>Not: Organs (allocation and access)</i>
	<i>Not: Long term care</i>	<i>Not : Long term care</i>
		<i>Not Vaccination programmes</i>

Legal basis

Commission	EP first reading	Council
Art 95 EC, now 114 TFEU <i>(internal market)</i>	Art 95 EC, now 114 TFEU	Art. 114 <i>And</i> Art. 168 TFEU <i>(public health)</i>

Responsibilities of MS of treatment

Commission	EP first reading	Council
<ul style="list-style-type: none"> • <i>Obligation</i> for quality and safety standards (COM supervises) • <i>Q and S monitored</i> 	<ul style="list-style-type: none"> • <i>Obligation</i> for quality and safety standards • Information on Q and S 	<ul style="list-style-type: none"> • Quality and safety standards <i>as set by MS</i> • Information on Q and S to patients • Exchange of info on Q and S between MS
Information by providers on availability, prices, ..	Information by providers to allow informed choice	Information by providers on availability, pricing,... <i>as for domestic patients</i>

Responsibilities of MS of treatment

Commission	EP first reading	Council
Systems for complaints, redress, professional liability	Similar	Similar
Privacy and personal health data protection	Similar	Similar
Equal treatment between EU citizens	<ul style="list-style-type: none"> •Added •Priority to domestic patients possible 	<ul style="list-style-type: none"> •Similar, focus on prices •Instruments to protect domestic patients

Responsibilities of MS of treatment

Commission	EP first reading	Council
Guidelines by COM for implementation	Similar	Deleted
	Transparent mechanism for cost calculation	

Responsibilities of MS of affiliation

Commission	EP first reading	Council
<ul style="list-style-type: none"> • Help patients to protect their rights and seek appropriate redress (NCP) 	<ul style="list-style-type: none"> • Redress 	-
<ul style="list-style-type: none"> • Information on entitlements and conditions, including when harm is caused and on quality and safety (NCP) 	<p><i>MS of aff. and of treatment</i></p> <ul style="list-style-type: none"> • Information on quality and safety norms, in accessible languages 	<ul style="list-style-type: none"> • Information on rights and reimbursement conditions (NCP)
<ul style="list-style-type: none"> • Access to medical record 	<ul style="list-style-type: none"> • Ensuring continuity of care and transfer of medical file (<i>MS of aff. and treatment</i>) 	<ul style="list-style-type: none"> • Access to copy of medical record

Responsibilities of MS of affiliation

Commission	EP first reading	Council
<ul style="list-style-type: none">•Mechanism for calculation of reimbursement tariffs	Similar	Similar


Rules on reimbursement

Commission	EP first reading	Council
<p>Reimbursement level and conditions of MS of affiliation</p> <ul style="list-style-type: none"> -Same or similar care -not discriminatory conditions 	<p>Reimbursement level and conditions of MS of affiliation</p> <ul style="list-style-type: none"> -<i>equally effective</i> care -not discriminatory conditions 	<p>Reimbursement level and conditions of MS of affiliation</p> <ul style="list-style-type: none"> -No specifications
		<p>Care for returning migrant pensioners paid by MS paying for the pension</p>

Rules on reimbursement

Commission	EP first reading	Council
	<p>Reimbursement of treatments for rare diseases</p> <ul style="list-style-type: none">•outside benefit package•Without prior authorisation	
	<p>European Ombudsman (Com: network of national ombudsman)</p>	

Prior authorisation system

Commission	EP first reading	Council
<ul style="list-style-type: none"> •Hospital care (overnight stay) •Care on a list defined by COM <ul style="list-style-type: none"> –Highly specialised –Presenting particular risks 	<ul style="list-style-type: none"> •No list defined by COM •Defined by MS 	<p>Care needing planning:</p> <ul style="list-style-type: none"> •With overnight stay •Highly specialised •Presenting particular risks <p>As defined by the MS</p>
<p>If evidence shows that outflows are likely to seriously undermine:</p> <ul style="list-style-type: none"> •financial balance of social security system <p> Ose Planning Observatory</p>	<p>If outflows could seriously undermine...</p>	<ul style="list-style-type: none"> •No concrete request to demonstrate risks

Prior authorisation system

Commission	EP first reading	Council
Necessary and proportionate	Similar	Similar
Conditions for refusal <ul style="list-style-type: none">•transparent	Similar, If authorisation, up front payments limited	Non exhaustive list of criteria <ul style="list-style-type: none">•No undue delay•Health risks•Doubts about care providers

Prior authorisation/notification

Commission	EP first reading	Council
	<p>If prior authorisation has been granted</p> <ul style="list-style-type: none">•Direct payment from purchaser to provider•Request for prior authorisation is a right•Limited top up payments?	

Relation to regulation 883/2004

Commission	EP first reading	Council
Patient may choose for planned care	Regulation has priority for planned care	Regulation has priority for planned care

Cooperation on health care

- Basic duty of mutual assistance
- Specific areas:
 - Mutual recognition of medical prescription
 - European reference networks
 - ICT and e-health
 - HTA
 - (Data collection and monitoring)

Cooperation on health care

Commission	EP first reading	Council
Basic duty of mutual assistance	Added: exchange of information on disciplinary and criminal findings against health professionals	Similar

Cooperation on healthcare

Commission	EP first reading	Council
Cross border medical prescriptions <ul style="list-style-type: none">•COM adopts measures to verify authenticity and identification	Similar	Adds specifications e.g. on compliance costs
European reference networks (ERN) <ul style="list-style-type: none">•COM adopts list with criteria that networks must fulfill	Similar	<ul style="list-style-type: none">•Voluntary participation•Criteria to receive COM support•No harmonisation

Cooperation on health care

Commission	EP first reading	Council
E-health <ul style="list-style-type: none">•COM adopts measures for interoperability	<ul style="list-style-type: none">•Similar•Includes issues on telemedicine	<ul style="list-style-type: none">•Com supports MS•Com draws up guidelines on<ul style="list-style-type: none">–lists for patient summary–Use of medical data–Identification and authentication

Cooperation on health care

Commission	EP first reading	Council
<p>Health Technology Assessment Network (compulsory) of national bodies</p> <ul style="list-style-type: none"> •Provision and exchange of information •Led by COM 	<ul style="list-style-type: none"> •Adds stakeholder participation; rewarding innovation in medicines; 	<ul style="list-style-type: none"> •Voluntary •Union supports and facilitates (including financially)
<p>Data collection on Cross border care</p> <ul style="list-style-type: none"> •To be transmitted to COM •COM adopts implementation measures 	<p>Similar</p>	<p>Deleted</p>

Committee

Commission	EP first reading	Council
<ul style="list-style-type: none">•MS representatives•Chaired by COM	Similar	•Similar
<ul style="list-style-type: none">•List of treatment assimilated to hospital care•List medicinal prescriptions•Criteria for reference networks•NCP implement		•Reduced delegated tasks (not on e-prescriptions, e-health, HTA, ERN)

Conclusions

- Important progress in the debates
- Still important divergences in the positions
 - Prior authorisation for hospital care
 - Powers of the Commission (delegation)
 - Quality and safety standards
 - Responsibilities of respective MS in information provision and redress
- Directive will not be an end, but a step in a continuous process