The New Directive on the Application of Patients’ Rights in Cross-Border Care

Regional Conference on health insurance - Sarajevo, 6 July 2011

Willy Palm
Dissemination development Officer
A partnership that reflects evidence-based policy-making

• **International agencies**
  - WHO Regional Office for Europe, the European Commission, the European Investment Bank, the World Bank

• **National and regional authorities**
  - Belgium, Finland, Netherlands, Norway, Spain, Sweden, Slovenia, Veneto Region, French Union of health insurance funds (UNCAM)

• **Academia**
  - the London School of Economics and Political Science (LSE), the London School of Hygiene & Tropical Medicine (LSHTM)
Health as part of EU policy

- **The Roman period (1951-1986)**
  - Health as a ‘quarantine’ provision
  - Health as an adjunct to the single market (free movement of workers, professionals, goods, occupational health and safety)

- **The Middle Ages (1986-1997)**
  - President Mitterand’s secret – Dr. Tubiana (Europe against cancer 1988)
  - HIV/AIDS pandemic (Europe against AIDS 1991)
  - Maastricht Treaty (1992): public health article (Art. 129) → 8 public health programmes

- **The Enlightenment (1997-2009)**
  - Amsterdam Treaty: (Art. 152) binding legislation; health strategy
  - Open Method of Coordination (OMC) to include health and LT care
  - Health services as part of the internal market (ECJ rulings)

- **The Modern Age (2009- )**
  - Treaty of Lisbon (Art. 168) broadening scope
  - Pharmaceuticals and medical devices → public health
  - Charter of Fundamental Rights: right to healthcare (Art. 35)
  - Patients’ rights Directive on cross-border health care

Source: B. Merkel (2010)
Health systems in the EU – common values and principles but different health priorities and backgrounds

• A model or approach to healthcare provision
  – Based on common values: universality, access to good quality care, equity, solidarity, patient-centredness and responsiveness
  – Distinguishing healthcare from a normally traded good or service
  – Common operating principles: quality, safety, evidence-based medicine, ethics, patient involvement, redress, privacy and confidentiality
  – Faced with common challenges
    • Ensuring financial sustainability and efficiency in the face of demographical evolution, medical and technological progress, economic downturn, changing needs and expectations, etc.

• EU Member States have chosen different ways to organise their health systems reflecting different social and economic backgrounds as well as varying health policy goals
  – Differing interpretations about the legitimacy of regulation, incentives and other levers (i.e. market forces, choice) to bring about change
  – But health systems increasingly get interconnected => there is value in collaborating, sharing experience and information

• EU Member States explicitly stated that equitable, effective and high quality healthcare systems are a means of promoting both economic growth and social cohesion in the EU
  – But for that steering capacity is essential!
Cross-border care: defining concepts and principles

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

- Territoriality principle
- Subsidiarity principle
- Free movement principle

- 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)

- The freedom to provide services includes the freedom for persons to receive medical treatment in another Member State (cf. Luisi and Carbone 1984)
Internal market: a double dynamic

- Positive integration
  - EU Harmonisation (secondary legislation)
    - Directive 36/2005 on the recognition of professional qualifications
    - Regulation 883/04 on the coordination of social security systems
    - Third non-life insurance Directive 49/92
    - Transparency Directive 89/105 on the pricing and reimbursement of medicinal products

- Negative integration
  - Deregulation: remove unjustified restrictions and distortions (direct application of Treaty rules)
Free movement of healthcare services

• Health care is considered an economic activity (transaction against remuneration) falling under the scope of free movement. The specific nature of (statutory) health care does not remove it from this ambit.

• Although the EU respects MS responsibilities to organise health care, MS have to comply with EC obligations. Any measure that would prevent or deter – citizens from applying to providers – providers from offering their services in another MS, is an obstacle to free movement

• Impediments to free movement can be justified if they prove to be necessary and proportional to achieve a public interest objective
  – Public health protection (art. 46.1 EC)
  – Sustainability of social protection systems (rule of reason)
Social security (health care) does not constitute an island beyond the reach of Community law (AG Tesauro 1998)

• The island mentality in health
  – Health is different
  – The health sector is different
  – Our (national) health system is different (better)
  – Our healthcare providers are different (better)
Fear for the EU creep

- Indirect (creeping) impact of EU integration seems to be more important than direct policies in the field of health and social protection

- The health paradox! Caught between subsidiarity and « negative » integration

Based on R. Baeten and B. Vanhercke
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)
Would you be willing to travel to another EU country to receive medical treatment?

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

Source: Eurobarometer 2007
For which of the following reasons would you travel to another EU country to receive medical treatment?

- To receive treatment that is not available in [COUNTRY]: 91%
- To receive better quality treatment than at home: 78%
- To receive treatment from a renowned specialist: 69%
- To receive treatment more quickly than at home: 64%
- To receive cheaper treatment than at home: 48%

For which of the following reasons would you not travel to another EU country to receive medical treatment?

- It is more convenient to be treated near my home: 86%
- I am satisfied with the health care I can receive at home: 83%
- I have not enough information about the availability and quality of medical treatment abroad: 61%
- For language reasons: 49%
- I cannot afford it to receive medical treatment abroad: 47%
Main focus for cross-border care

- Smaller countries / Border regions
- High mobility areas (tourist zones) / Pensioners
- Rare diseases and high-tech services (reference centers and networks)
- Long waiting times
- Treatments with high user charges (e.g. dental care)
- Well-informed and mobile citizens
- Ethically controversial treatments
- Telemedicine
### The road to the Directive of 9 March 2011 on the application of patients’ rights in cross-border healthcare

#### Milestones 1998-2011

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1998</td>
<td>First rulings Kohll &amp; Decker</td>
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<td>2001</td>
<td>Smits-Peerbooms rulings</td>
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<td>2002</td>
<td>Revision of the sickness benefits chapter of Reg. 1408/71 on social security coordination</td>
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<td>2003</td>
<td>Müller-Fauré/van Riet ruling</td>
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<td>2004</td>
<td>Report on the application of internal market rules to health services</td>
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<td>2004</td>
<td>High level reflection process on patient mobility and healthcare developments in the EU</td>
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<td>2005</td>
<td>Commission proposal on services in the internal market</td>
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<td>2005</td>
<td>Creation of the high level group on health services and medical care</td>
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<td>2006</td>
<td>Adoption of Reg. 883/04 on social security coordination</td>
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<td>2006</td>
<td>Introduction of the European Health Insurance Card</td>
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<td>2007</td>
<td>EP report on the impact of the exclusion of health services from the Services Directive</td>
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<td>2007</td>
<td>Consultation process on Community action on health services</td>
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<td>2008</td>
<td>Adoption of the new proposal by the College of Commissioners</td>
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<td>2009</td>
<td>Adoption of implementing Reg. 987/09 on social security coordination</td>
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<td>2010</td>
<td>First reading in EP</td>
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<td>2010</td>
<td>Monti Report on Single Market Commission/France ruling</td>
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<td>2010</td>
<td>Council adopts common position</td>
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<td>2011</td>
<td>Second reading in EP</td>
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<td>2011</td>
<td>Adoption of the Patients’ rights Directive</td>
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## Comparing positions

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<th>Commission</th>
<th>Parliament</th>
<th>Council</th>
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<tr>
<td><strong>Perspective of the provider and consumer</strong>&lt;br&gt;Internal market, free movement, free choice</td>
<td><strong>Perspective of (mobile) patient:</strong>&lt;br&gt;Perspective of healthcare system, management, financial sustainability, quality control&lt;br&gt;Patients who stay at home</td>
<td><strong>Perspective of</strong>&lt;br&gt;Subsidiarity, no harmonisation&lt;br&gt;Voluntary cooperation and exchange</td>
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<td><strong>Harmonisation, compulsory cooperation</strong></td>
<td><strong>Limit the financial burden for patients</strong>&lt;br&gt;Information provision</td>
<td><strong>Subsidiarity, no harmonisation</strong>&lt;br&gt;Voluntary cooperation and exchange</td>
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Directive on the application of patients’ rights in cross-border healthcare

Aims
• Provide more legal certainty about rights and entitlements to care in another Member State
• Facilitate access to safe and high-quality cross-border healthcare
• Promote cooperation on healthcare between Member States
• (In full respect of the national competencies in organising and delivering healthcare)

Legislative process
• Proposal by the Commission (July 2008)
• Co-decision procedure
  – Revised draft adopted by the European Parliament (1st reading: April 2009)
  – EU Council Presidencies
    • France (2008)
    • Czech Republic (2009)
    • Sweden (2009)
    • Spain (2010): common position (June)
    • Belgium (2010)
    • Hungary (2011)
« old » vs. « new » patient rights in cross-border healthcare

Social protection (MS of affiliation)
- right to reimbursement of (planned) treatment abroad
  - As if treatment was received at home (country of affiliation)
- Alternative to the social security coordination Regulations 883/04 and 987/09
  - As if the person was insured in the country of treatment

Consumer protection (MS of treatment)
- Common operating principles (and structures to support them) that citizens would expect to find in any health system in the EU
  - Quality and safety standards
  - Informed (consumer) choice
  - Redress mechanisms and complaint procedures
  - Liability insurance or similar
  - Privacy and data confidentiality
  - Access to personal medical record
  - Non-discrimination
Reimbursement of cross-border treatment

- **What healthcare?**
  - services (excl. LTcare, organs, vaccination) provided by a health professional to assess / maintain / restore health
  - Provided or prescribed in a MS other than the MSoA
  - among the benefits to which the insured person is entitled in the MSoA

- **What patients?**
  - Persons insured under a social security or public health system

- **What conditions?**
  - Up to the level of costs that would have been assumed if it had been provided in the MSoA (without exceeding actual costs)
  - No price discrimination (same scale of fees)!
  - Same conditions, eligibility criteria, regulatory and administrative formalities apply (if not discriminatory and justified by planning requirements to ensure access or contain costs and avoid waste)
  - Prior authorisation only allowed for
    - care subject to planning involving hospital accommodation or use of highly specialised or cost-intensive medical infrastructure or equipment
    - treatments involving a particular risk for the patient or the population
    - providers raising serious concerns relating to quality and safety

So what about private (non-contracted) care and provider choice?
The quality and safety paradox

• Initial obligation to establish quality and safety standards reframed into obligation to inform (art. 4.2(a)) and duty to cooperate on Q&S standards and guidelines (art. 10.1) and exchange information on the right to practice (art. 10.4)

• Prior autorisation (reimbursement) can be refused if healthcare is provided by a provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions, whether these standards are laid down by laws and regulations or through accreditation systems established by the Member State of treatment (Art. 8.6(c))
The importance of information

- Role of national contact points
  - In treatment state: Q&S standards and guidelines, providers (right to practice), patient rights, redress mechanisms and complaints procedures
  - In affiliation state: rights and entitlements to cross-border care, incl. procedures
  - Language?
  - Collaboration and exchange

- Role of providers (informed choice):
  - treatment options, availability, quality and safety, prices/invoices, authorisation-registration status, professional liability insurance
  - Not more than for domestic patients

- Patients acting as informed consumers (choice, information) will push for performance assessment and comparison (independent broker?)

- What about information for policy-making?
The importance of cooperation

• Basic duty of mutual assistance and cooperation
  – Quality and safety
  – National contact points
  – Border regions
• Specific areas:
  – Mutual recognition of medical prescription
  – European reference networks
  – Rare diseases
  – e-health
  – Health technology assessment (HTA)
  – (Data collection and monitoring)
Cross-border care: some reflections

• After the adoption of the Directive, the challenge of its transposition!
• Although the Directive does not intend to foster XBC, it is likely to further expand.
• Legal uncertainty will continue to exist in domains beyond cross-border care (e.g. planning!)
• Member States will remain in control of their benefit baskets, however …treatment methods (cf. Elchinov ruling)
• The quality and safety paradox: towards European quality and safety standards?
• How to fit this approach with continuity of care, integrated forms of care and financing?
There are enormous potential benefits to be gained from integrating the European dimension into health. Europe’s health systems represent the greatest collective commitment to health anywhere in the world. Yet, though European health systems are all trying to do similar things, they do them in very different ways. **This makes Europe a giant “natural laboratory” for health systems, with enormous potential for countries to learn from each other.** European cross-border health care is the key to unlocking that potential, by facilitating the transfer of expertise and knowledge; by improving choice for patients; and by enabling greater efficiency in providing health care through cross-border cooperation. This is the real challenge of cross-border health care.

Nick Fahy
Head of Health Information Unit
DG Health and Consumer Protection
European Commission

- Access to services
- Benefit baskets and tariffs
- Quality and safety
- Patient rights
- Cross-border collaboration
- Impacts and data
Thank you for your attention

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Analysing Health Systems and Policies
<table>
<thead>
<tr>
<th><strong>Legal basis</strong></th>
<th><strong>Reimbursement</strong></th>
<th><strong>Applicable rules</strong></th>
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</table>
| **Regulations 883/04 & 987/09** | • Free movement of persons (Art. 48 TFEU) | • Prior autorisation required for all care  
  • Except for care becoming medically necessary during a temporary stay in MoT  
  • PA can not be refused if  
    • Care is part of the benefit basket  
    • Care cannot be delivered within medically justifiable time-limits (undue delay) | • Member state of treatment (MoT)  
  • « as if person was insured in MoT »  
  • Formalities and conditions of MoT apply  
  • MoA pays directly |
| **Directive 2011/24** | • Free movement of goods and services (Art. 114 TFEU) | • Prior autorisation not required, except for care  
  • subject to planning  
  • presenting a risk for patient/population  
  • Provider raising quality and safety concerns  
  • Insofar  
    • necessary and proportionate  
    • Transparent, non-discriminatory criteria  
    • Accessible procedures and reasonable delays | • Member State of affiliation (MoA)  
  • « as if person was treated at home »  
  • Formalities and conditions of MoA apply  
  • Patient advances cost and MoA reimburses  
  • Except: if conditions of Dir 883/04 are met, these rules apply |