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@Tapani_Piha

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#SIP2016action

Societal Impact of Pain (SIP) 2016
Brussels, 23 - 24 May 2016

Implementation of the Cross-Border Healthcare Directive and European Reference Networks



Tapani Piha

Head of Unit

Cross-Border Healthcare and eHealth

Health Systems, Medical Products and Innovation



Patients' rights in Cross-border Healthcare

Directive 2011/24/EU



A major step towards a Europe for Health



described as....

*“...the most significant and wide-ranging
European health legislation
in a generation.”*

- How to get healthcare services across borders
 - *Emergency care*
 - *Planned care*



The Regulations and the Directive (2011)

Regulations on coordination of social security schemes

- *Emergency treatment*
- *Prior authorisation for planned care*
- *Reimbursement between institutions*
- *Public providers only*



Directive on patients' rights in cross-border healthcare

- *Main rule: no prior authorisation*
- *Pay directly to the provider*
- *Reimbursement based on national tariffs*
- *Public and private providers and medicines*



Directive focuses on patients' rights & healthcare across the EU



Seeking healthcare in another EU Member State: your rights

Did you know?

You have the right to receive medical treatment in another EU Member State and the right to have your home country cover some or all of the costs.

You have the right to be informed about the treatment options open to you, how other EU countries ensure quality and safety in healthcare, and whether a particular provider is legally entitled to offer services.

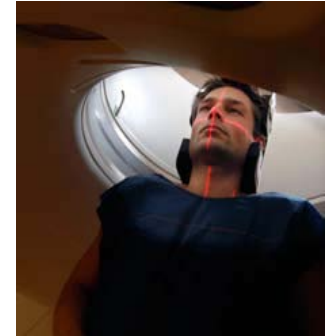
[Look inside to find out more...](#)

Health and Consumers

- **Right to choose and be reimbursed**, under certain circumstances, for healthcare provided by public or private providers located in the EU.
- **More transparency** about patients' rights, treatment options and, the quality and safety of healthcare providers
- **Cooperation** among Member States:



Cooperation between Health Systems and cross borders



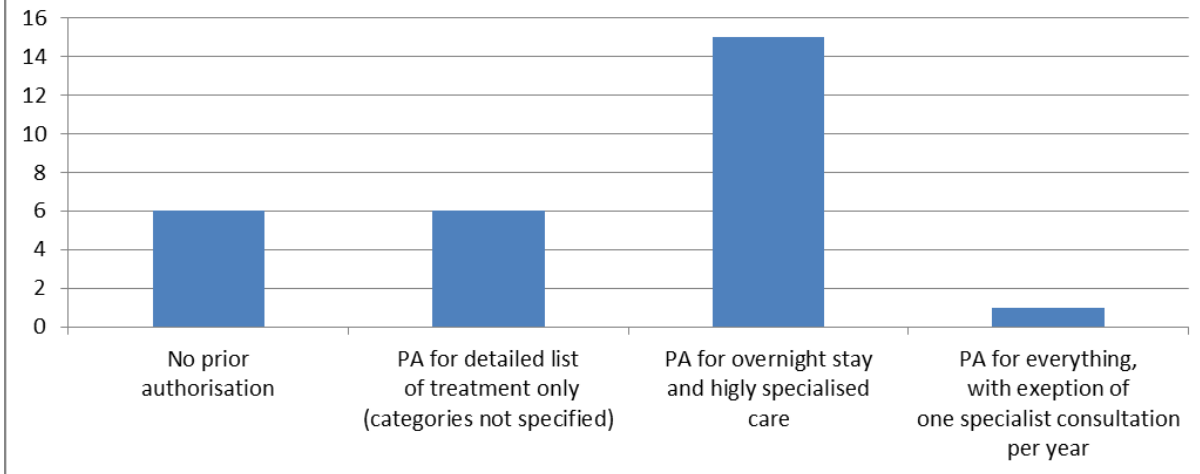
- Recognition of prescriptions
- Health Technology Assessment
- eHealth
- European Reference Networks
- Cross-border healthcare in border regions



Commission report on the operation of the Directive 2011/24 on the application of patients' rights in cross-border healthcare

Patient mobility - Prior Authorisation (PA)

Use of prior authorisation
(number of MS)

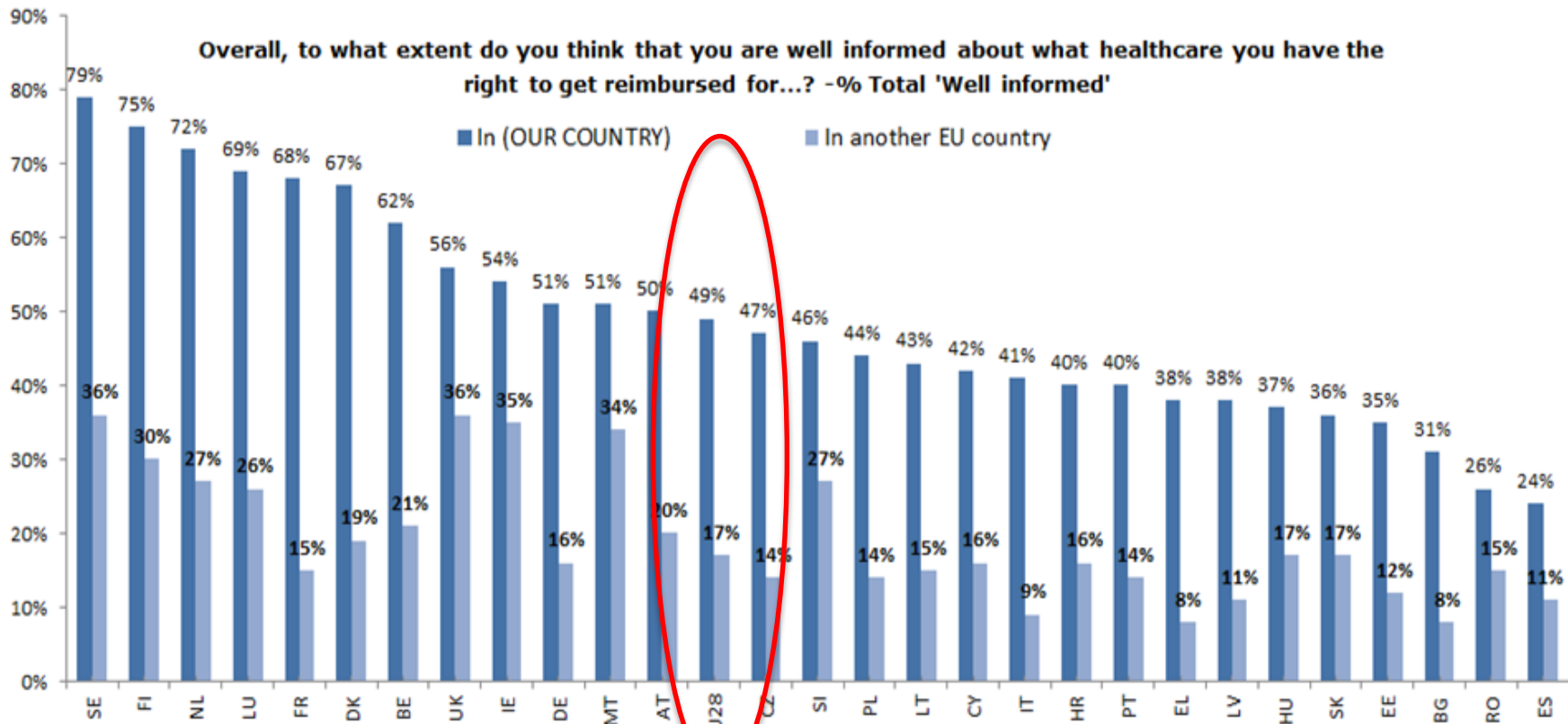


- PA must be necessary and proportionate, and may not constitute an unjustified obstacle;
- MS must make publicly available which healthcare is subject to PA

Assessment

- Majority of MS legislation: no clear specifications
- Some MS overuse PA
- In at least 14 MS, it is unclear exactly which treatments are subject to PA

Information to patients



Are foreign providers/clinicians safe?

Am I entitled to the treatment?

Is there someone who can make all the arrangements?

I can't afford to pay up front?

Can I get help with travel costs?

What about treatments not approved by NICE?

How much will I be reimbursed?

What if something goes wrong?

Where can I get more information?

What are the clinical success rates?





Directive and pain – Article 8 (5)

- Member State of affiliation may not refuse to grant prior authorisation ... based on an **objective medical assessment** of the patient's medical condition, the history and probable course of the patient's illness, the **degree of the patient's pain** and/or the nature of the patient's disability

Conclusions

- 1. Patients mobility for planned healthcare remains low
 - *Late implementation by MS*
 - *Low awareness*
 - *Obstacles*
- 2. Patients' rights better defined
 - *More transparency on health services in EU – the Directive provides a framework to improve information to patients*
 - *Liability, complaints procedures...*
- 3. Directive created frameworks for cooperation between MS – eHealth, ERN, HTA, ...

Cross-Border Possibilities



European
Reference
Networks

Key features of European Reference Networks

- ✓ Provide diagnosis and treatment in rare diseases
- ✓ Pool scarce expertise
- ✓ Patient centered and clinically lead
- ✓ 10 Members - hospitals, clinics - in at least 8 countries
- ✓ Based on Article 12 of the Directive on Patients' Rights





Players

- Healthcare providers
- Member States
- Commission
- Assessment process and Assessment Bodies



Healthcare Providers are Principal Constituents of the Networks

- ✓ Provision of **clinical care**, virtually or through referrals
- ✓ **Cooperation among themselves** in fields of expertise
- ✓ **In accordance with legislation** of their Member States



- ✓ Responsibilities and tasks defined in the **governance bodies of the ERN**
- ✓ **Hub (interconnector)** between national healthcare providers and the ERN



Survey of network coordinators: digital needs

- **Clinical consultation:** multi-disciplinary virtual boards (tumour boards...), transmission and consultation on images (x-ray, scans...)
- **Telemedicine** - different specialities and domains
- **Diagnosis support** tools: Shared decision trees, other diagnostic tools
- **Interactive production** of guidelines, technical documents
- **E-Libraries** of technical documents
- **E-Training** and at distance learning activities
- **Research:** shared protocols for clinical trials, shared databases etc.
- **Patient registries** for secondary use of information



Call for ERN

16 March - 21 June 2016

How are things going?

- ✓ More than **50 interested groups** or pilot networks identified
- ✓ **Up to 20 mature and broad thematic** networks potential applications
- ✓ **Dynamic interaction** of stakeholders with MS and Commission
- ✓ **Interaction among professionals** of the same thematic diseases groups
- ✓ Active implication of **EU patients and professional/scientific societies**
- ✓ Cooperation and **support of the RD Joint Action to the ERN implementation**



ERN timeline & milestones



2014



**Entry into force
legal acts**

2014-2015



**Assessment
Manual**

2015-2016



**selection
independent
assessment bodies**

March-June 2016



**Call for Proposals
for Networks**

**3rd quarter
2016**



**Assessment
proposals**



**4th quarter
2016**

**Designation of
the Networks**



**March
2017**

**Kick-off
Conference**



@V_Andriukaitis



@EU_HEALTH



@EU_Commission



@EU_eHEALTH

DG Health and Food Safety site

http://ec.europa.eu/health/ehealth/policy/index_en.htm

DG Connect site

<http://ec.europa.eu/digital-agenda/en/eu-policy-ehealth>



Conclusions: Patients mobility for planned healthcare remains low

- Late implementation by MS
- Low awareness of patients' rights on cross-border healthcare
- Obstacles:
 - *Extensive use of Prior Authorisation or lack of clarity when it is required;*
 - *Unreasonably low reimbursement tariffs;*
 - *Burdensome administrative requirements*

Patients have right to receive healthcare abroad (Directive 2011/24/EU)

- ✓ Main rule: No prior authorisation (overnight stay and highly specialised and cost intensive care);
- ✓ Direct payment to providers;
- ✓ Reimbursement based on tariffs and rights in the MS of affiliation
- ✓ Public / private providers and medicines are available;

Coordination of social security schemes (Regulation (EC) No 883/2004)

Necessary treatment

- ✓ Medically necessary care;



- ✓ Reimbursement between institutions based on the tariffs of treatment, (No co-payment);
- ✓ Public (contracted) providers only

Planned treatment

- ✓ Prior authorization in case of undue delay;





Mutual recognition of prescriptions

- *Implementing Directive 2012/52/EU on measures to facilitate the recognition of medical prescriptions issued in another Member State: on-going assessment of transposition measures*

European Patients' Forum



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Look inside to find out more...

Health and
Consumers



- Patients' free, prompt and timely access to their own medical records
- eHealth and database interoperability – improve global patient records and continuity of care

“ A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE ”