UK Implementation of Directive 2011/24/EU – on patients’ rights in cross-border healthcare

Rob Dickman – International Division

Malta Health Network – 24 June 2013
Directive 2011/24/EU

“...the most significant and wide-ranging European health legislation in a generation.”
Drivers: Choice & Confidence

- Regulation EC 1408/71 (now 883/2004) - E111 (EHIC) & E112 (S2) etc.

- A new generation of Europeans: accustomed to ease of travel and purchasing goods and services from any part of the European Union

- Less willing to accept constraints on where their healthcare may be obtained – rules tested via ECJ
“Houston: We have a Directive”
Directive 2011/24/EU

- DG SANCO’s flagship health policy – goes further than all previous arrangements
- Fundamental right under Treaty principles (freedom of movement)
- Basic principle: *if you are entitled to it here, you can get it there*
- Planned, unplanned, State & private
- Same as or equivalent to…(*not* a route to additional entitlements)
- Prior authorisation in certain (limited) circumstances
- Patient pays for treatment & claims reimbursement from national authority - limited to home cost/tariff
Key points

- Art 4 – Requirements on providers & MS of treatment
- Art 5 – Responsibilities on MS of affiliation; patient information (including on entitlements)
- Art 6 – Set up and functions of National Contact Point
- Art 7 – (Patient) reimbursement rules and principles
- Art 8 – Prior authorisation systems & criteria for refusal
- Art 9 – Administrative arrangements
- Art 10 – MS cooperation (exchange of information etc.)
- Art 11 – Prescription recognition
- Arts 12 to 15 – Comitology & “voluntary” arrangements: European Reference Networks; Rare Disease; ehealth; Health Technology Assessment
Positive effects?

- Patient / citizen focused: covers all healthcare (including privately provided)
- EU-wide legal framework confirming patients’ rights & entitlements
- Requires MS to provide citizens with clearly understandable / accessible procedures
- Ensures access to information via National Contact Points
- Sweeps away obstacles to freedom of movement - effectively extends patient choice to whole of EU
- Greater choice / empowered citizens
- Lever for improvements in home system provision?
But questions remain….

- Are foreign providers/clinicians safe?
- Am I entitled to the treatment?
- I can’t afford to pay up front?
- What about treatments not approved by NICE?
- What if something goes wrong?
- Is there someone who can make all the arrangements?
- Can I get help with travel costs?
- How much will I be reimbursed?
- Where can I get more information?
- What about treatments not approved by NICE?
- What are the clinical success rates?
UK Implementation
Key policy & delivery issues

5 territory implementation
Patient information / set up of NCPs
Centralising functions (NHS England)
Patient entitlements / basket of benefits
Equity / liability issues
Risk of fraud
“Undue delay”
PA / reimbursement / pricing

Context of patient choice, empowerment, rights and entitlements
Consultation

- First consulted in 2008
- Subsequent Parliamentary hearings & evidence gathering
- 2010 ‘interim’ Regulations & Directions
- On plans for implementation: carried out in England, Wales & Scotland
- In England, 31 formal responses (low-key approach required by Government)
- No substantial disagreement with Government’s overall approach
- Majority of respondents expressed positive views on the scope and effect of the new legislation
Key findings (England)

- Strong support for centralisation of functions
- Real desire for the NCP to play a key role in providing clear, transparent and good quality information to patients
- Direct payments supported
- Crucial to have effective exchange of information between clinicians, regulators, competent authorities and MS (including on right to practice)
- PA seen as a necessary measure, but avoiding too many restrictions
- Voluntary prior notification supported
- Need for clear and consistent information on entitlements
- Questions over responsibility for providing language and translation services (including medical notes)
Negative effects?

- Limited grounds to refuse (or require) prior authorisation
- Reduces healthcare to a purchase / reimbursement arrangement
- Inequity – those that can afford to pay up front take an advantage from earlier treatment
- Likely to benefit EU migrant communities
- The act of reimbursement is money leaving health systems – does not recirculate
- Patients are on their own
- Liability issues (currently untested)
- Risk of fraud
- Potential to marginalise the use of PMI / PHI?
National Contact Point(s)
NCP functions (1)

Supply patients with “relevant information”* on:

- Standards and guidelines on quality and safety in UK and Union legislation
- Provisions for the supervision and assessment of healthcare professionals
- Information on which health providers are subject to such standards
- Information on hospital accessibility for persons with a disability

NB. * “Relevant Information” is not defined
NCP functions (2)

- Consult with patient organisations, healthcare providers and healthcare insurers
- Cooperate with other NCPs and the Commission & provide patients with contact details of NCPs in other MS
- Provide information on right of a healthcare provider to provide services and any restriction(s) on its practice
- Provide information about patient rights, complaints procedures, mechanisms for seeking redress etc.
- Ensure that information is easily accessible, available by electronic means and in formats accessible to people with disabilities
The European Commission’s view

• Increasing clear and accessible information is central to the successful operation of the Directive: without it patients' ability to use their rights will be diminished

• Ambition is an effective, EU-wide network of NCPs talking to each other, giving & exchanging information etc. for the benefit of citizens / patients

• Cannot only be a website; must be capable of interacting with citizens, other MS, & Commission

• Commission will be active in ensuring that MS meet their obligations under the Directive in this area - by infraction if necessary

• May seek to “add” responsibilities to the NCP role in the future by agreement
UK approach

• NCP England to be set up within NHS England
• Agreed to set up territorial NCPs in each UK capital: London, Edinburgh, Cardiff, Belfast &…Gibraltar
• Initial thinking is that a lot of information is already in the system, so NCP will act more as a “signpost”
• No role in decision making, nor in “recommending” providers (domestic or foreign)
• Consequently, do not anticipate NCP being a large function (but must demonstrate we meet Directive’s obligations)
• However…strong support for the NCP role from consultation – need to reflect on how to meet expectations
The Challenges Ahead....
There’s (still) a lot to do!

**For (UK) Government**
- Programme of delivery across 5 UK territories
- Assess impact / consultation / scrutiny
- Support NHS to deliver its obligations
- National Contact Point(s)

**For Providers**
- Managing patient inflow
- Charging mechanisms
- Non-discrimination
- Clinical liaison / governance

**For Commissioners / National Authorities**
- Provision of information
- Develop expertise / systems
- Decoding receipts / calculating reimbursement
- Decisions that are fair and defendable
Post October – what happens?

- Implementation arrangements to be notified to European Commission by 25 October
- By March 2014, the Commission will have carried out their initial assessment of MS transposition; highlighting areas or MS where there are problems
- By autumn of 2014, the Commission will have prepared the first substantial infractions against MS on the issues of high importance to them. These are:
  1. National Contact Points & patient information
  2. Patient entitlements / baskets of benefits
  3. The use of prior authorisation
  4. Pricing and reimbursement
Possible EU action

Scenarios:
1. MS does not implement on time or does not notify
2. The Commission claims MS has not implemented fully or properly
3. Direct citizen or MS complaint

(European) Court action may follow and fines derive from a calculation based on GDP, with the fixed penalty lump sum being a minimum of €11m.

Recent example:
Commission v France (fish) [2005] ECR I-6263, the fine applied by the ECJ was €58 million per six-month period of incorrect implementation, plus a €20m lump sum.

NEED TO GET THIS RIGHT!
Questions?
Rob Dickman
International Division
Department of Health, London

Rob.Dickman@dh.gsi.gov.uk