

Beyond the Directive

Reactions from industry

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Brussels, 19 March 2009



Health care provided in another Member State (Art 6)

1. “[...] The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. [...]”

2. “The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received”.

Health care provided in another Member State (Art 6)

If reimbursement level is higher in “visiting” member state: **Patient co-pay**. Need to offer the same choice to “domestic” patients.

If reimbursement level is lower: is there a risk that authorities in home member state use this **as means to save costs** by sending patients abroad? Or by avoiding investment in “highly specialised and cost-intensive medical infrastructure” and “free-ride” instead on the investments made across the border?

How do we ensure quality of care? Solely focusing on price is not justifiable. Can we ensure that **quality criteria** are objective and comparable?

What happens to follow up activities? E.g. implant of pacemaker, defibrillator, hip etc abroad: follow up care in home country?

Are the market **imperfections in health care**, which for long have been a justification for MS governmental activities (from market access regulation, professional resource planning, to price controls, etc), now all been removed to allow for patients acting in a well-informed way on the single, internal European market for health?

European reference network (Art 15)

1. *“Member States shall facilitate the development of the European reference networks of healthcare providers. Those networks shall at all times be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria.*

2. *The objective of European reference networks shall be:*
 - (a) *to help to realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems from **innovations** in medical science and health technologies*
 - (b) *to help to promote access **to high quality and cost-effective healthcare** for all patients with a medical condition requiring a particular concentration of resources or expertise.*
 - (c) *to **maximise cost-effective use of resources** by concentrating them where appropriate;*
 - (d) *to help to **share knowledge** and provide training for health professionals;*
 - (e) *to provide **quality and safety benchmarks** and to help develop and spread best practice within and outside the network;*
 - (f) *to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide a full range of highly specialised services of the highest quality [...].”*

European reference network (Art 15)

Centers of excellence have indeed the potential to optimise highly specialised care and to support the introduction of innovations

“Traditionally” cost-effectiveness is about a certain treatment on a certain indication in a certain patient, compared to one or more alternatives. It is context-dependent and not easily comparable across borders (Sculpher, Drummond, 2006).

Here, the idea of cost-effectiveness of a provider is introduced instead of cost-effectiveness of a therapy. Is perhaps rather a matter of economies of scale (scope) and certainly also one of mastering the learning curve, which is of particular importance for the medical technology industry

E-health (Art 16)

“The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them.

Those measures shall reflect developments in health technologies and medical science and respect the fundamental right to the protection of personal data in accordance with the applicable law.

They shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services.”

E-health (Art 16)

A number of barriers remain to the introduction of e-health within a Member State, not a few of those being related to lack of funding. Was addressed again by the Commission Communication on telemedicine in Nov 08 and by the recent E-Health Conference under the Czech Presidency.

E-health has the potential to actually bring the “care to the patient” instead of the other way around and applying it on a European scale might actually make some of the implications of this Directive not needed anymore.

Cooperation on management of new health technologies (Art 17)

*“1. Member States shall facilitate development and functioning of a **network** connecting the national authorities or bodies responsible for **health technology assessment**.*

2. The objective of the health technology assessment network shall be:

*(a) to support **cooperation** between national authorities or bodies;*

*(b) to support provision of objective, reliable, timely, transparent and transferable **information on the short- and long-term effectiveness** of health technologies and enable an effective exchange of this information between national authorities or bodies.*

3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.

4. The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt the necessary measures for the establishment and the management of this network and specifying the nature and type of the information to be exchanged.”

Cooperation on management of new health technologies (Art 17)

Collaboration has indeed the potential to overcome the **hurdles of incompatibility** of HTA between countries.

“Decision makers and analysts need to work together to streamline and where possible harmonise guidelines on methods for economic evaluations, whilst recognising legitimate variation in the needs of different healthcare systems. Otherwise, there is the risk that scarce resources will be wasted in producing country-specific analyses in situations where these are not justified.”

Sculpher, Drummond, 2007

Could contribute to “globalize the evidence – localize the decision-making” or “harmonise the methods – decentralize application”.

Cooperation on management of new health technologies (Art 17)

Eucomed strongly supports amendments (am.) 42 and 43 in conjunction with recital 5 of Mrs. Grossetête and am. 37 and 40 of Mr. Bowis, which are seen as being complementary.

ITRE OPINION: Amendment 42: Proposal for a directive Article 17 – paragraph 1 a (new):

The Commission shall establish, in agreement with the European Parliament, an operational framework for the network referred to in paragraph 1, based on principles of good governance, including procedural transparency, objectivity and impartiality, and on the participation of stakeholders from all the social groups concerned, including doctors, patients and industry.

Text proposed by the Commission

2. The objective of the health technology assessment network shall be:

(a) to support cooperation between national authorities or bodies;

(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies.

Amendment

2. The objective of the health technology assessment network shall be:

(a) to find long-term ways of striking a balance between the objectives of public health and access to medicines, rewarding innovation and management of healthcare budgets;

(aa) to develop transparent procedures and methodologies with which to pursue these three objectives;

(ab) to ensure that all the parties concerned, particularly patients, the medical community and industry, participate in addressing choices which can affect public health, innovation and competitiveness in Europe in the medium and long term;

(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies;

(ba) to consider the nature and type of information that could be exchanged.

Eucomed suggests adding two further elements to the process in order to strengthen the credibility of the cooperation on the management of health technologies:

The governing bodies of the network shall have an appropriate representation of all relevant stakeholders.

*Third-parties should have access to a **formal appeal process** to challenge any future recommendation or decision of the network.*

Some considerations on HTA

Health policy decision-makers, fundholders, physicians and patients have a right to be informed about the value of medical technologies. The medical device industry in Europe is accepting its responsibilities to deliver this evidence.

Decision-makers need to understand and appreciate the peculiarities of medical devices. The “pharma-approach” to the generation of evidence does not fit all.

Collaboration on HTA on a European level can help to “globalise the evidence”, as one ingredient to “localised decision-making”

Collaboration can also help to harmonise the methodologies, taking into account specificities of medical devices

The link between Health Technology Assessment and clinical practice is still too weak. Implementation needs to be improved, in order not make HTA a fruitless fourth hurdle, delaying access to technology innovation.

Some, but not all innovations can be cost-saving. What are we willing to pay for gains in morbidity and mortality? Patients and citizens need to be part of the value debate.

General conclusions

A further maturing of the internal market also for healthcare is probably unavoidable. It has been set in motion by ECJ rulings, as a reaction to patient demands.

Management of change is never easy and in a market as complex as healthcare it might be even more difficult.

Transition will always bring obstacles and difficulties and temporary winners and losers, also amongst industry. We will not fight battles that we cannot win.

The medical devices industry in Europe needs a stable and permanent seat at the tables of European and national decision making in healthcare.

Prejudices about biased perceptions and wrong motives need to make way for open, constructive and transparent dialogue on structures and procedures governing healthcare.

In the long run then, the patient will have more choice, will be better informed and will receive more appropriate care.

Thank you



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