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HTA cooperation in the EU

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Andrzej Rys

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Presentation outline

- Objectives of the EU on HTA
- On-going initiatives on HTA
- Long term perspectives on HTA

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Commission's objectives

- All health technologies to be covered, but particular action needed for pharmaceuticals
- Provide decision makers, health professionals and managers, patients with robust scientific evidence on technologies
- Reduce duplication of work for MS

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Commission's objectives (2)

- Support MS + stakeholders with little HTA capacity
- Provide decision makers, health professionals and managers, patients with robust scientific evidence on technologies

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Commission's objectives (3)

- Reduce the national hurdles to market access faced after licensing
- Promote the early dialogue (scient. advice) between sponsors and HTA bodies/ payers during the tech. development process
- Establish clear and transparent stakeholders' involvement rules

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On-going initiatives at EU level

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1st Joint Action EC/MS EunetHTA

- Period: 2010-2012, 24 MS
- Budget: 6 Mio € (50 % supported by EU)
- EUnetHTA's objectives:
  - To further develop the "core HTA" methods
  - To develop specific methods on relative effectiveness assessment of pharmaceuticals + improvement of EPAR's
  - To set up an information management system + long term business model
  - To set up a policy on stakeholder's involvement

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2nd Joint Action 2012/ 2014

- Overall objective: need for better knowledge/ feedback on opportunities and limitations to joint HTA production
- Production of joint HTA's + core HTA's (early assessments of pharma + MD)
- Increase capacities of stakeholders
- Test real life governance of the cooperation + collect info on costs and organisational matters
- Total budget: up to 9.4 Mio €

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Actors of the decision making process (DMP)

- DMP currently split between:
  - Industry/ promoter
  - Regulators: does the drug do more good than harm (benefice / risk) in a defined group of patients and in clinical trial?
  - HTA bodies: what are the health impact the drug, relative to other interventions, in a defined group of patients and in real world?
  - Payers: what are the costs impact (…)?
  - Prescribers: how does the drugs compare to other interventions?

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Room for defragmentation?

- Yes, but:
  - Keep separate regulatory process from post MA process: no regulatory interference of HTA in the MA/ benefice risk approach
  - Keep separate institutional organisation regulators/ HTA bodies/ payers

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Defragmentation (2)

- Improvement of the information flow between the actors:
  - Improvement of the MA info + evidence (EPARs) to suit HTA/ payers requirements
  - Early dialogue between the actors to guide the phase III clinical trials:
    - Choice of the clinical/ surrogate endpoint
    - Choice of the comparator
  - Role of the new PRAC committee?

Long term perspectives

The proposed directive on cross-border health care (CBHC)

Art. 14 ⇨ From project-based to permanent cooperation on HTA

- The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States.
- The objectives of the ***HTA*** shall be to:
  - support cooperation *between* national authorities or bodies;
  - support Member States in the provision of objective, reliable, timely, transparent, *comparable* and transferable information on the *relative efficacy as well as on the* short- and long-term effectiveness *when applicable,* of health technologies and to enable an effective exchange of this information between the national authorities or bodies.
  - *support the analysis of the nature and type of information that can be exchanged;*
  - *avoid duplications of assessments.*
- That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.

The CBHC (2)

- Art. 13 Cooperation on eHealth: overall objectives
  - Emergency care
  - Continuity of care
  - Support to innovation
- 3 concrete areas of work at EU level:
  - Data to be included in patients summaries; (to be shared between health professionals to enable continuity of care and patient safety across borders)
  - Collection of medical information for public health and research;
  - Identification & authentication measures to facilitate transferability of data in cross-border healthcare.

Issues at stake

- How binding should the conclusions be? "Avoid duplication of assessments"
- How much money are MS/ industry ready to put? Impact on the HTA production?
- Degree of stakeholders' involvement
- Decision making process for adopting HTA reports/ recommendations

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Governance of the cooperation

- What is taken for granted is:
  - MS HTA bodies will do the work
  - HTA process should remain separate from the regulatory process
- Reflection process on the structure:
  - EC/ MS coordination and hosting? Decision making process?
  - Capacity to cover all and cross technologies
  - Build on existing synergies, expertise and other regulatory requirements (PRAC)
  - Cost/ efficiency of the structure itself

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Conclusions

- HTA part of the overall EU strategy on innovation
- There is a strong added value in considering HTA at EU level:
  - Pooling of expertise
  - Minimised duplication of efforts
- Final objective is not harmonisation of the decisions. But some standardisation may be agreed between MS.

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Conclusions (2)

- All actors involved need to explore new ways of working together. Defragmentation is needed.
- A sustainable cooperation is needed. Long term solutions are currently being evaluated.

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Further information

- www.eunethta.eu
- http://ec.europa.eu/health/index_en.htm
- http://phis.goeg.at http://ppri.oebig.at
- http://ec.europa.eu/enterprise/sectors/healthcare/process_on_corporate_responsibility/index_en.htm