

HTA cooperation in the EU



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P/R network of competent authorities

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Key messages

- HTA decision should serve patients overall interest and reward innovation
- HTA objective is broader than costs containment
- HTA is not only focusing on pharma products but also MD and interventions

Key messages (2)

- Implementation of HTA decisions more relevant at national level, because of values issues... and economic capacities.
- EU cooperation added value is significant to address clinical issues, where substantial scientific questions are at stake
- Core methods and data can be jointly developed for possible reuse at national level

Key messages (3)

- Pooling of expertise will avoid duplication of efforts/ resources for industry, HTA bodies and payers
- New decision making processes between industry, regulators, HTA bodies and payers deserve being tested to produce more evidence on the true value of technologies

Key messages (4)

- All Member States should benefit from HTA expertise
- Sustainable cooperation is needed: the directive on CBHC is the solution
- Short term initiatives valuable for pharma products

Available instruments to support the cooperation on HTA

- The joint action Member States/ Commission on HTA 2010/2012
- The public Health programme and the FP7
- The directive on cross border care
- EMEA's initiatives

The joint action 2010/2012

- Objectives and governing rules defined by the MS and the Commission
- 24 MS involved, 6 Mio€ (financed at 50% by EU), starts early 2010
- Objectives:
 - Get clear orientations on what can be better achieved on HTA at EU level: “core HTA”
 - Develop transparent governance tools, notably vis à vis stakeholders
 - Produce a number of joint scientific assessments
 - Implement the Pharma Forum’s recommendations on relative effectiveness of pharmaceuticals
- *To set the scene for the implementation of the directive on CBHC*

The joint action (2)

WP5: implement recommendations of the High Level Pharma Forum (HLPF)

- Use the definitions and principles adopted:
 - Efficacy/ relative efficacy of drugs
 - Effectiveness/ relative effectiveness (RE)
 - Relevant distinction RE/ cost-effectiveness assessment (CEA)

The joint action (3)

- Strengthen the methodological quality and rigour of RE assessment
- Consolidate scientific evidence on RE
 - Better understanding the barriers for the generation of the data
 - Better understanding transferability limitations

The joint action (4)

- Involve all actors interested in HTA
 - Competent authorities make the final decisions on Pricing/ Reimb. but:
 - Need to listen to the views of stakeholders: patients, health prof, industry, payers
- Explore avenues for early dialogue between Market Authorization Holders and decision makers
- Make best use of the EMEA's EPAR and NPAR

The joint action (5)

Possible “pilots”:

- Complete the work engaged under the HLPF for the 5 sampled molecule: identify variety of approaches
- Test capacity to make joint rapid assessment, in view of P/R decisions
- Test capacity to make joint observational studies

The public health programme and the FP7

- Draft public health program 2010:
 - Call for proposal on the development of HTA capacities in MS
 - Call for tender on effectiveness of orphan drugs
- FP7 call 2009: 64 Mio€ (22 projects) dedicated to research on optimizing delivery of health care

The directive on crossborder care

- EP supportive in 1st reading, discussions ongoing in Council
- Agreement on a long term and sustainable cooperation on HTA
- No common position reached on 1st December 09
- Follow up to be discussed

Conclusions

- There is a strong added value in considering HTA at EU level:
 - Pooling of expertise, for instance to face the challenges specific to PM
 - Minimisation of duplication of efforts
 - Increased quality and transparency of the national decisions made eventually
- Final objective is not harmonisation of the decisions. But some standardisation may be agreed between MS

Conclusions (2)

- First, need to focus on clinical issues, rather than cost/ eff. issues
- The sustainability of the cooperation is needed: the directive on CBHC is the solution