EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Setting up a joint action on HTA: building on the conclusions of the Pharma Forum on relative effectiveness assessment

Brussels, 20 February 2009

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Presentation outline

- Pharma forum: overview of the decision making process
- Main deliverables and conclusions
- The way forward

1. The Forum Decision making process

http://ec.europa.eu/pharmaforum

The overall structure of the Forum

- **Members**
  - 27 Member States, 5 industry, 5 public health sector and social insurers, European Parliament (EP), EMEA
- **Forum**
  - Two Commissioners, ministers, high level representatives
  - Role: Political and strategic direction
- **Working Groups**
  - Relative effectiveness, information to patients, pricing and reimbursement
  - Role: Making proposals, models, pilots, recommendations

2. The deliverables of the Forum

Endorsed by the 27 MS and the stakeholders on 2 October 2008

Recommendations (1)

- Common definitions and core principles
  - Efficacy/ relative efficacy of drugs
  - Effectiveness/ relative effectiveness (RE)
  - Relevant distinction RE/ cost-effectiveness assessment (CEA)
  - RE most appropriate at national level but EU cooperation can bring added value for developing data on RE and dealing with methodological challenges
  - All actors involved invited to promote the use of the definitions

Recommendations (2)

- Cooperation should focus on:
  - 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

Recommendations (3)

- Involvement of all actors involved 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

Recommendations (4)

- Explore avenues for early dialogue between Market Authorization holders and decision makers, during the drug development process
- Make best use of the EPAR and NPAR
- Identify any scope for common approaches, as appropriate

3. The way forward

From relative effectiveness of drugs to HTA in general

- Article 17 of the proposed directive on cross border care calls for sustainable cooperation on health technologies
- The EUNET HTA project's deliverables on medical devices and interventions need further development
- With the conclusions of the Forum, works on drugs can now be integrated into the scope of an EU cooperation mechanism

3.1 What EU cooperation on HTA should bring about

- HTA expertise should benefit all MS
- HTA expertise should be more integrated
- HTA should be considered as a reliable contributor to sustainability of health care systems

While respecting the competences of MS in health

HTA expertise should benefit all MS

- Not all MS have necessary capacity and expertise on HTA
- They should be able to develop their own capacity and benefit from the expertise developed by others.
- They should also be able to contribute to large HTA's

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HTA expertise should be more integrated

- Information is fragmented between licensing authorities, HTA bodies, industry, payers and academics
- Better cooperation should benefit all, scientifically and in terms of resources
  - MS can agree to share/ access to expertise, avoiding duplication of efforts
  - Savings of resources can be used for the purpose of unmet needs on HTA.

HTA expertise should be held reliable for supporting HCS

- HTA can help the sustainability of health care systems, by
  - Providing expertise on most effective treatments
  - Rewarding innovation for most efficient products and interventions
  - Providing information on relevant cost containing measures

3.2 For discussion: how to run the cooperation mechanism?

- A political ownership is needed, hence the process of a joint action where MS decide on the scope of work
- Work should be done at scientific level to address scientific concerns
- Scope of work should not be too wide to avoid dilution of outputs

- The status of the national HTA bodies involved has to be transparent:
  - Status vis à vis final decisions on pricing and reimbursement?
  - Distinction to be made between assessment and appraisal bodies?
- The cooperation mechanism has to be manageable: how to manage with multiple decentralised/ local bodies?
- The cooperation mechanism has to be transparent as regards stakeholders involvement

- SMART objectives should be defined:
  - Goals to be reached within 3 to 5 years, relevant to cross-border mobility
  - What can be shared and done at EU level? What remains most appropriate at national level?
  - Build on existing expertise, also at international level
  - Illustration with concrete cases

- Role of the Commission
  - Bring financial support, after adoption of the proposal
  - Be part of the steering committee of the mechanism
  - Ensure liaison with political sphere, possibly:
    - Council working party on health, set up 9 December 2008
    - The network of the Competent Authorities for Pricing and Reimbursement of Pharmaceuticals

Conclusions

- HTA is one solution towards sustainable health systems (CZ presidency priority)
- That solution can be reached through different approaches; there is no model as such
- MS keep the ownership of the deliverables: it is a national responsibility
- There is a lot of scope for cooperation between MS, avoiding duplication of efforts