Establishment of Negotiation Committee and HTA

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Stages of HTA implementation

Assessment (the research part)
- public HTA agency
- academic researchers
- pharmaceutical companies
- consultants

Appraisal (the policy part)
- critical appraisal by public HTA office
- HTA recommendation
Key question:
How HTA recommendation is taken into account by MoH and/or Health Insurance Committee?

Verifiable criterion: cost-effectiveness

- Political attitude in lower income countries is based on implicit decision-making
- How to interpret cost-effectiveness ratio?
  - no threshold
  - implicit threshold(s)
  - explicit soft threshold(s)
  - explicit hard threshold(s)
- How many thresholds?
  - one
  - lower and upper
  - moving threshold according to disease severity or rarity (e.g. end-of-life therapies; orphan drugs)
- How to determine threshold? In Visegrad countries
  - economic status (GDP or salary level)
  - Threshold in CEE countries is equal with NICE/SMC
Verifiable criterion: budget impact

- In difficult economic periods policymakers may put more emphasis on budget impact analysis than cost-effectiveness analysis.
- explicit or implicit thresholds?
- portfolio deal?

Major Questions of HTA / MCDA Implementation

- HTA submission: confidential or published?
- Performance matrix or MCDA scores: confidential or published?
- Rule vs. tool?
- Management of uncertainties: risk-sharing?
- MCDA tool: single or repeated use?

Foundation work for MCDA

- "Non-scientific" MCDA
- MCDA system developed by expert group with ongoing validation (revealed preferences)
- Research based MCDA (stated preferences)
Mandatory HTA for pharmaceuticals and medical devices prior to pricing and reimbursement decisions

HTA Office with trained professionals

HTA process
- HTA submission by pharmaceutical companies
- critical appraisal by HTA Office
- multistakeholder technology appraisal committee
- pricing, budget impact and risk-sharing negotiation by health care payer
- final decision by relevant ministries

Published methodological guidelines & critical appraisal checklist

Explicit cost-effectiveness & implicit budget impact threshold

No transparency: none of the below documents are in the public domain
- submission dossier
- critical appraisal and HTA recommendation
- justification of pricing and reimbursement decisions

HTA consultancy
- driven by insights and relationships
- annual turnover: 3-5 million Euros