

# Accountability for reasonableness in drug reimbursement systems

International comparison and  
policy recommendations

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# Research objectives

- Describe 5 European drug reimbursement systems  
*(Austria, Belgium, France, the Netherlands and Sweden)*
  - ➔ Presented today at **16u30 in Ambar Room**
- **Identify best practice systems i.t.o. “accountability for reasonableness”**

# Methods

Accountability for reasonableness

Requirements according to the ethical-theoretical framework of Daniels and Sabin (1997):

**Transparency** of grounds / rationales

**Relevance** of appraisal / decision criteria

**Revisability** i.c.o. new evidence

**Enforcement** previous requirements

# Decision process

Assessment: descriptive, technical department

Appraisal: weighing, expert committee

Decision: weighing, minister / expert committee

# Transparency

How?	Operationalisation
Documentation & Publication	AU: only decision FR: key issues discussed + voting results BE: Day 60 assessment report + Q&A industry SW: state of process + summary final decision & rationale
Definition of roles	Assessment & appraisal intertwined processes in all countries (NL: <i>Appraisal committee (2008)</i> )

# Relevance decision criteria

Relevant criteria are **socially accepted** criteria for decision-making (**rational and fair-minded**)

- No scientifically right or wrong set of criteria
- Observation: No explicit hierarchy in assessment and appraisal criteria

Question	Possible criteria
Does the product target a <u>medical, therapeutic and societal need</u> ?	Disease severity, prevalence, availability of alternative treatments, health inequity
Are we, as a society, <u>prepared to pay for a</u> treatment that will improve this indication out of public resources?	Own financial responsibility, life-style
Are we, as a society, <u>prepared to pay for this</u> particular treatment?	Relative effectiveness, Significance of health gains
Are we <u>prepared to pay more</u> for this treatment than for the best alternative?	Added therapeutic value, savings elsewhere in the HC sector, quality of evidence, uncertainty
How much more are we <u>willing to pay</u> out of public resources for this treatment (P&R)?	Added therapeutic value, budget impact, ICER, disease severity, savings elsewhere, limits to cost sharing, quality of evidence

# Revisability

- All:
  - case-by-case revisions
  - Ad hoc drug cluster revisions
- Sweden & France:
  - Limited full package revisions



# Enforcement

- Outcomes: drug expenditures only
- Procedures: ad hoc (parliamentary) audits

# POLICY RECOMMENDATIONS

# Transparency

- Disentangle assessment and appraisal:

Assessment report: describes (level of) evidence, uncertainty, evidence gaps

Appraisal using explicit decision framework

Coherent decisions

## Relevance of decision criteria

- Balanced representation of societal preferences in appraisal committees

## Revisability

- Especially in case of much uncertainty
- Reasons: new treatments, lower effectiveness/ higher costs than predicted, changing economic/societal context
- Large across-group revisions

## Enforcement

- Monitoring performance i.t.o. transparency, relevance of decision criteria and revisability of decisions
- Indicators to be developed/refined



THANK YOU!

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