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Sustainability of drug reimbursement systems

A comparison of the Austrian, Belgian, Dutch, French and Swedish drug reimbursement systems

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Drug reimbursement systems: international comparison and policy recommendations. Brussels: KCE reports 147C. Available at: www.kce.fgov.be

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Research objective

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Analyse and evaluate five European drug reimbursement systems to:

- *Obtain insight into strengths and weaknesses*
- *Identify opportunities to improve system efficiency and sustainability*

(Austria, Belgium, France, the Netherlands and Sweden)

Accountability for reasonableness in drug reimbursement systems
(presented previous session Ônix room)

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Research method

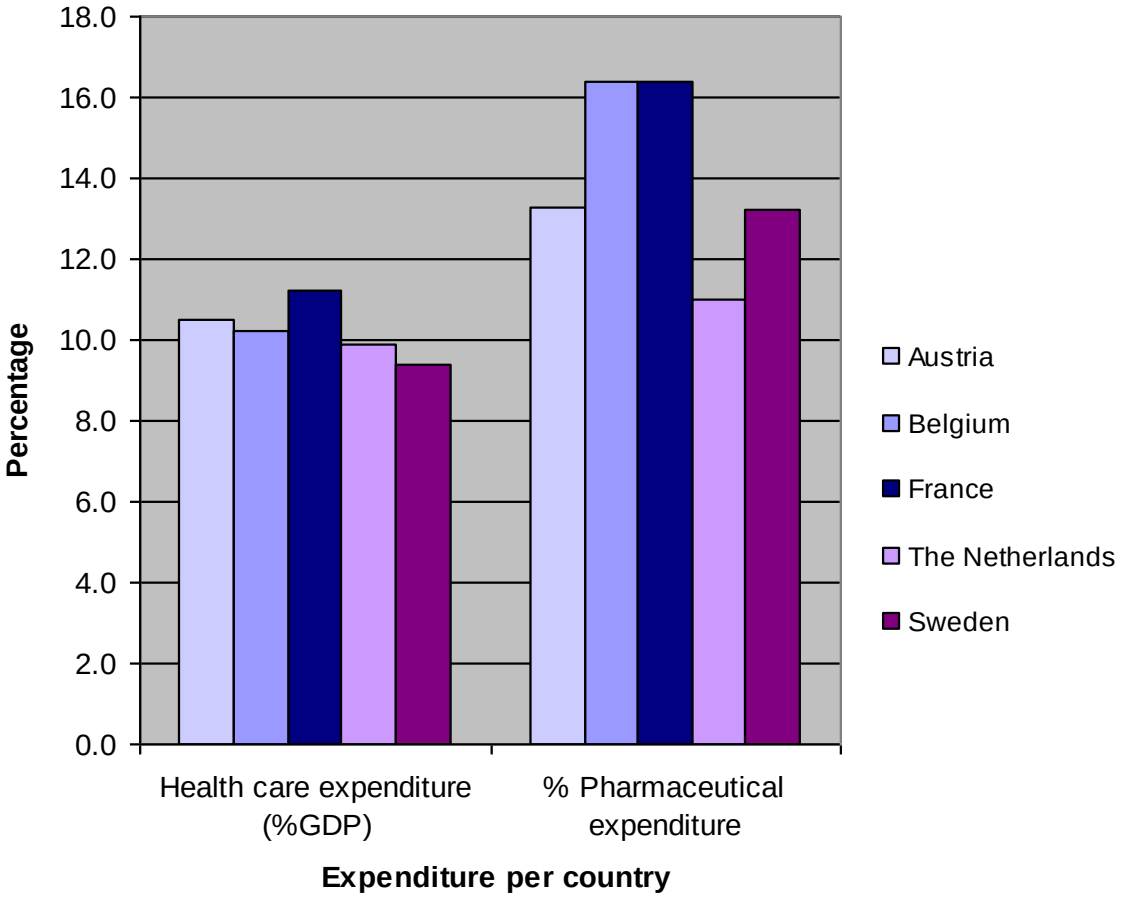
- Policy documents
- Literature review
- Interviews
- Analytical *"Fourth Hurdle"* (Hutton) framework

Analysing "Fourth Hurdle" systems[1]

- **Policy Implementation Level *(system level)***
  - *Establishment*
  - *Objectives*
  - *Implementation*
  - *Accountability*
- **Technology Decision Level *(drug level)***
  - *Assessment*
  - *Decision Process*
  - *Outputs and Implementation*

[1] Hutton J. et al. 2006. Framework for describing and classifying decision-making systems using technology assessment to determine the reimbursement of health technologies (fourth hurdle systems). *Int J Technol Assess in Health Care* 22(1):10-18

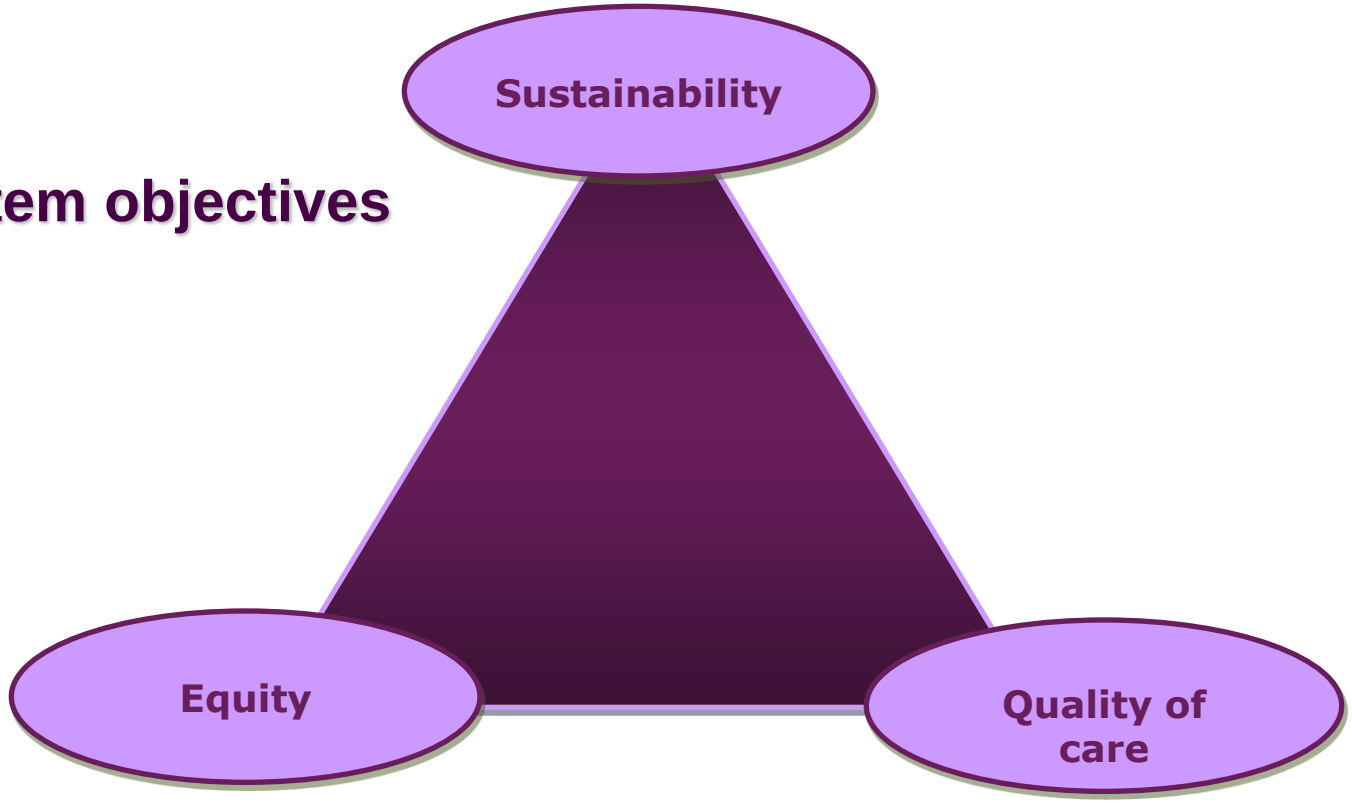
Expenditure per country



*Source: OECD 2008

Policy implementation level (I)

System objectives



Policy implementation level (II)

- **Centralised independent reimbursement agency**
- **Scope of the drug reimbursement system**
  - *Outpatient drugs: AU, BE, FR, SW, NL*
  - *Inpatient drugs: BE; pre-launch: FR; expensive: FR + NL*
- **“Separated” pricing and reimbursement decision**
  - *SW: combined decision in one committee*
- **Impact assessment only on drug expenditure**

Assessment criteria

- **No explicit hierarchy in criteria**
- **Therapeutic value *(most prominent)***
  - *Efficacy & effectiveness*
  - *Safety & side-effects*
- **Cost-effectiveness**
  - *France: no*
  - *Actual c/e ratio (SW) versus robustness c/e evidence (AU & NL)*

Assessment versus appraisal

- **Separated process?**
  - *NL: Appraisal committee (2008)*
- **No explicit hierarchy in assessment and appraisal**
- **Appraisal criteria**
  - *Added therapeutic value*
  - *Disease severity & rarity*
  - *Budget impact (not in SW, FR)*
- **Varying degree detail of operationalisation**
  - *Added therapeutic value*
  - *Medical need and disease severity*

Appraising value for money ?

- **Added therapeutic value → higher reimbursed price**
  - *NL + BE: yes/ no*
  - *FR (5 categories –ASMR–) + AU (6 categories)*
  - *SW: sliding scale*
- **Level of reimbursement**
  - *AU + NL + SW: 100%*
  - *BE (treatment necessity): 100, 75, 50, 40, 30%*
  - *FR (clinical benefit –SMR– & disease severity): 100, 65, 35, 15%*
- **No cost-effectiveness threshold (range)**
  - *Implicit: increasing threshold (disease severity)*
  - *Lenient towards orphan drugs*

Reimbursement decision

- **Conditional reimbursement**
  - *Diverse restrictions (e.g. groups, prescriber, time)*
- **Financial risk sharing agreements**
  - *Price/ volume FR + BE (only a few contracts signed)*
- **Minister of Health: final decision *(BE, FR, NL)***
  - *Additional appraisal criteria (societal criteria)*
  - *Discretionary power*
  - *AU+ SW: no role on individual reimbursement decision*

Outputs and implementation

- **Implementation of decision**
  - *Mandatory positive reimbursement list*
  - *National: AU, BE, FR, NL versus regional: SW*
- **Revisions (case-by-case versus group)**
  - *Ad hoc case-by-case: all*
  - *Systematic: AU: none; BE: class 1; FR: all 5 yearly; NL: exp inpatient; SW: all <2002*
  - *Systematic group revisions: FR and SW (Ad hoc: B)*
- **Consequences revisions**
  - *Modifications reimbursement levels: BE, FR*
  - *Delisting: BE, FR, SW, (AU)*
  - *Awaiting: NL*

Conclusions

- **Impact assessment of system**
  - *System sustainability (expenditure), not on other two objectives*
- **Decision making process often not transparent**
- **Role assessment versus appraisal not transparent**
- **Reimbursement criteria:**
  - *Therapeutic value is the most prominent criterion*
  - *Role cost-effectiveness unclear*
  - *Disease severity & rarity seem to have an important role*
  - *Budget impact*
- **Case-by-case decisions & revisions**

Is value for money a real criterion?

- **Increasing importance of pharmacoeconomics?**
  - *For the time being, cost-effectiveness seems to play a rather undefined role (no threshold, unclear relative importance)*
- **How to deal with uncertainty?**
  - *Better research, conditional/ temporary reimbursement, establish link between uncertainty & (reimbursed) price?*
- **Temporary decisions?**
  - *Revise all decisions?*
  - *Implementing large (across) group revisions?*
- **From supply-driven towards a demand driven system?**
  - *Target medical, therapeutic and societal needs*