Cost-effectiveness in the Swedish reimbursement process

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Nordic NICE?

"The LFN is regarded by the industry as something of a Nordic NICE, as a result of what is perceived as a purist approach to pharmaco-economics. The outcomes of its work are expected to prove influential both regionally and internationally" *(IMS, Pharma Pricing & Reimbursement)*

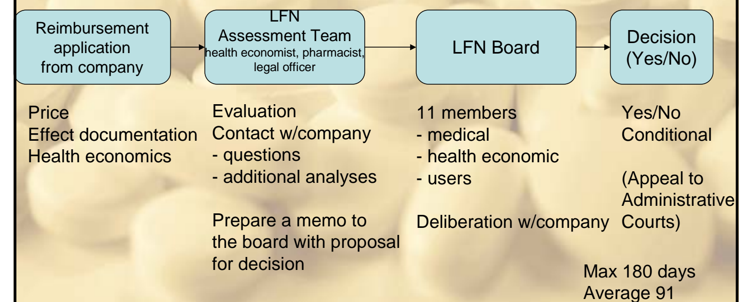
A very flattering comparison but there are differences …

Background

The Pharmaceutical Benefits Board (LFN): a government agency (instituted in 2002)

- Pricing and reimbursement (ex ante)
- New products
- Reviewing all existing products

Reimbursement decision process



Assessments

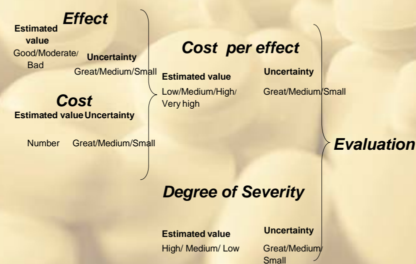
- Focus on cost-effectiveness from a societal perspective (Cost/QALY)
- Comparison with most relevant comparator (not necessarily a drug)
- The type and scope of the analysis can vary
- General practice

Prices

- Prices are proposed by the applicant
- The price is an integral part of the cost-effectiveness assessment

- No price negotiations
- No reference pricing
- No jumbo groups

Evaluation



Cost-effectiveness

- The effect of the medicine
  - What effect does the medicine have?
  - Which treatment is the most relevant comparator?
  - Is this medicine better than the comparison alternative(s)?
  - How good is the evidence for the medicine's effect? High/Medium/Low?

Cost-effectiveness

- Costs
  - What are the treatment costs?
  - How large are the costs for this treatment compared to the alternative(s)?
  - How good is the evidence for the cost estimations? High/Medium/Low?
  - How big is the uncertainty surrounding these costs?

Need – the severity of the disease

- The disease
  - Symtoms
  - Ability to function
  - Quality of life
  - Risk of premature death
  - Risk of permanent disease/injury
  - Risk of worsened quality of life incl. decreased autonomy
- Estimated severity of the disease
  - High/Medium/Low

  with
  - Great/Medium/Small uncertainty

Guidelines for Health Economics

- Cost effectiveness analysis is preferred
- Costs must describe the situation in Sweden
- Societal perspective
  (Costs in added years of life (net consumption))
- QALYs are the preferred measure of effect
- QALY weights based on patient preferences
- Relevant comparator
- Good empirical data important, but modelling is often necessary
- Provide the model - Transparency

Key challenges

- Correct comparator
- Defining need
- Transparency

Imperfect information

"… the danger is that the perfect will be the enemy of the merely good. Therefore it is important to recognize that … reimbursement decisions are made at a time when only imperfect information is available. … whether they lead to a better decision than would have been made in their absence."

Drummond, Sculpher (2005)

Decision-making criteria

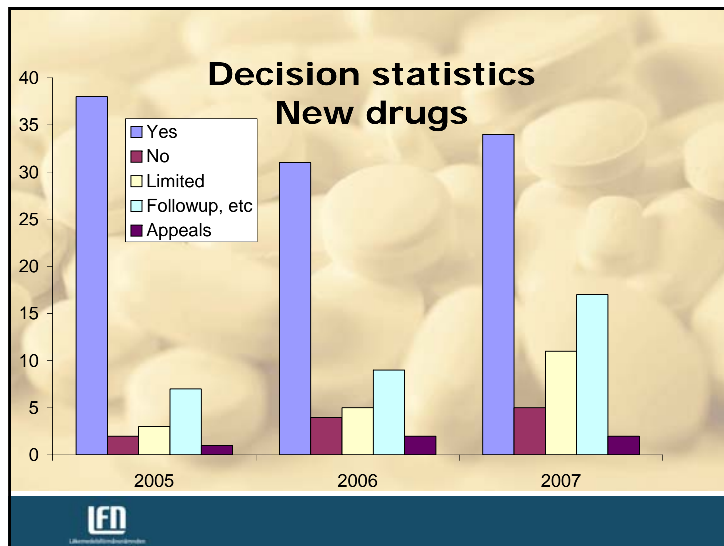
- **Human value**
  - respect for equality
- **Need and solidarity**
  - those in greatest need take precedence
- **Cost-effectiveness**
  - from a societal perspective

Decisions

- Full reimbursement or none.
- Restricted/limited reimbursement
  - Specific patient group
  - Time limited
  - Marketing requirements
- Request for follow-up data

Cost-effectiveness in the decision making process

- In Sweden the law on pharmaceutical reimbursement states that cost-effectiveness shall be balanced against the principle of need and solidarity.
- Similar aspects of need, disease severity etc are present in many other European countries either explicitly in law or implicitly in the way decisions are made.



Why balance against other factors?

- In theory C-E should lead to the maximum amount of health if applied to all interventions

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However most societies seem to have a preference for the distribution of health across individuals.

As societies we want to help the more severly ill first.

Fairness matters!

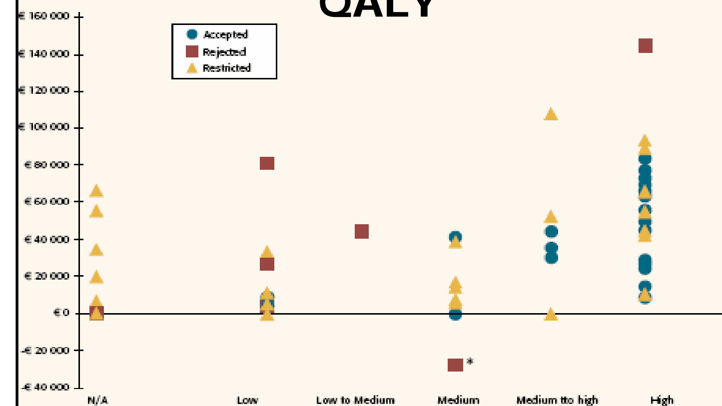
Solutions?

Differentiated willingness to pay for a QALY

The preference for fairness could be expressed by society being willing to pay more for a QALY gain if it benefits a patient with a higher need.

This is the approach used by the LFN. There is however no explicitly stated threshold value for a QALY in Sweden.

Willingness to pay for a QALY



Evaluation cont.

- Is a restriction needed?
  - -Would it contribute to a more cost-effective use of the medicine?
  - -Disease dependent
- Would it work in everyday clinical practice?
  - -Is it possible to clearly define a patient group?
  - -Will the restriction be understood/accepted?
- Are conditions needed?
  - -Would it contribute to a more cost-effective use of the medicine?
  - -Improved information within a reasonable amount of time?

Thank you for your attention!

Backup slides

Yes

Prezista (darunavir) for HIV

- A new protease inhibitor (PI) for use in patients who have failed on at least one PI-regimen
- More expensive than other PIs
- The health economic analysis showed that the cost per QALY was fairly low (~ €11 000) compared to relevant comparators
- High severity of disease with a need for more treatment options

Approved for reimbursement for the given indication. If a new indication is approved the company must apply again.

No

Procoralan (ivabradin) for angina

- Indicated for use when beta-blockers not appropriate.
- But calcium channel blockers are cheaper
- Health Economic comparison as last line vs. Surgery
- Procoralan was cheaper than surgery but also less effective

The cost savings per QALY lost were not considered large enough.

Restricted

Champix (vareniclin) for smoking cessation

- Health economic model shows cost-effectiveness compared to bupropion

Reimbursed if given in combination with motivational support and as a second line treatment

The company shall provide information showing this by 2010

Inform of the restrictions in their marketing

The reimbursement review

Sales value in 2003 determines the order

- 49 therapeutic groups

1. *Migraine*
2. *Diseases caused by stomach acid*
3. *Hypertension*
4. *Asthma, COPD and coughs*
5. Depression
6. High cholesterol
7. Pain and inflammation
8. Diabetes
9. Incontinence and prostate
10. Rheumatism
11. Osteoporosis