Reimbursement and drugs clinical guidelines in Sweden: Are decisions based on economic evaluations?

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The Swedish Health Care Organisation

**National level**
- Parliament
- Ministry of Health and Social Affairs
- Central administrative agencies
  - National Board of Health and Welfare (SoS)
  - The Medical Products Agency (MPA)
  - The Swedish Council of Technology Assessment in Health Care (SBU)
  - Pharmaceutical Benefit Board (LFN)

**Local Level**
- 21 county councils
- Hospitals
- Primary Care
- 38 Formulary Committees

**Laws and ordinances**
Impacts on the development of the pharmaceutical costs in Sweden

• Changes in user-charges in 1997
• Generic substitution October 2002.
• LFN, October 2002,
  – allow price cuts (and rises to the highest price within a group of substitutable medicines) without further investigations
  – C/E analyses of new medicines and a review of the existing 2 000 medicines
Increased costs for pharmaceuticals (for humans) in Sweden

- 1990s: 10% annually
- 2002: 8.5%
- 2003: 2.1%
- 2004: 2.8%
- 2005: 2.9%
Total Pharmaceutical Sales per Main ATC-group
1988-2004, Retail Prices, SEK million, Current prices (1€=9SEK)
Sales of pharmaceuticals for the cardiovascular system, retail prices, current prices, €1=SEK9.

Source: Apoteket, pharmaceutical statistics.
Sales of neoplasm and immunomodulating agents, retail prices, current prices, €1=SEK9.

Source: Apoteket, Swedish drug statistics.
Important Reforms in the Swedish Pharmaceutical Market Since 1997

Cost-effectiveness

National Board of Health and Welfare (SOS), Treatment guidelines (1999)
Pharmaceutical Benefits Board (LFN) (1st October 2002)
Formulary committees (1997)
Decentralised drug-budgets (1998)
Changed user-charges (1997)
Generic substitution (1st October 2002)
Parallel trade (1997)

Cost-control

1997

2004
LFN (Läkemedelsförmånsnämnden) The Swedish Pharmaceutical Benefit Board

- Decide reimbursement and establish price for drugs
  - within the national benefit scheme for prescription drugs
- Based on application from manufacturer or own initiative
- Decisions based on 4 principles:
  - Equal value of all human beings -
  - Need & solidarity-
  - Cost-effectiveness-
  - Marginal utility
- Product-oriented
- The new reimbursement system will develop gradually as a consequence or the Committee’s decisions
- Assessment of all existing drugs within the benefit scheme starts in 2004 (finalized within 5 years)
  - starting with anti-acid (PPIs etc.) and anti-migraine treatment
LFN (Läkemedelsförmånsnämnden)  
The Swedish Pharmaceutical Benefit Board

• Decisions on pricing and reimbursement are made by an expert Committee within the agency.

• Ten Committee members and a chairman are appointed by the Government to serve for two years.
  – They all have personal substitutes.
  – Members have experience in the field of medicines, clinical practice, research and health economics. Two members have background in user groups. The chairman is a legal advisor.
Cost-effectiveness analysis

<table>
<thead>
<tr>
<th>Additional costs</th>
<th>Additional effects</th>
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<tbody>
<tr>
<td>Less effective</td>
<td>More effective</td>
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<tr>
<td>Higher costs</td>
<td>Higher costs</td>
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<td></td>
<td>0</td>
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<tr>
<td>Less effective</td>
<td>More effective</td>
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<tr>
<td>Saving costs</td>
<td>Saving costs</td>
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</tbody>
</table>
Cost-Effectiveness

Costs

Unacceptable

Acceptable

Effects

0
Consequences in a social economic perspective

- Other pharmaceuticals
- Outpatient care
- Inpatient care
- Social services (home care, rehabilitation)
- Value of lost production
- Life expectancy
- Quality of life
- Relationship between costs and Quality Adjusted Life Years gained (QALYS)
Swedish Guidelines for Economic Evaluation (www.lfn.se)

• 12 points of requested data plus reference literature and information needed by LFNs to conduct quality control

Note – important:
• Social economic perspective
• Comparator – most appropriate alternative treatment in Sweden
• Sub-group analysis is demanded
• Incremental Cost/QALY
• Standard Gamble, Time-Trade-Off based on appraisals of persons in the health conditions in questions are preferred
• Model analyses with specific Swedish information about treatment practice, costs and characteristics of the patient population are acceptable
The 107 significant decisions by the LFN, October 2002 – March 2005

• 82 reimbursed without limitation (i.e. for all licensed indications without conditions):
  • 12 with limited reimbursement and/or conditioned:
  • 13 denied reimbursement:
Examples:

Approved without conditions

• Aldurazyme (enzym insufficiency) – orphan drug
• Bondil & Caverject (ED) – only severe ED
• Carbaglu (hyperammonaemia due to enzyme insufficiency) – orphan drug
• Concerta (ADHD) – C/E
• Fuzeon (HIV) – C/E
• Glucosine (worn joints) – C/E to be reviewed later
• Humira (rheumatiod arthritis) – C/E
• Relestat (eye allergy) – price comparison sufficient
• Somavert (overproduction of growth hormone) – orphan drug
• Zavesca (gaucher’s disease) – orphan drug
Examples: Approved with conditions

• Crestor (lipid lowering) - subgroup C/E, marketing restriction, hard endpoints, market data
• Ezetrol (lipid lowering) – “
• Lantus (diabetes) - subgroup C/E, hard endpoints
• Reductil (obesity) – subgroup C/E, marketing restrictions, market data
• Xenical (obesity) – subgroup C/E, marketing restrictions.
Diminishing marginal utility of drug treatment

Benefit of health:

Number of treated patients

Indication 1
Indication 2
Indication 3
Examples:

Non-subsidised drugs

- Cerazette (contraceptive-pill) - not C/E, no significantly proved effect
- Flutid (suspension for nebuliser) – Not cost-effective; dose effect relation not proved
- Viagra & Cialis (ED) – low degree of desirability
- Stocrin, new dose 600 mg (HIV) – not C/E, superior compliance not proved
The review

- 2 000 medicines
- 49 therapeutic groups
- Sequence: biggest first (antihypertensive, asthma/cough, depression, high cholesterol, pain killers, diabetes, incontinence/prostate disorders, contraceptives/climacteric disorders, anaemia, bleeding disorders
- Pilots: Migraine and antacids
Migraine

LFN decisions:

• No longer reimburse Imigran (sumatriptan) 100 mg
• Grant reimbursement to the new medicine Imigran Novum (sumatriptan) 100 mg at a price 42% lower than Imigran
• Decrease of the price of Naramig (naratriptan) 2.5 mg by 14%
Antacids

LFN decisions:

- Proton pump inhibitors (PPI) are the cost-effective alternative – generic omeprazole most cost-effective - reimbursed
- The price of Pantoloc was decreased to accommodate the pricing band (+/-25%) - reimbursed
- H2 antagonists may cost less, but low cost cannot compensate for the difference in effect – not reimbursed
- Patent drugs only reimbursed as second line treatment, if they are cost-effective
Two drugs (L₁ and L₂) and their price over time. L₁ patent expire at time tₙ and its price decrease immediately as a consequence of competition from generics L₃ at price p₃.
Experiences from LFN

• Use of cost-effective drugs are encouraged
• Increased costs are acceptable (for cost-effective drugs)
• Important that decisions on reimbursement are made by an expert Committee within the agency.

• Threshold value, cost per QALY?
Willingness to pay for a QALY

LFNs’ decisions on reimbursement for pharmaceuticals based on cost-effectiveness require a "threshold value", reflecting the citizens’ valuation of health gain.

In England, NICE use £30,000 as a "threshold" value (in January 2005, about SEK 390 000, or €43,000).

A similar value of a statistical life (VOSL) in transport in Sweden is SEK16.3 million (about £1.3 million or €1.8 million), Persson (2004). This corresponds to SEK 655 000 (£50,000 or €73,000) per QALY, Persson & Hjelmgren (2003).
Experiences from SoS
(National Board of Health and Welfare)

• Use of cost-effective drugs are encouraged
• National treatment guidelines with limited compliance

• Time delay to get the drugs available for the patients?
Evidence based medicine and C/E results for new cancer treatments

<table>
<thead>
<tr>
<th>Data on file</th>
<th>Abstract or other early presentation</th>
<th>Publication – one RCT</th>
<th>Cochran review – two RCT</th>
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Length of follow-up data

Piggy-back study:

- C/E
- Not C/E
- Not C/E
- Not available

Modeling study:

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<th>C/E</th>
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<th>Not C/E</th>
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<tr>
<td>LFN approach</td>
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<td>Most desirable data for the SoS approach</td>
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Differences between the European countries with regard to the level of uptake and the time period over which cancer drugs become available to patients

- Austria, Spain and Switzerland were the top three countries in terms of adoption of the newest drugs between 1999-2004
- The Czech Republic, Hungary, Norway, Poland and the UK were identified as below average adopters for the treatment of breast cancer, colorectal cancer, lung cancer and non-Hodgkin’s lymphoma and supportive care

Experiences from Formulary committees

• Cost containment is important
• Lack of health-economic expertise

• Budget impact models are useful
Sweden
Summary: Experiences from LFN, SoS and the Health care providers

• For LFN the cost-effectiveness is a clear criterion for decisions and there is substantial input by health economists to the process
• Use of the most cost-effective drugs are encouraged at the national level (LFN and SoS)
• Evidence based medicine has an impact on:
  – C/E results
  – Level of uptake and time to adoption of new pharmaceuticals
• Drug committees at the health care providers are mainly concerned about the budget impact