The Drug Reimbursement System in Sweden

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The Swedish health care system
The recent reforms within the drug market
Problems from different perspectives
TLV – The Dental and Pharmaceutical Benefits Authority
- Organisation and mandate
- Assessment and appraisal within TLV
- Stakeholder interaction
- Perspective and ethics
- Single cases and reviews of therapeutic classes
The Swedish Health Care System

### The organization of Swedish health services

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<th>Central government</th>
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<td>Ministry of Health and Social Affairs</td>
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MPA – Medical Products Agency
SBU – Swedish Board for Health Technology Assessment
National Corporation of Swedish Pharmacies – state run monopoly since the 70ies.
The Drug Reforms of 2002

Goal – to integrate drugs fully in the decision making process and prioritization of health care

- Responsibility for the pharmaceutical benefit scheme (PBB) divided between the government and the counties
- Devolution of drug budgets within the counties
- Law regulating Drug and Therapeutics Committees
- Mandatory generic substitution
- LFN (later TLV) a national governmental authority responsible for pricing and reimbursement of drugs within the PBB formed
Effect of Generic Substitution on Price

Figure 2. Cost/DDD for six products contained within the top 25 prescribed ambulatory care products in Sweden on a DDD basis where multiple copies became available just before or after 2002. The dotted line denotes the instigation of mandatory generic substitution.
The Swedish Drug Market

Million SEK

- Prescription drugs – total costs
- Prescription drugs – total costs in 2007 SEK
- Pharmaceutical Benefit Scheme
- Hospital drugs – total costs
- OTC costs

- Mandatory generic substitution

Hoard due to reform of the PBB with initial higher co-payment & no free drugs

Year:
- 1988
- 1989
- 1990
- 1991
- 1992
- 1993
- 1994
- 1995
- 1996
- 1997
- 1998
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- 2000
- 2001
- 2002
- 2003
- 2004
- 2005
- 2006
- 2007
Generic drugs vs. Patented drugs
Problems from Different Perspectives

Provider
Prescriber
Producer
Public
Problems from the Perspective of the Health Care Providers

Imbalance! Does the system address the major issues?
Coherence?
Effectiveness - efficacy?
Imbalance & Major Issues

- Generic drugs
- Patented drugs
- Oligopoly market

Hospitals & Outpatient clinics
Coherence: Transfer of Responsibility

MPA

TLV

Health Care Provider

Pharmacy

Cost-effectiveness

Safety & Efficacy

MPA

TLV

Decision for groups

Decision for individuals
Coherence: Transfer of Responsibility

Health Care Provider

Pharmacy

Cost-effectiveness

TLV

Safety & Efficacy

MPA

Decision for groups

Decision for individuals
The Prescriber

Role of the prescriber?

Fragmented and dynamic benefit scheme
Lack of decision support within EPR
Why doesn’t the health care providers use drugs included into the pharmaceutical benefit scheme to the extent expected by the industry?

• Health-care vs. Society perspective …
• In and/or out …
The Pharmaceutical Benefit Board of TLV – individuals, not representants

Law
Economics

Health economy

Health care providers

Medical ethics

Health care professionals

Patient / public
The Role of TLV

TLV is an independent authority under the Department of Health and Welfare financed through a governmental grant and NOT through application fees

- Decides on price and reimbursement for drugs and medical products – no budget restraints
- Decides on price and reimbursement for dental interventions – fixed budget
- Decides on the sales margins for the pharmacies
- The executive office prepares and assesses all cases and give their recommendation for decision to the board
The Ethical basis

All decisions are based on three criteria:

• The principle of equal human value
  - respect for the equal human value of all people
• The principle of need and solidarity
  - those in greatest need take precedence) and
• The cost-effectiveness principle where TLV uses a societal perspective

A citizen’s council with representatives from patient organisations act as reference discussion group
The two first principles are overriding principles to which the cost-effectiveness principle has to be applied. The consequence is that there is NOT a clear cut-off value for cost per quality-adjusted life-year.
Need and solidarity

Methodology per se
Scientific uncertainty
Effectiveness - efficacy
Adverse drug reactions

Human value

Cost-effectiveness
The Decision Making Process of TLV

1. An application is sent in by the company
2. The assessment is done by a project group at the executive office
3. Normally the company and the officers have regular contact on issues related to the application
4. The project group writes a memorandum which is sent both to the board and to the company
5. The company have the right to one deliberation with the board if the assessment is negative for the product
6. A final appraisal = decision is made within 180 days
7. The decision can be appealed to a higher court
Limitations

The Swedish pharmaceutical benefit scheme is a product-based system.
In "exceptional" cases TLV can limit the reimbursement using for instance
- indications or levels of disability
- patient groups such as age or gender
- physician characteristics, e.g. specialty
- treatment failure
Other restrictions can also be applied, such as demands for follow-up within a certain time
If possible the TLV will compare a drug price with the price for the cheapest available comparable drug, most often a generic.
We can seldom agree with the companies on a just comparison
Limitations, cont’d

Pharmaceutical manufacturers have to inform TLV about new indications in order for TLV to decide on whether or not to start a new appraisal.

To many applications are being withdrawn before negative decision.

We had over 2 000 drugs with reimbursement when we started.

Not enough structured collaboration with the MPA on evaluation of effectiveness due to legal restrictions.

Problem with dissemination of information about, and thus also adherence to, restrictions in reimbursement of drugs.
Percentage of patients started on rosuvastatin during 2008 who had previously been treated with simvastatin up to two years before

Percentage: 81%, 77%, 76%, 73%, 71%, 71%, 71%, 71%, 71%, 71%, 71%, 70%, 69%, 69%, 69%, 68%, 65%, 64%, 61%, 61%, 60%, 55%, 54%

Examples

Long-acting insulin analogues (Lantus, Levemir)
  • clinical outcome / nocturnal hypoglycemia
  • quality of life assessment / nocturnal hypoglycemia

SSRIs
  • clinical outcome / defining a responder
  • comparator
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Publication pattern for studies of the five selective serotonin reuptake inhibitors approved in Sweden between 1989 and 1994 for treating major depression

*BMJ 2003; 326: 1171-1173*
Reviews of Therapeutic Classes

49 therapeutic classes
The largest/most costly first

Three basic conditions:
• The process must be evidence-based
• There is a limited time for each review
• When the review is done the TLV must make a decision, even if the information is limited / not perfect
Reviews of Therapeutic Classes

• Information is gathered about the effect and cost effectiveness of all the drugs within the therapeutic area
• Documentation from HTA organizations, Swedish authorities and the drug companies is considered
• External medical experts and separate hearing with relevant patient organisations
• Drugs that can not prove superior efficacy is not permitted a premium price
• In order to guarantee access to therapeutic alternatives different price corridors are constructed
• Some drugs lose their reimbursement and some are only reimbursed with restrictions
Finalised groups

- Migraine Febr 2005
- Stomach acid related disorders Jan 2006
- Asthma, COPD and cough suppressants May 2007
- Hypertension Febr 2008
- Depression Dec 2008
- Hyperlipidemia Febr 2009

Ongoing

- Diabetes Oct 2009
- Incontinence and prostate disorders Dec 2009
- Contraception and HT in the menopause Feb 2010

Ongoing as part of a cooperation on musculoskeletal diseases between the Swedish national authorities

- Analgetics Nov 2009
- Rheumatoid arthritis Nov 2009
- Osteoporosis Nov 2009
Number of patients in Sweden initiated on therapy with different therapeutic classes during three time-periods

Source: The Swedish Prescribed Drug Register, The National Board of Health and Welfare
Proportion Initiated on ARB Prescribed an ACEI
(September-December, 2007)
Mandatory Generic Substitution

The pharmacies have to substitute branded drugs for the cheapest generic if the patient doesn’t choose to pay the difference themselves.

The physician can oppose generic substitution on medical grounds, in which case the more prescribed drug is fully covered (if within the PBS). Seldom used.

TLV will allow price changes (up and down) every month. About 7,000 every year.

The cheapest generic will have the whole market (9 million people) for one month.

Total direct savings have been over €1.5 billion in five years. €500 million Euro in 2006. Dynamic changes have been estimated to be at least as large.