

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

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Ulf Persson, Ph.D.

IHE,

The Swedish Institute for Health Economics

Address: Box 2117, 220 02 Lund, Sweden

Phone: +46 46 32 91 00

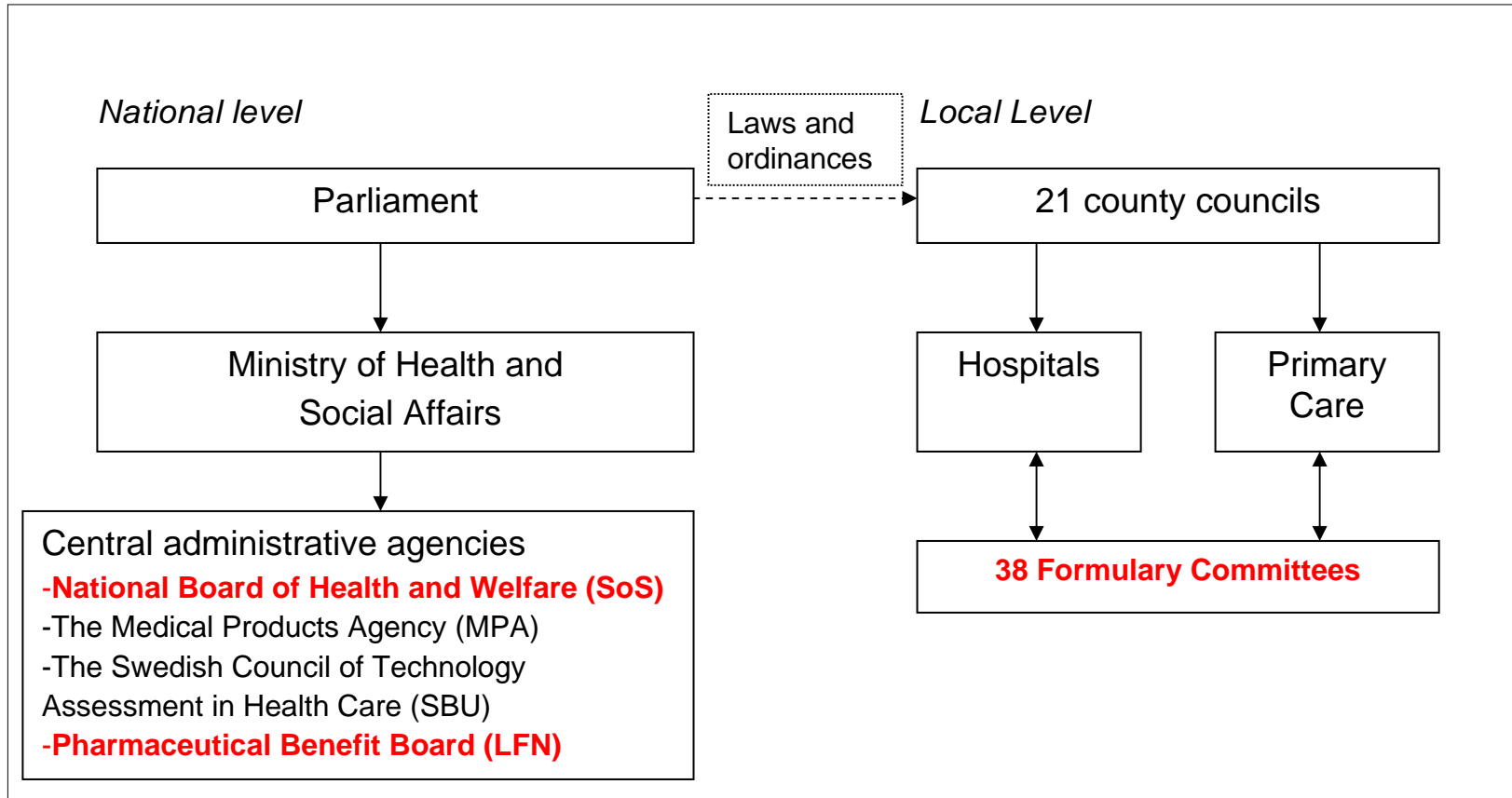
Fax: +46 46 12 16 04

E-mail: up@ihe.se

Internet: www.ihe.se



The Swedish Health Care Organisation



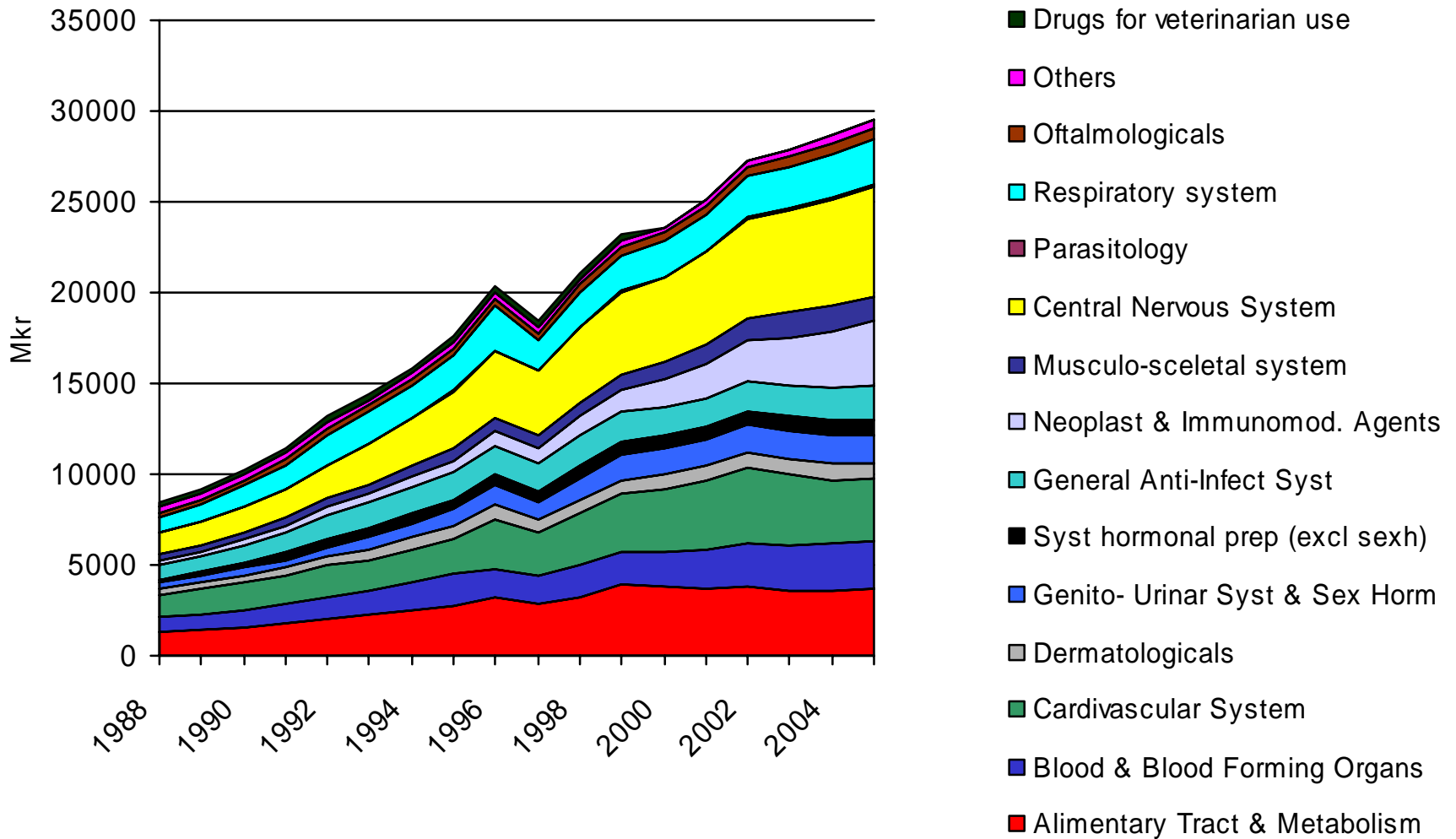
Impacts on the development of the pharmaceutical costs in Sweden

- 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

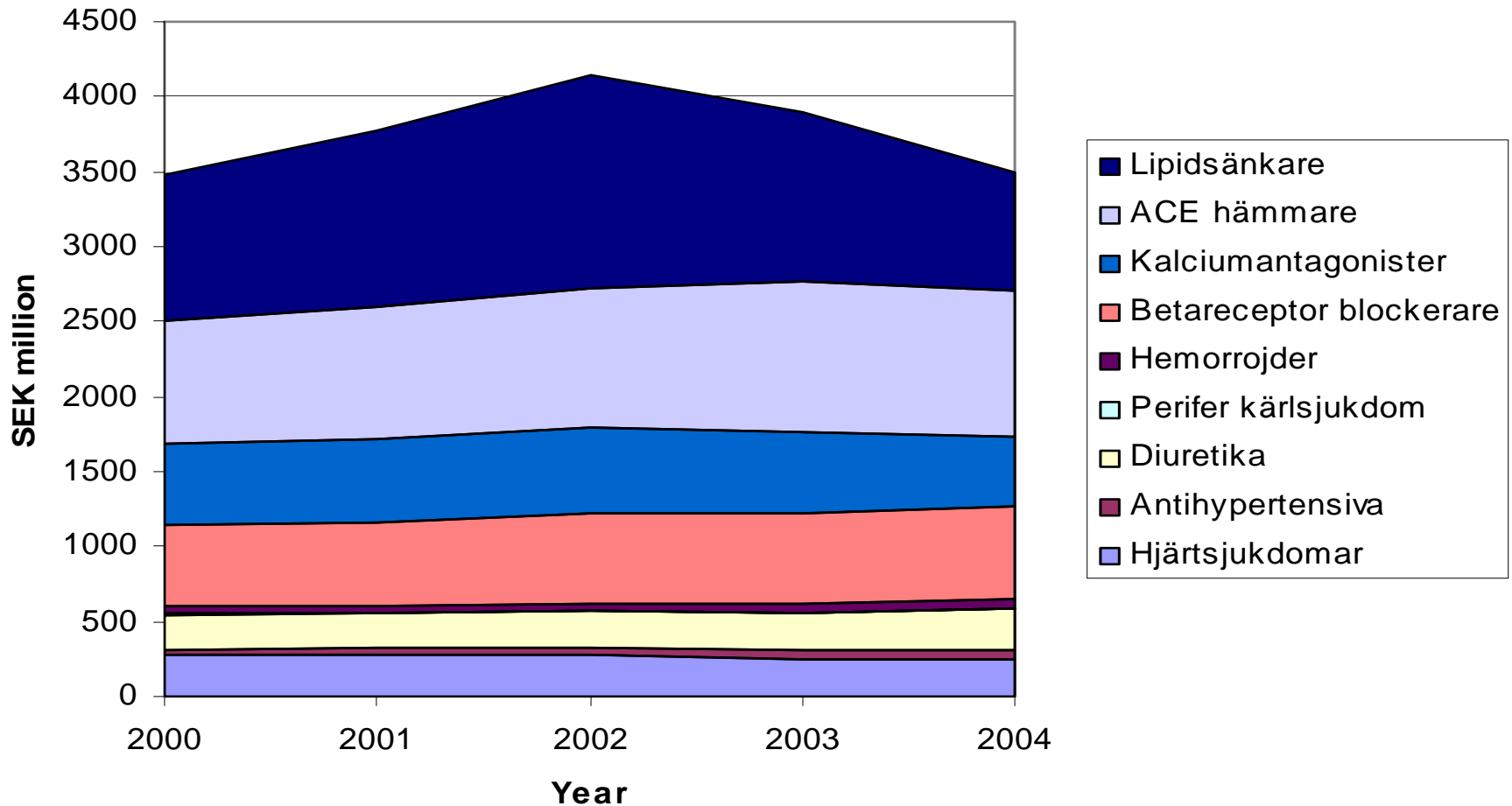
Increased costs for pharmaceuticals (for humans) in Sweden

- 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)

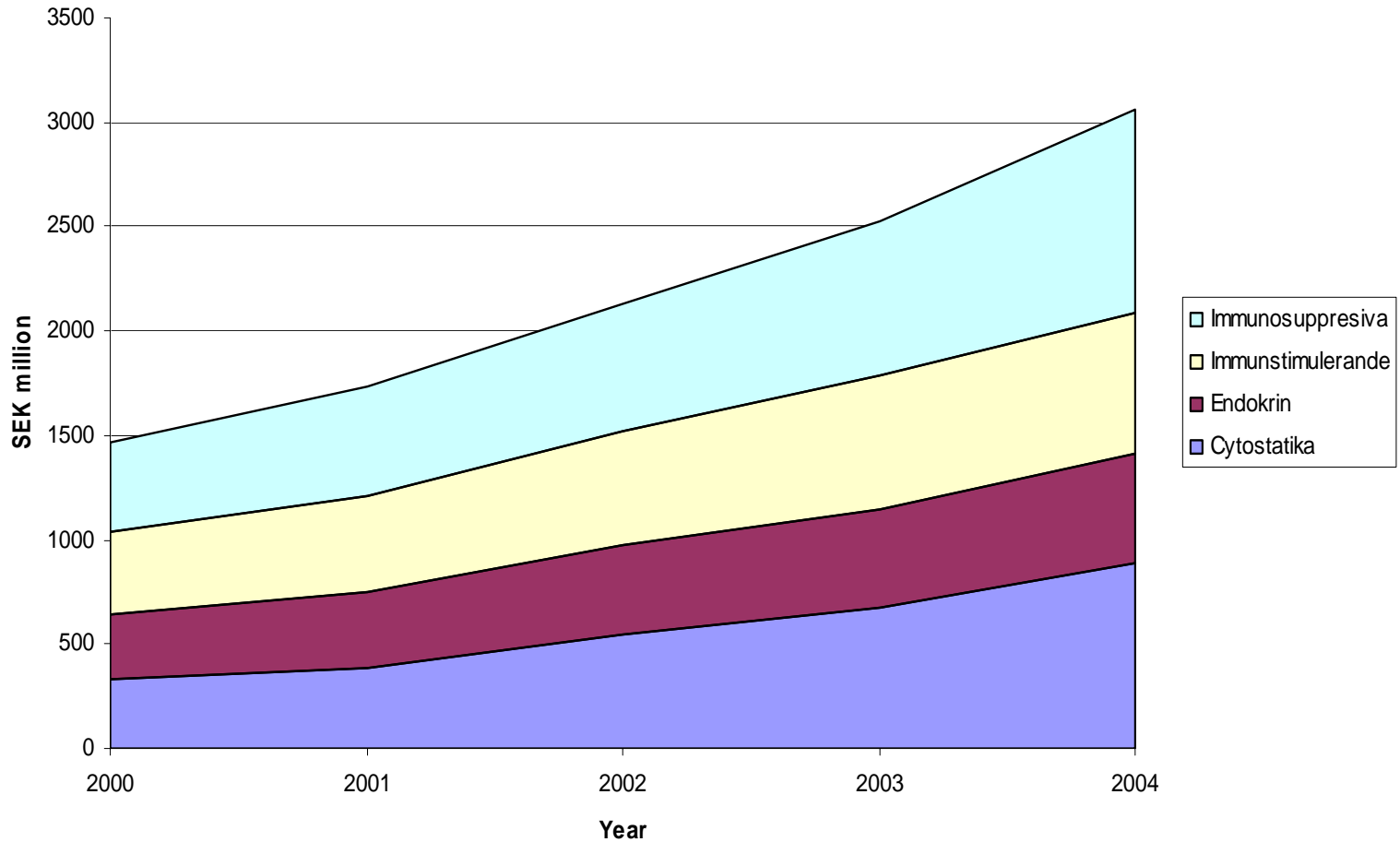


Sales of pharmaceuticals for the cardiovascular system, retail prices, current prices, €1=SEK9.



Source: Apoteket, pharmaceutical statistics.

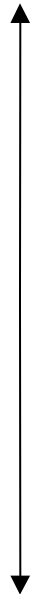
Sales of neoplasm and immunomodulating agents, retail prices, current prices, €1=SEK9.



Source: Apoteket, Swedish drug statistics.

Important Reforms in the Swedish Pharmaceutical Market Since 1997

Cost-effectiveness



Formulary committés
(1997)

Changed user-
charges (1997)

Parallell trade (1997)

National Board of Health and
Welfare (SOS), Treatment
guidelines (1999)

Decentralised drug-
budgets (1998)

Pharmaceutical Benefits Board (LFN)
(1st October 2002)

Generic substitution
(1st October 2002)

Cost-control

1997

2004

LFN (Läkemedelsförmånsnämnden)

The Swedish Pharmaceutical Benefit Board

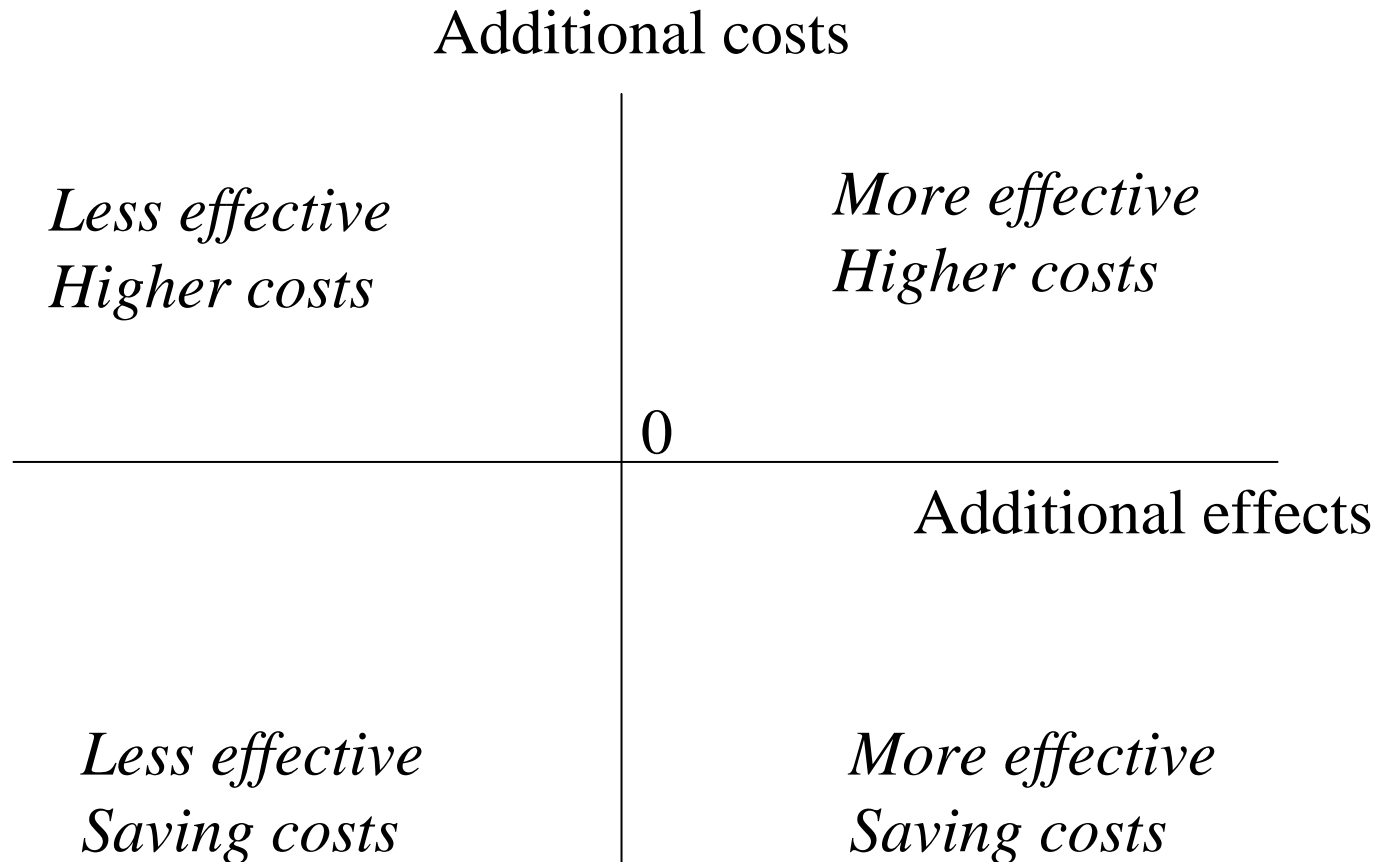
- **Decide reimbursement and establish price for drugs**
 - within the national benefit scheme for prescription drugs
- **Based on application from manufacturer or own initiative**
- **Decisions based on 4 principles:**
 - Equal value of all human beings -
 - Need & solidarity-
 - Cost-effectiveness-
 - Marginal utility
- **Product-oriented**
- The new reimbursement system will **develop gradually** as a consequence of 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)

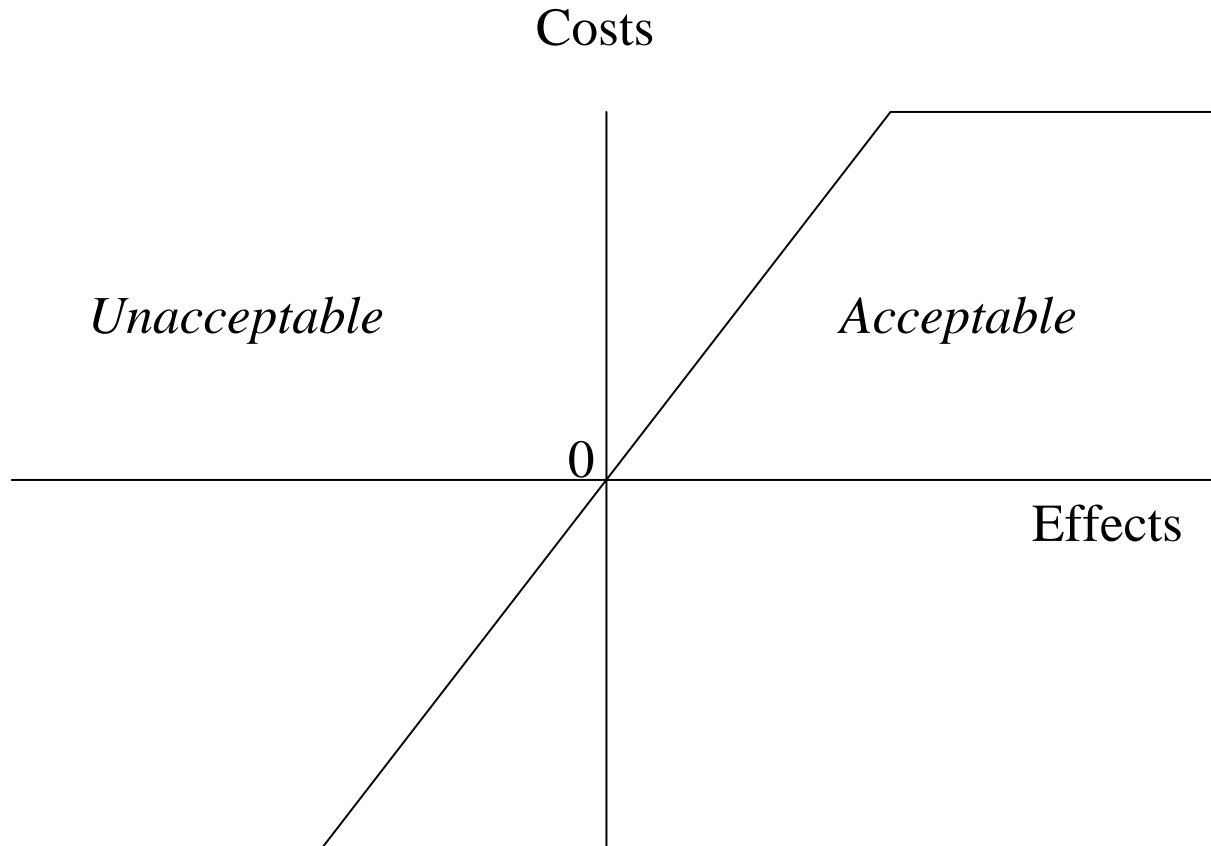
The Swedish Pharmaceutical Benefit Board

- 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



Cost-Effectiveness



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 (rheumatoid arthritis) – C/E
- Relestat (eye allergy) – price comparison sufficient
- Somavert (overproduction of growth hormone) – orphan drug
- Zavesca (gaucher's disease) – orphan drug

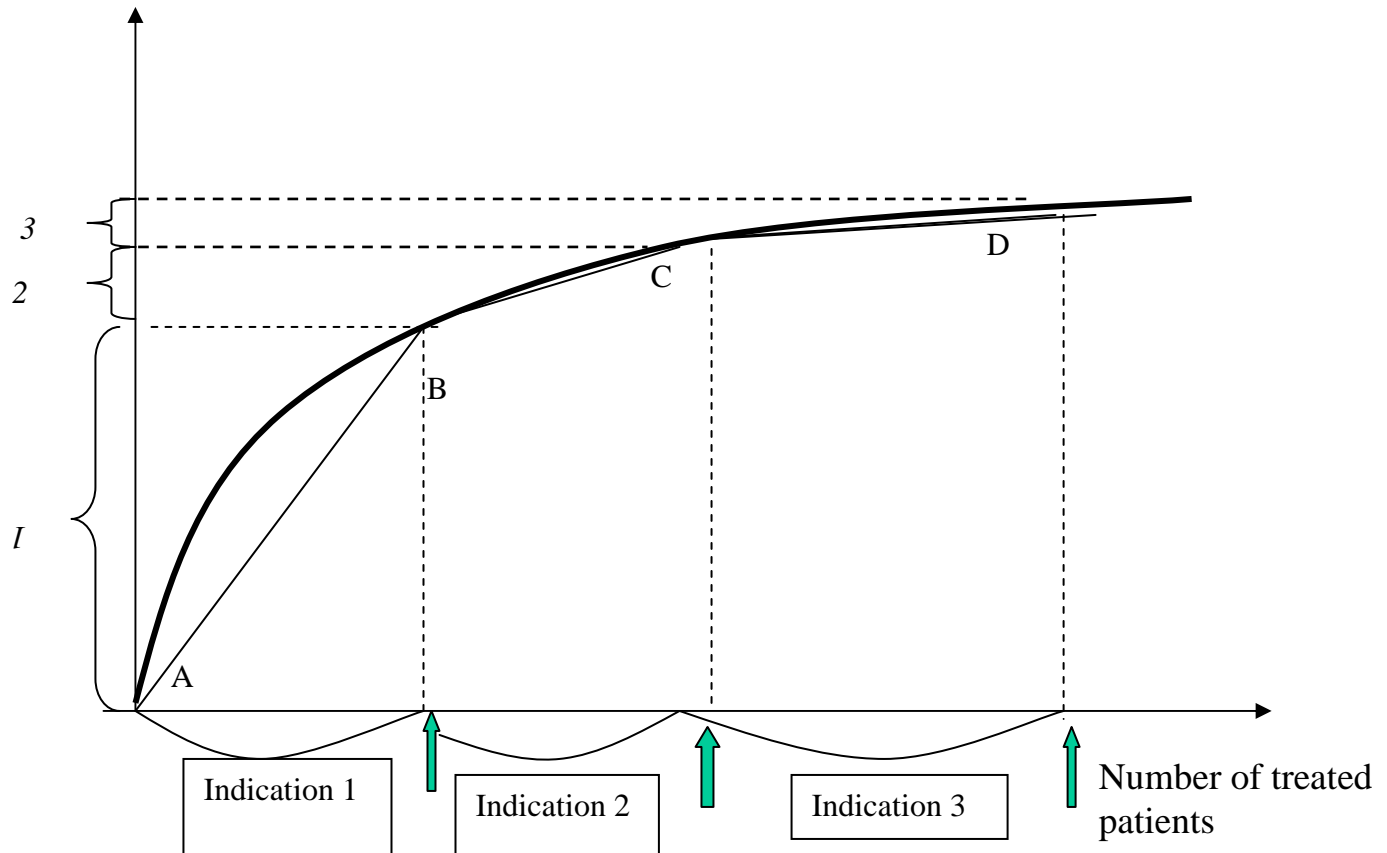
Examples:

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:



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:

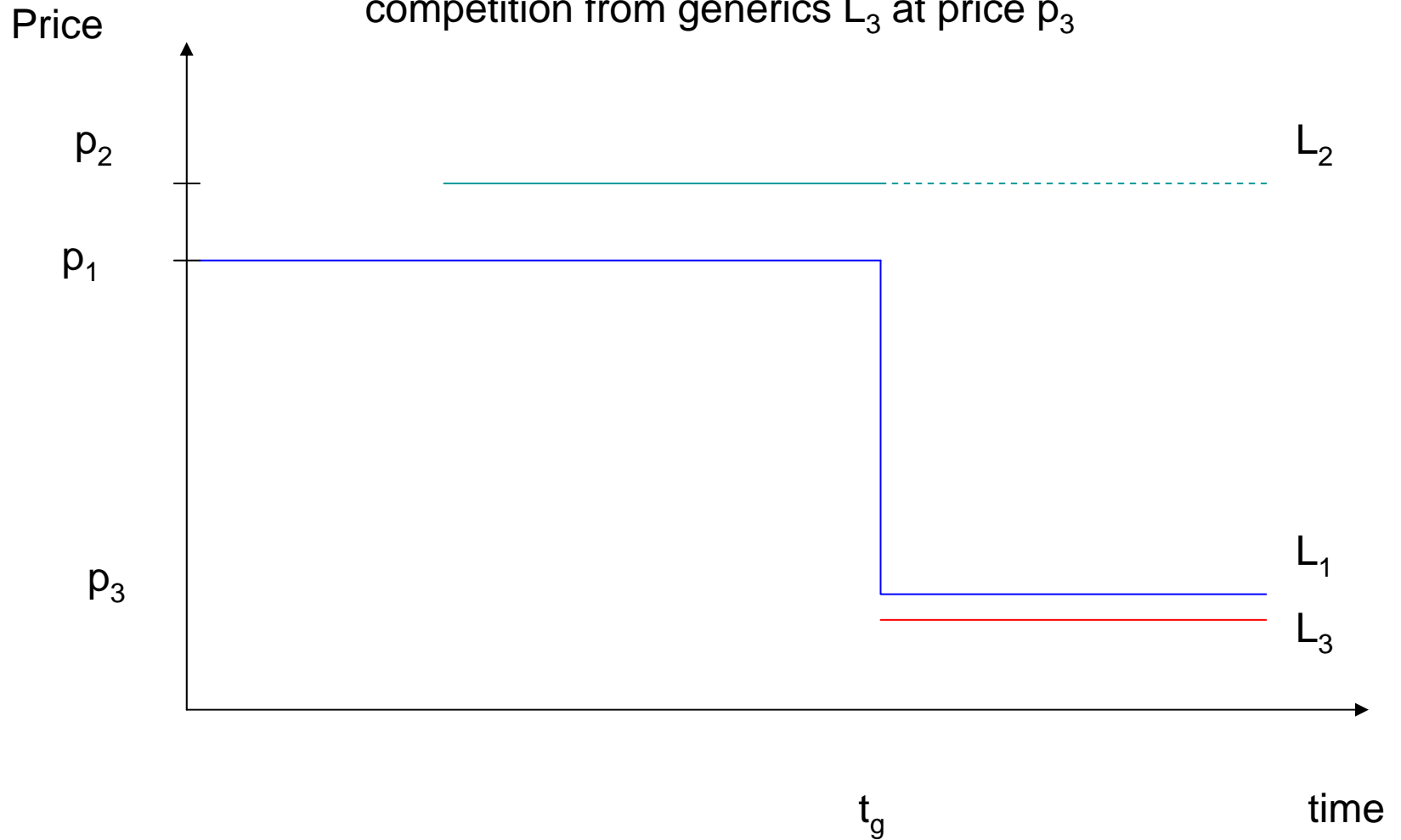
- No longer reimburse Imigran (sumatriptan) 100 mg
- Grant reimbursement to the new medicine Imigran Novum (sumatriptan) 100 mg at a price 42 % lower than Imigran
- Decrease of the price of Naramig (naratriptan) 2.5 mg by 14%

Antacids

LFN decisions:

- Proton pump inhibitors (PPI) are the cost-effective alternative – generic omeprazol 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 for the difference in effect – not reimbursed
- Patent drugs only reimbursed as second line treatment, if they are cost-effective

Two drugs (L_1 and L_2) and their price over time. L_1 patent expire at time t_g and its price decrease immediately as a consequence of competition from generics L_3 at price p_3



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.
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- 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 Januari 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

Data on file	Abstract or other early presentation	Publication – one RCT	Cochran review – two RCT
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Length of follow-up data

Piggy-back study:

C/E	Not C/E	Not C/E	Not available
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Modeling study:

C/E	C/E	Not C/E	Not available
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LFN approach

Most desirable data for the SoS approach

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

Source: Wilking & Jönsson (2005)

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