Health Technology Assessment and the Demands of the Fourth Hurdle Experiences from TLV in Sweden

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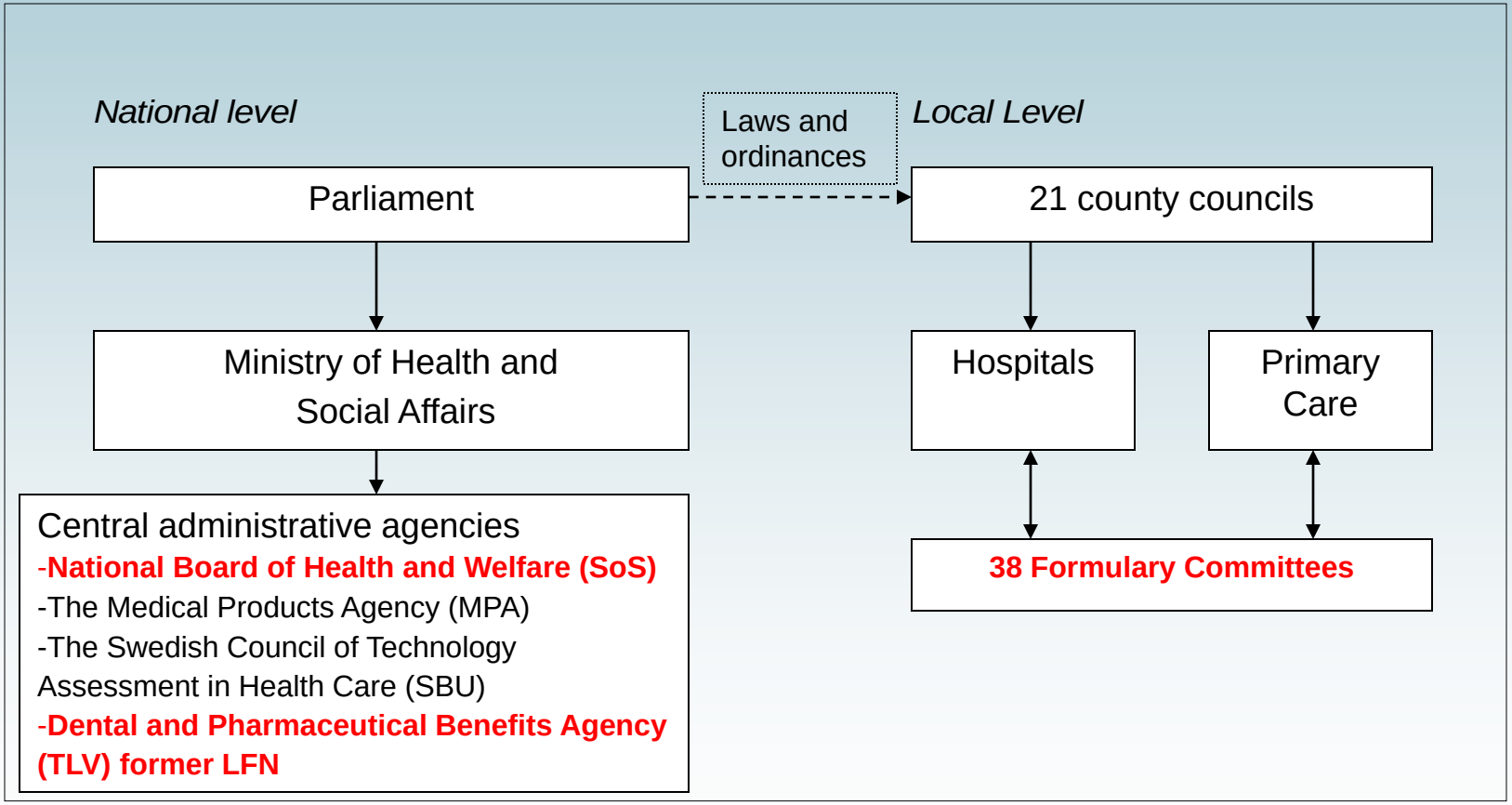
The Swedish Health Care Organisation



Organizations undertaking or commissioning Health Technology Assessment (HTA) in Health Care in Sweden

- SBU (Swedish Council on Technology Assessment in Health Care)
- SoS (National Board of Health and Welfare)
- Regional P&T Committees & Regional Mini-HTA
- TLV (Dental & Pharmaceutical Benefits Agency)

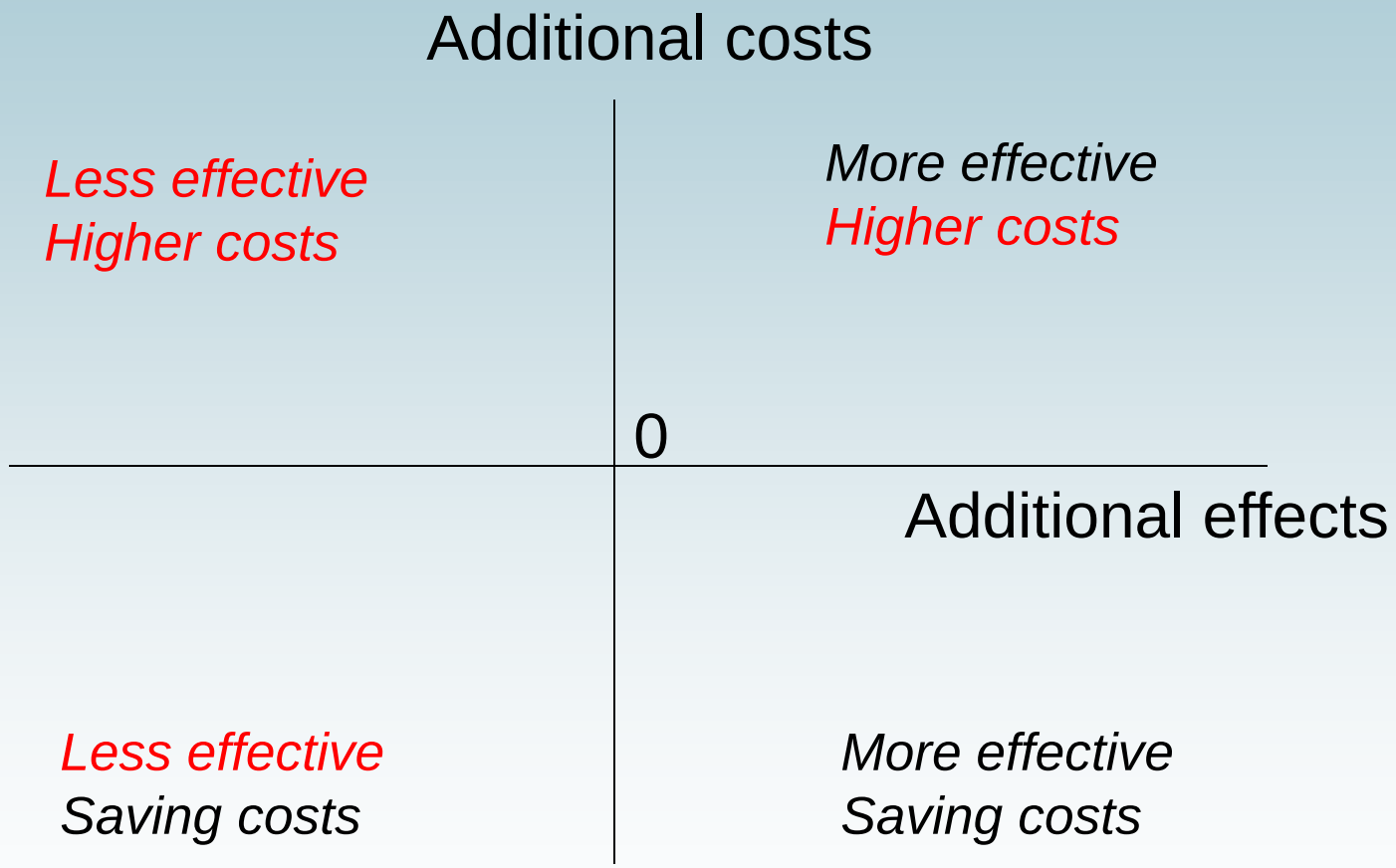
The Swedish Health Care System
Pricing and reimbursement of new pharmaceuticals (innovations) for outpatient use (prescriptions)

- National level
  - Free pricing – no reimbursement
  - Reimbursed pharmaceuticals – Value Based Pricing (VBP) system formalized with the LFN establishment in 2002
  - Reimbursement is based on Cost-Effectiveness; but also other factors relevant for value should be taken into account

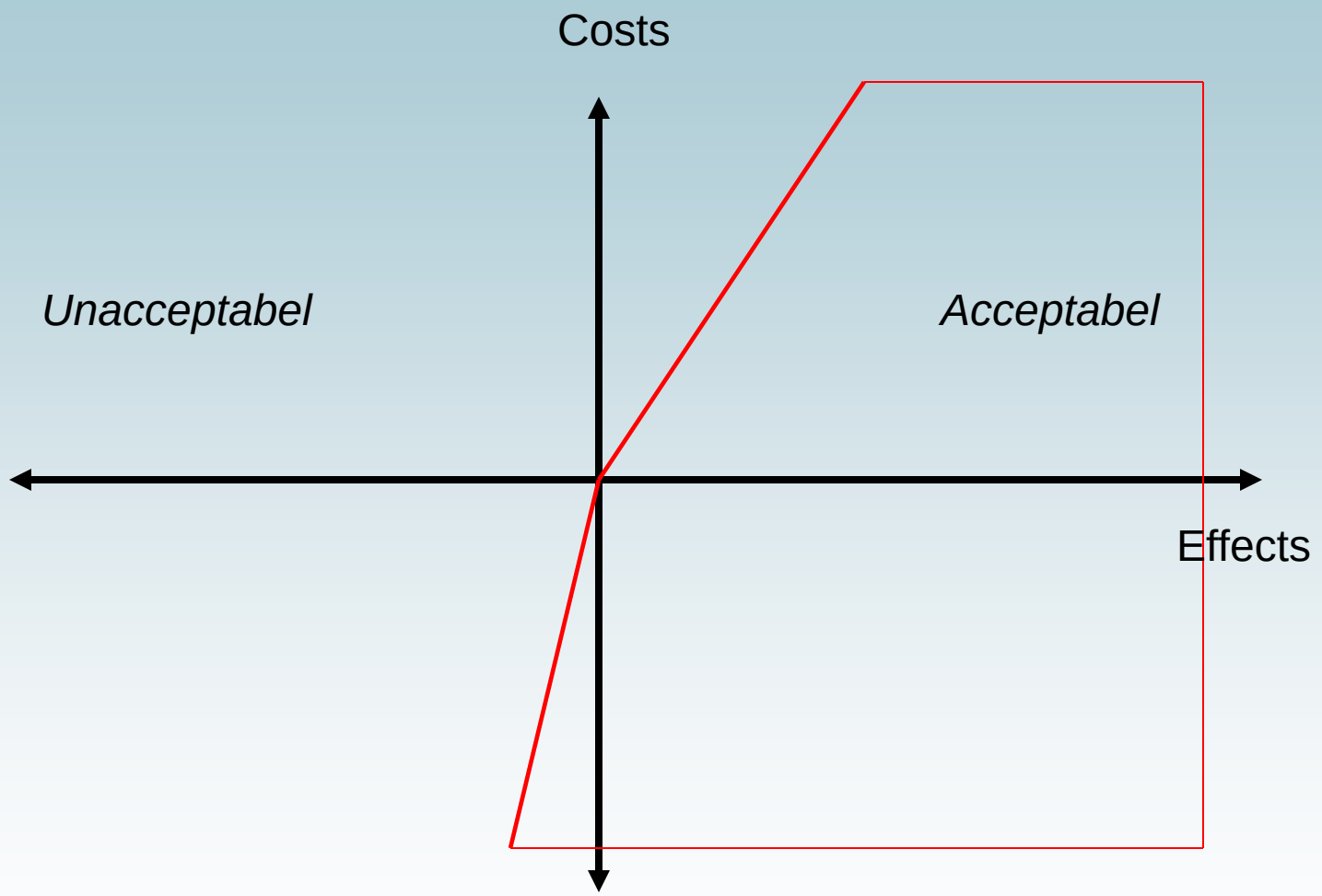
Dental and Pharmaceutical Benefits Agency (TLV) in Sweden (former LFN)

- 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 3 criteria:
  - Equal value of all human beings
  - Need & solidarity
  - Cost-effectiveness
- Product-oriented

Cost-effectiveness analysis



Cost-Effectiveness Analysis



Reimbursement decisions on Pharmaceuticals from TLV/LFN 2002 – 2011

Year	Reimbursement without limitation	Reimbursement with limitation	Reimbursement denied	Total number of decisions
2002 Oct-	-	-	-	-
2003	16 (55 %)	4 (14 %)	9 (31 %)	29
2004	56 (89 %)	2 (3 %)	5 (8 %)	63
2005	51 (88 %)	3 (5 %)	4 (7 %)	58
2006	54 (73 %)	7 (9 %)	13 (18 %)	74
2007	41 (62 %)	11 (17 %)	14 (21 %)	66
2008	31 (30 %)	37 (36 %)	36 (35 %)	104
2009	21 (36 %)	22 (37 %)	16 (27 %)	59
2010	29 (41 %)	23 (33 %)	18 (26 %)	70
2011	62 (70 %)	20 (22 %)	7 (8 %)	89
2012-March	9 (60 %)	4 (27 %)	2 (13 %)	15
Summary	370 (59 %)	133 (21 %)	124 (20 %)	627

Key principles of Value Based Pricing (VBP) of pharmaceuticals in Sweden

1. ***Societal perspective*** in order to consider cost offset in other sectors/budgets than the health care
2. ***A threshold value***, based on individuals maximum willingness-to-pay for a QALY gained
3. ***Marginal decreasing utility*** of treatment, e.g. the benefit varies by indication or by degree of severity

1. 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)

2. Threshold value in Value Based Pricing (VBP) in Sweden, TLV 2012

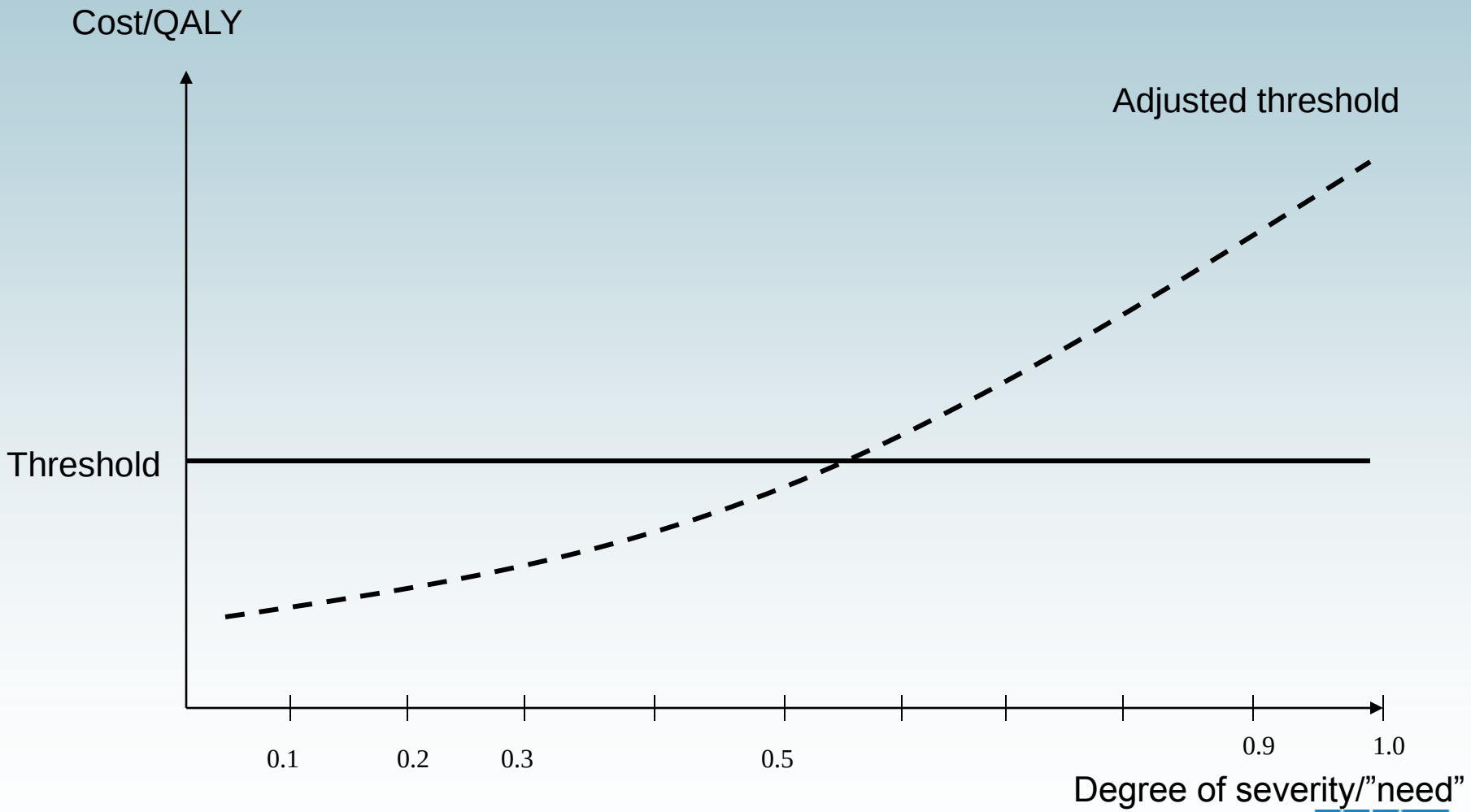
No official threshold value per QALY in Sweden

However there are some reference points:

- About €90,000 from the transport sector
- About €40,000 from a pilot study
- "Three times Gross Domestic Product (x3 GDP) per capita", proposed by WHO 2002.
- International figures (NICE £30,000)

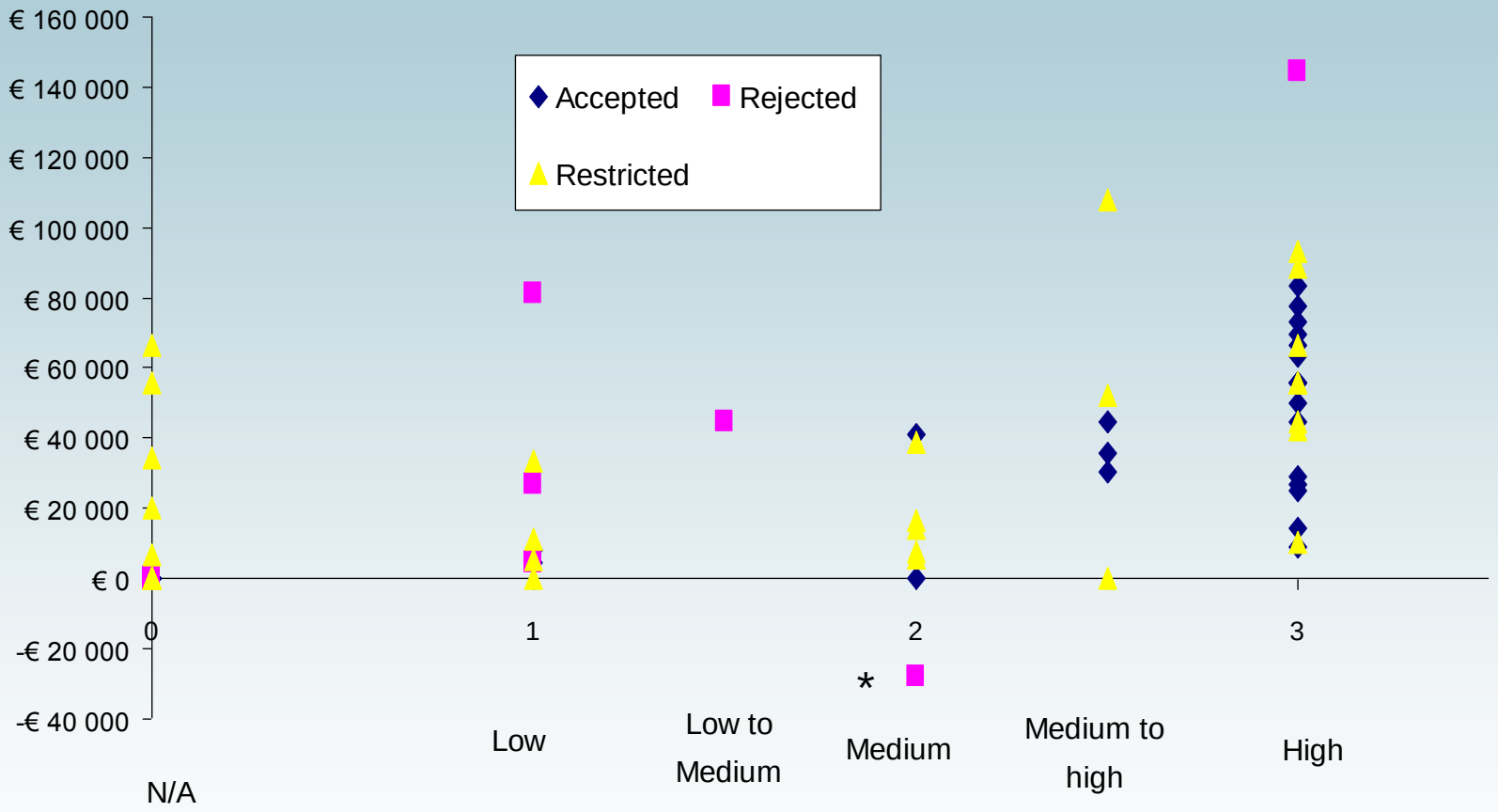
Accepted value of a QALY vary by degree of "severity"

2. A threshold value (cont.)
Equity /"need" adjusted reimbursement decisions compared with a constant cost-effectiveness threshold



Cost-effectiveness (cont.)

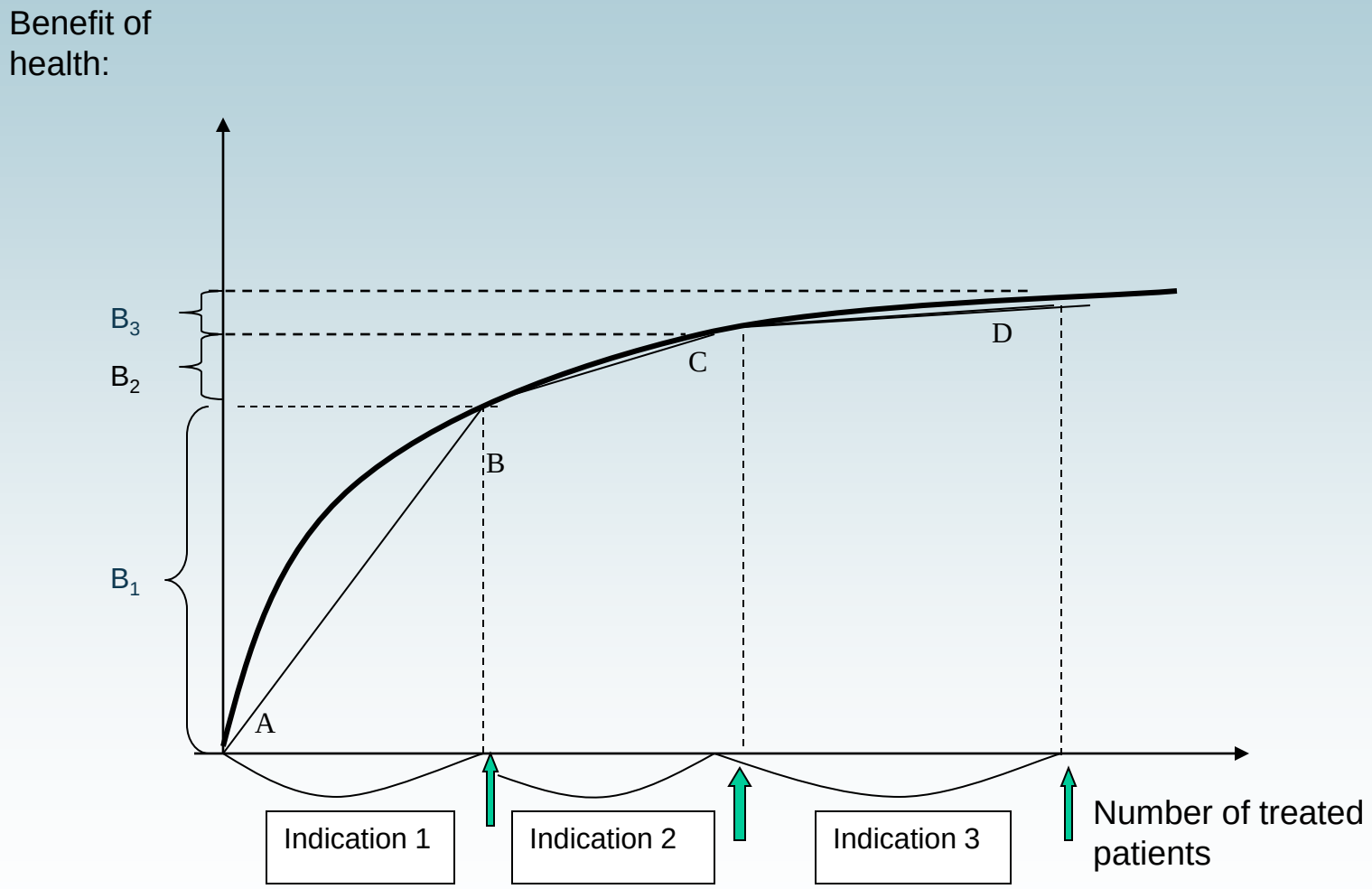
Cost per QALY and disease severity



*Lower effect and lower cost than the comparator. Thus a saving per QALY lost

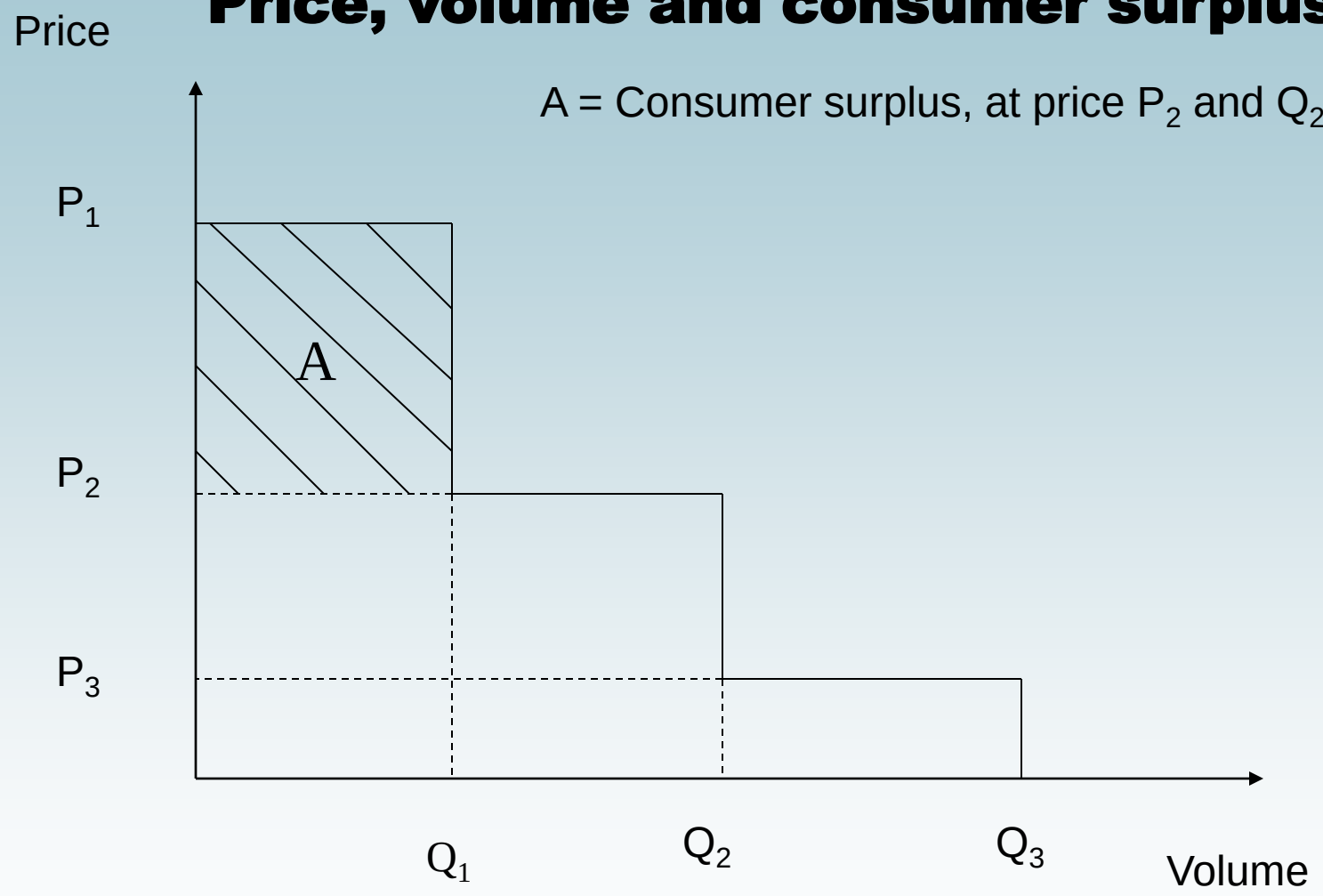
Source: TLV

3. Diminishing marginal utility of drug treatment



Value Based Pricing (VBP)

Price, volume and consumer surplus



Cost containment instruments

TLV
Ex ante – Ex post

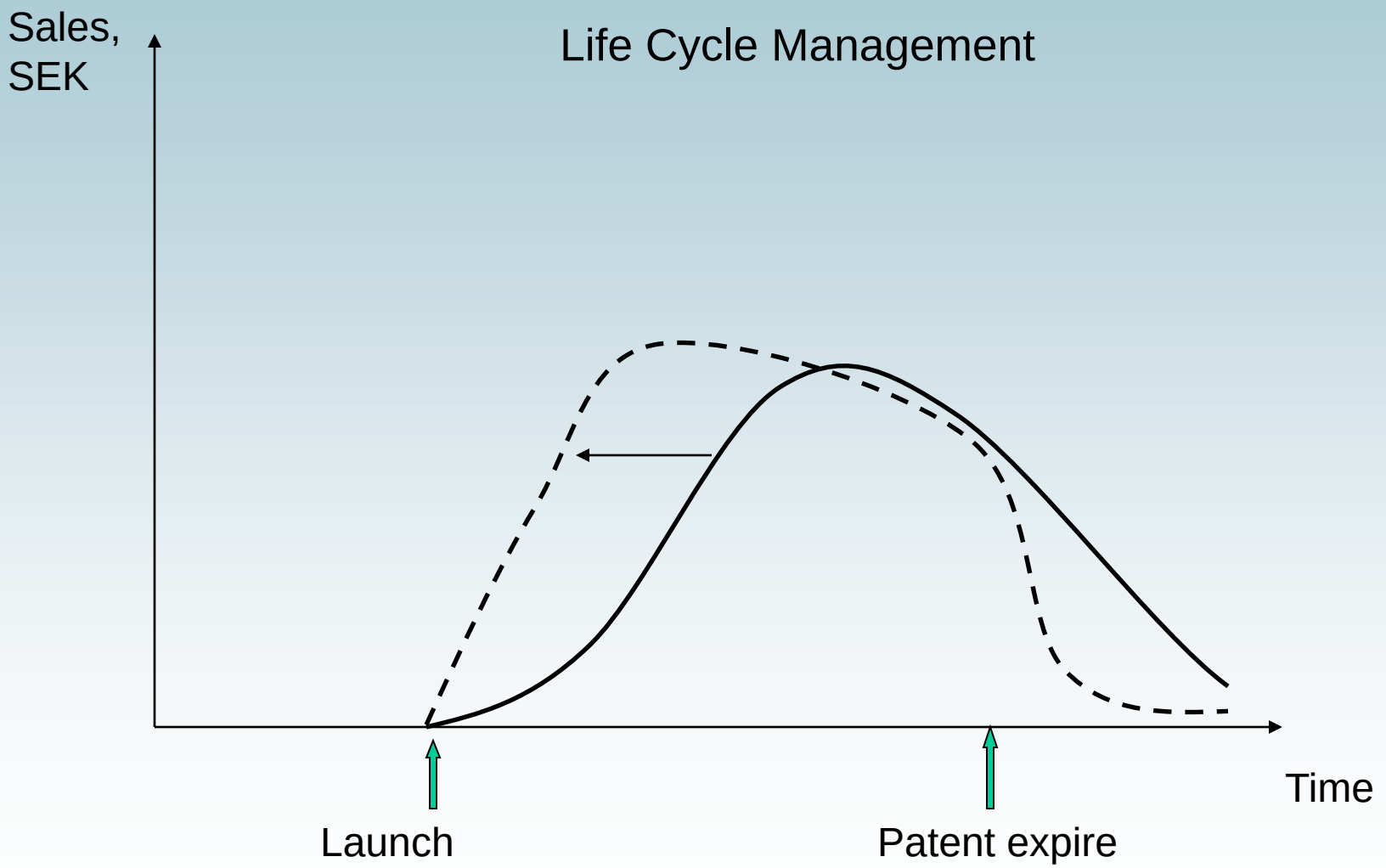
Economic Analys - Ex ante (before the drug is on the market)

- Decision within 3-4 months for new pharmaceuticals

Economic Analys - Ex post (include drugs on the market)

- Evaluation process often takes about 12-15 months

Cost containment (Cont.)



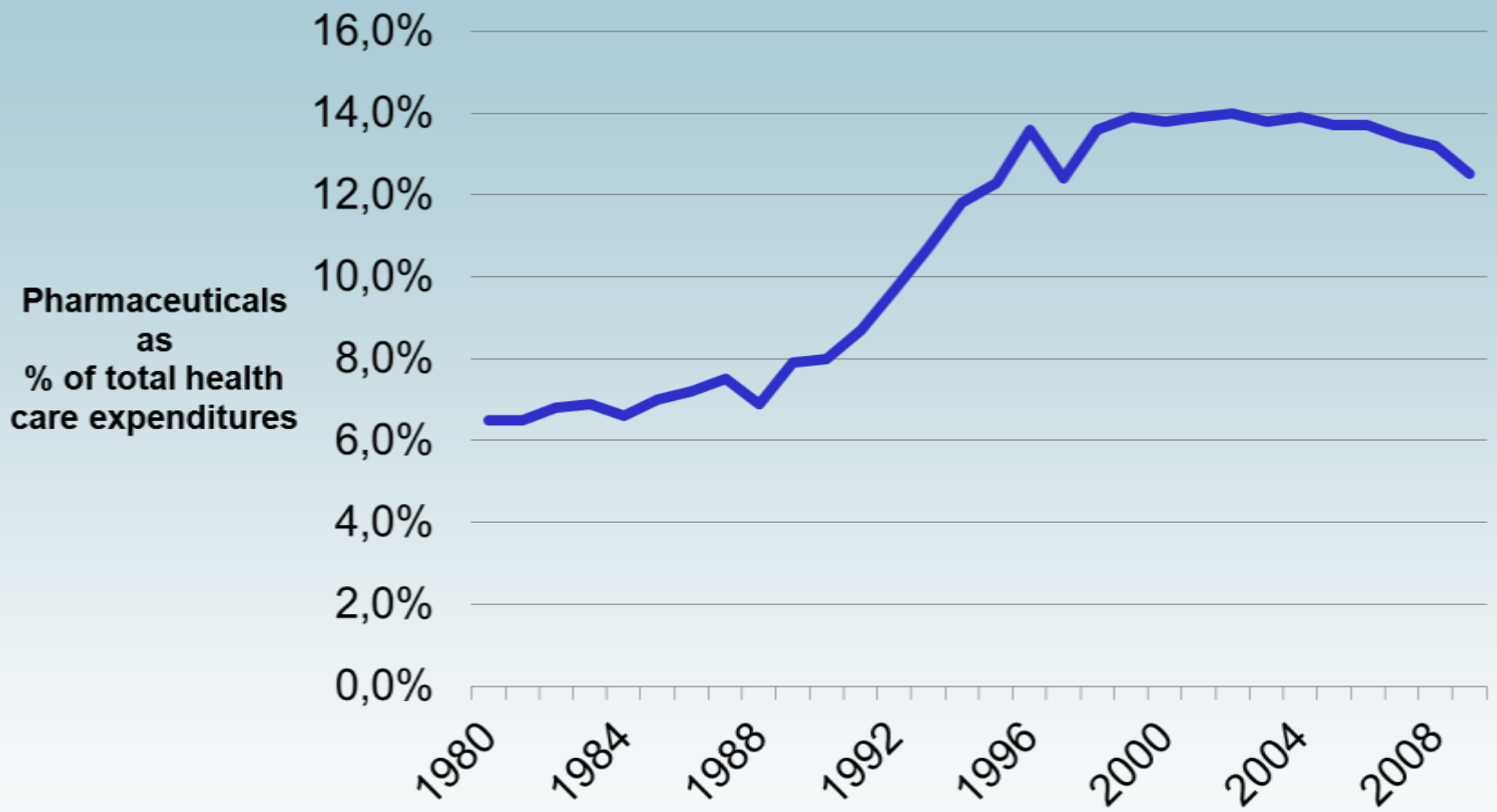
Cost containment

Increased costs for pharmaceuticals (for humans) in Sweden,
Total 2011, SEK 36 780 000 (€ 4,100 million)

1990s	10 % annually
2002	8.5 %
2003	2.1 %
2004	2.8 %
2005	2.9 %
2006	5.1 %
2007	6.1 %
2008	5.2 %
2009	2.9 %
2010	1.5 %
2011	1.9 %

TLV appraisals

→ **Pharmaceuticals increased share of Health care costs during 1990s, now it decreases**



Source: OECD Health Data 2012, www.oecd.org

However
Intrinsic problem or contradiction in the Swedish system:

National reimbursement decision but regional health care system

- Decisions on use (quantities) are taken at regional level
- Focus on budgets (price times quantities)
- Consequence: Regional variations in the use of new innovations; over or under (most common) the indications for which Value was established

National vs. Regional/Local

- National
  - VBP
  - Price & Reimbursement decisions
  - ”Arm lengths” approach
  - Broad societal perspective
  - Individuals WTP for QALY gain
- Regional/Local
  - Politicians responsible for resource allocations
  - Media influence important
  - Silo perspective
  - Cost containment
  - Budget responsibility

”Post-code” prescription of TNF inhibitors for Rheumatoid arthritis in Sweden

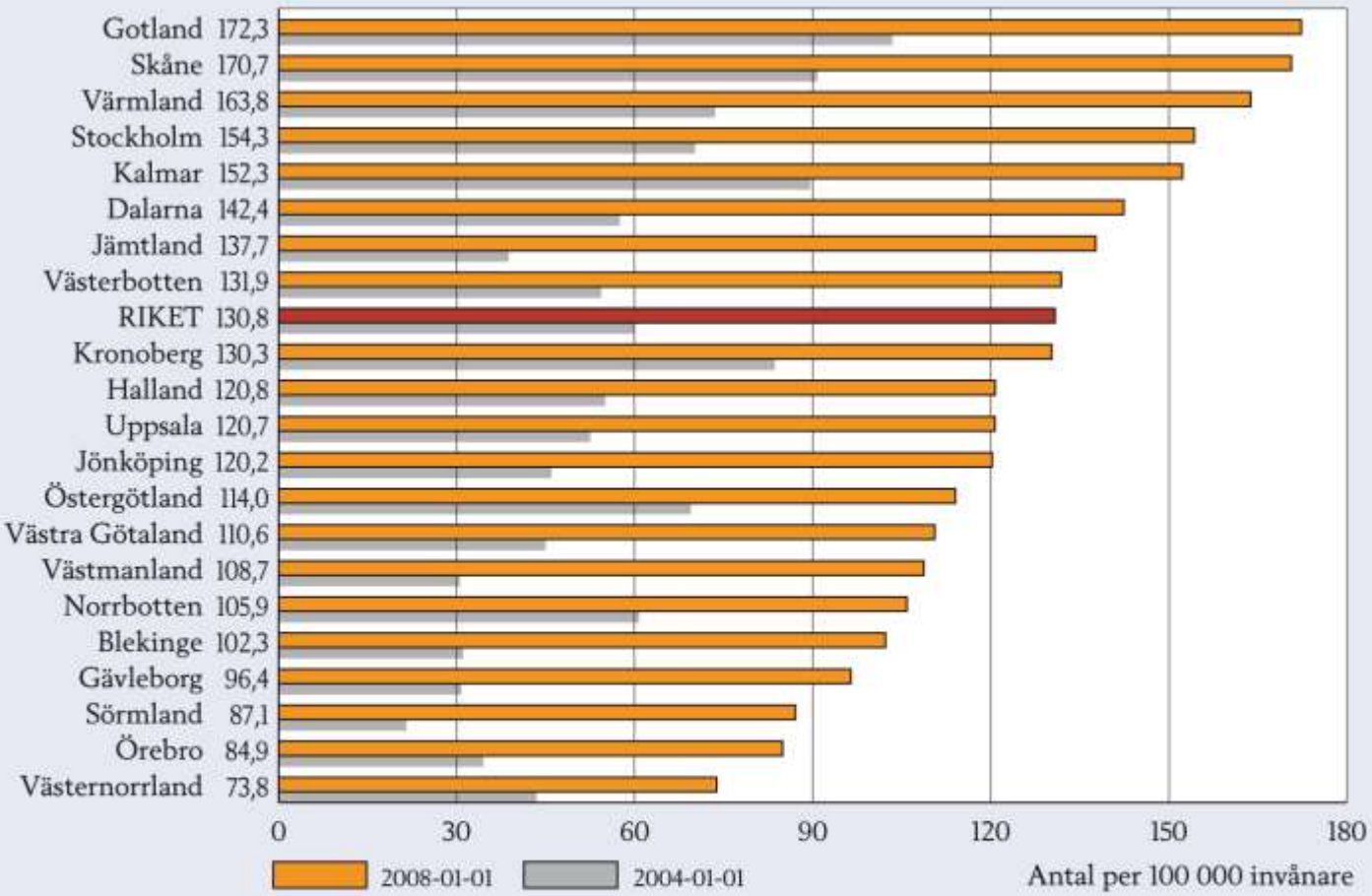


Diagram A:13 Antal patienter med biologiska läkemedel vid reumatoid artrit per 100 000 invånare, 2008-01-01.

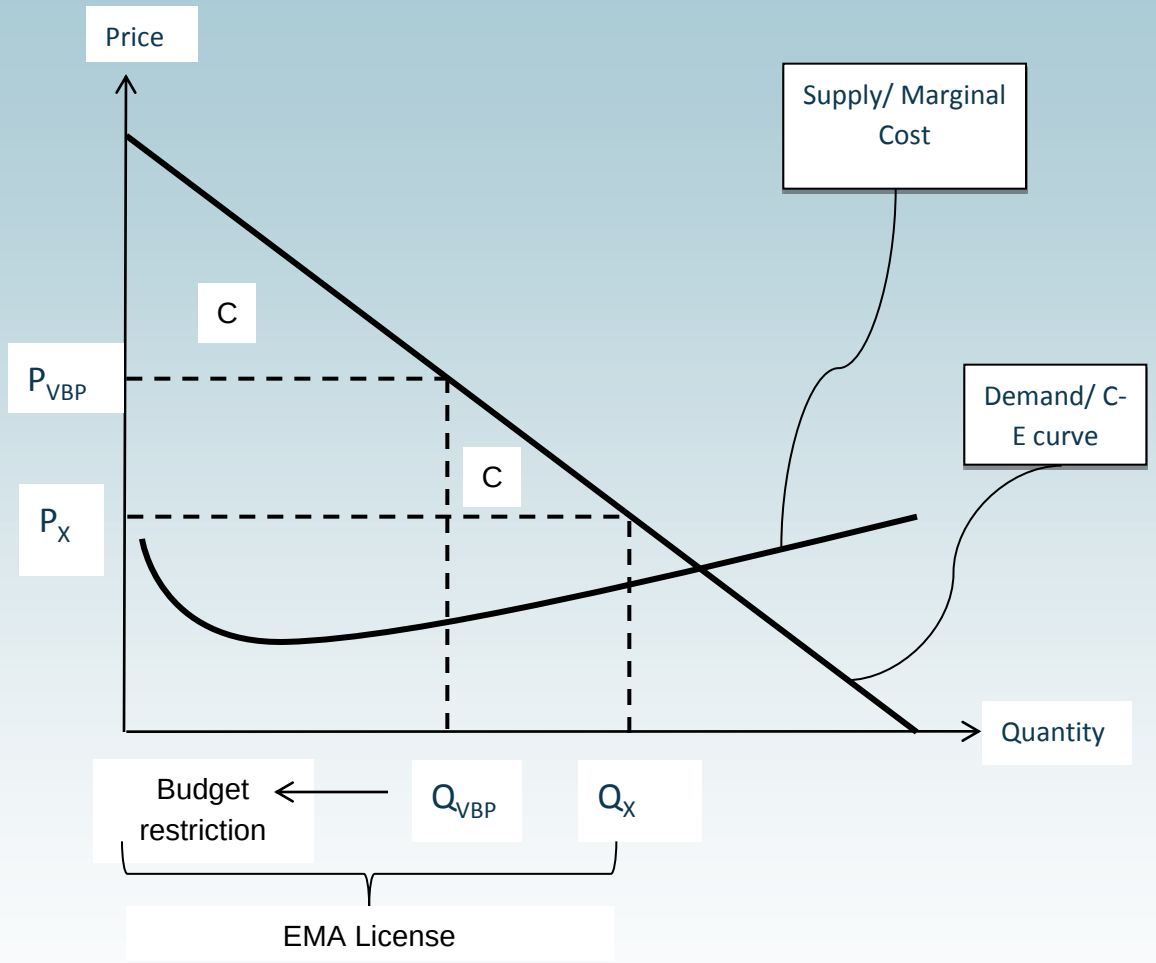
Källa: Svenska Reumatologiska kvalitetsregistret

Suggestions to improve the Swedish VBP system for innovative pharmaceuticals

Split the payment for pharmaceuticals between the regional and national level

- Regional funding of the drug volumes at cost plus pricing.
- Regional drug budget responsibility but only for the costs of pharmaceuticals priced with cost plus pricing
- National budget responsibility of the value of innovations by use of VBP

VBP justified price (P_{VBP}) paid by the state combined with a Cost plus price (P_X) paid by the county councils and a corresponding volume (Q_{VBP} /Q_X).



Where is HTA and VBP heading in Sweden?

- Expanding the mandate for TLV for hospital drugs (decided 2010)
- Medical devices – Cost per QALY- same as for pharmaceuticals (starting with a limited number of appraisals in 2012)
- Focus on cost containment and procurement. Procurement and VBP?
- From VBP to international price comparisons, without looking at value?

A balance between three goals

1. Cost containment
2. Cost-effective implementation
3. A sustainable system require instruments encouraging innovations