

# **How Does Europe Do It? Balancing Adoption and Affordability of Medical Devices**

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and

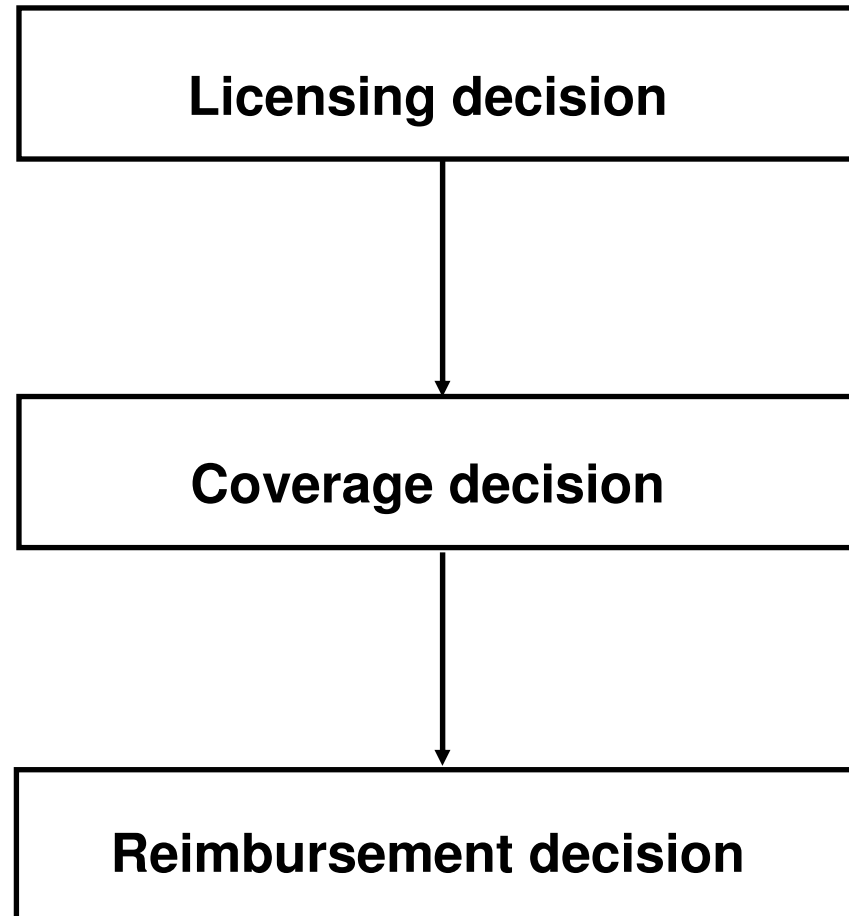
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- Evidence suggests that health interventions are associated with dramatic improvements in life expectancy (Hunink 1997, Cutler and McClellan 2001, Cutler 2007)
- Technological change has accounted for a large part of health care expenditures
- Spending on pharmaceuticals and medical devices seems to be a stronger driver of expenditures than demographic change (Busse et al. 2007)
- Regulations for pharmaceuticals have been subject to numerous studies, whereas the regulation of medical devices has rarely been analyzed

## Expenditures on medical devices

Country	THE Billion €	THE % GDP	EMD Billion €	EMD % THE	EMD % GDP
Europe Total/ Average	1034.4	8.7%	63.6	6.3%	0.5%
Germany	232.2	10.3%	20.0	8.6%	0.9%
France	172.6	10.5%	10.0	5.8%	0.6%
Italy	126.0	8.8%	7.0	5.6%	0.5%
UK	148.3	8.4%	6.7	4.5%	0.4%
Spain	67.3	7.4%	5.5	8.2%	0.6%
Poland	12.6	6.5%	0.9	6.9%	0.4%
USA	1440.5	15.3%	79.4	5.5%	0.8%

Source: based on Eucomed 2007



<b>Licensing regulation</b>	EU regulation (medical devices directives), transposed into national law
<b>Actual licensing decision on a certain medical device</b>	Notified bodies in 27 member states (but decision is also valid in all other 26 countries) – decision depends on safety concerns

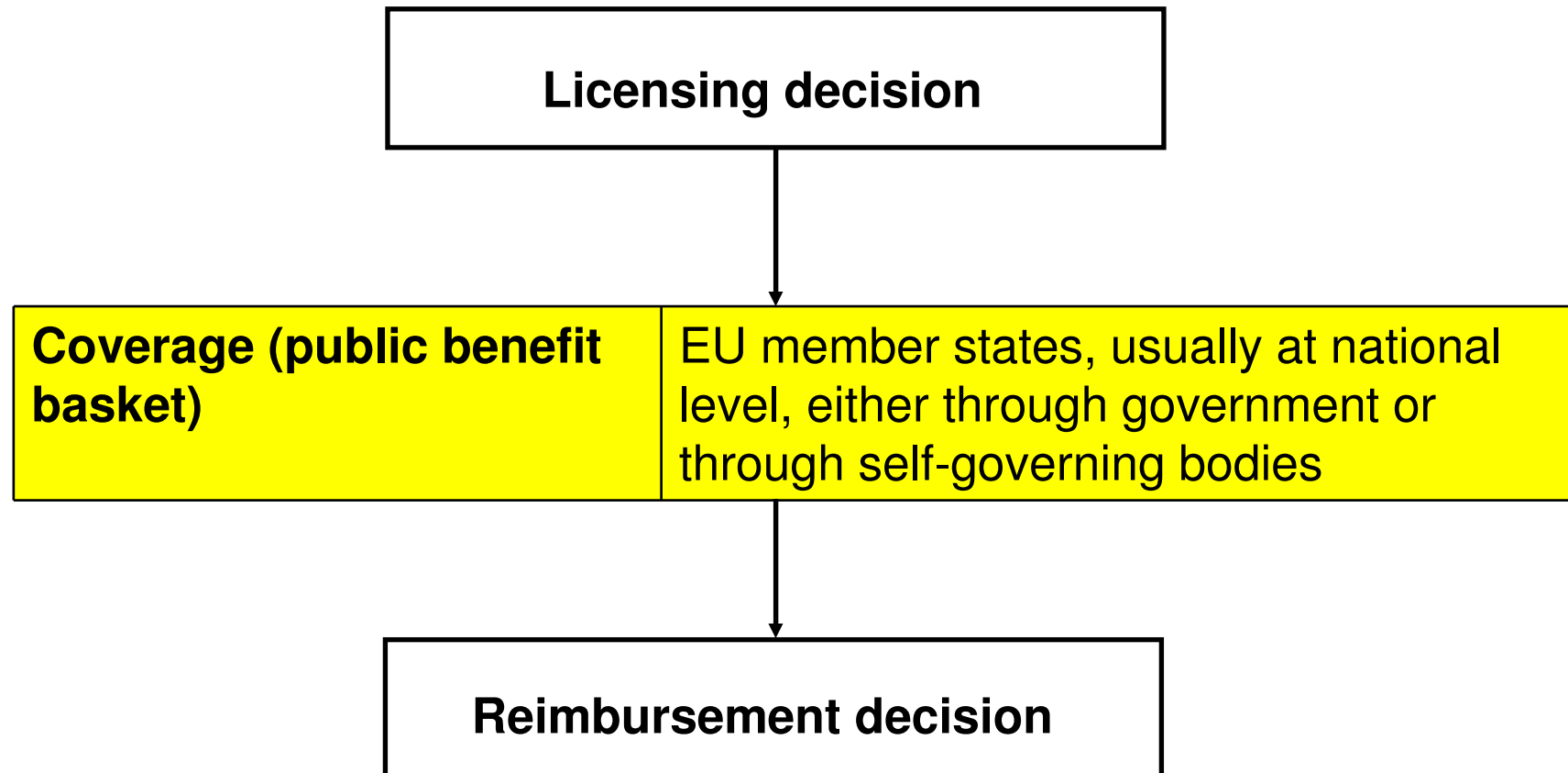
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**Coverage decision**

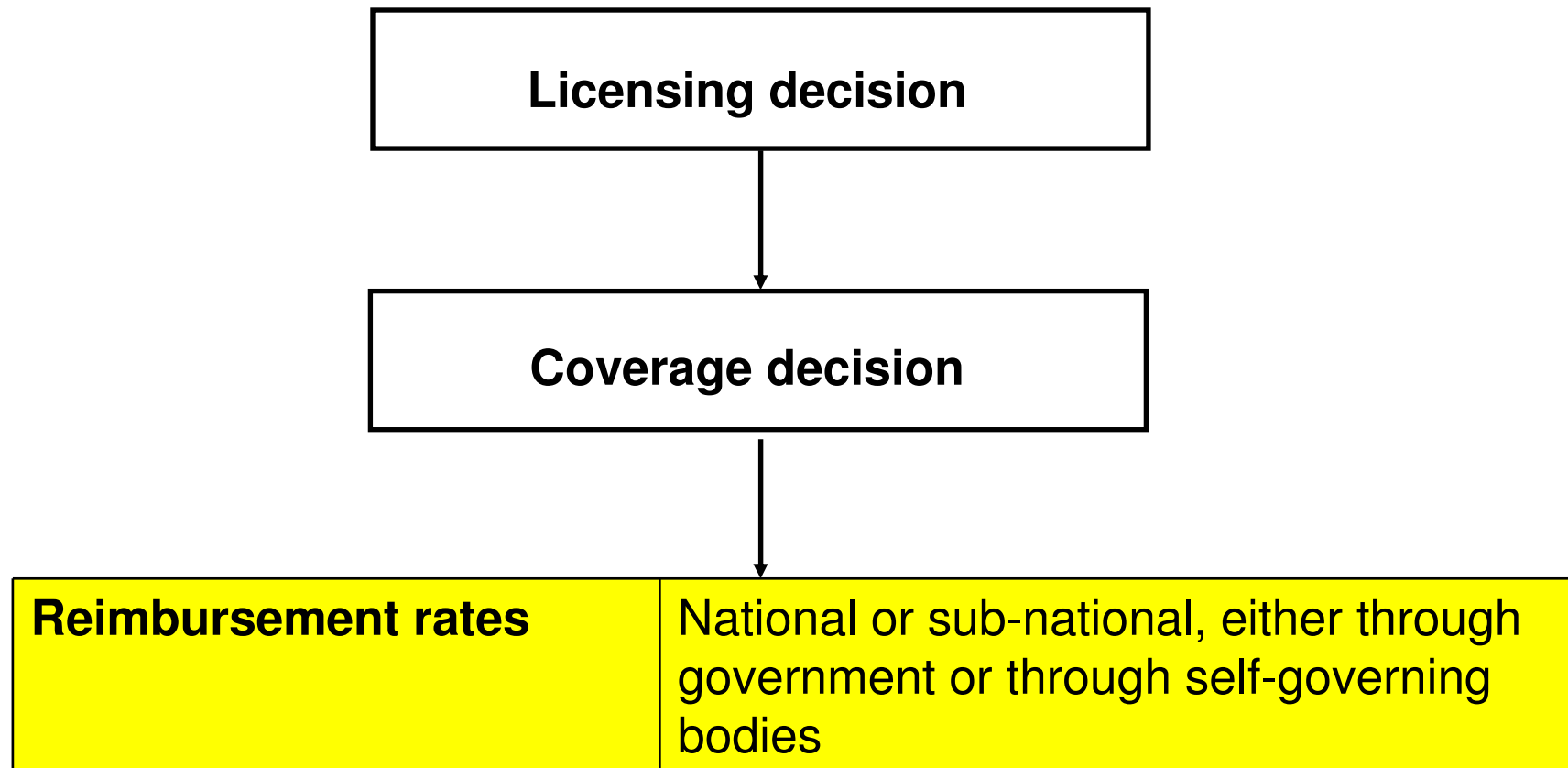
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**Reimbursement decision**

## Coverage decision in the EU



## Reimbursement decision in the EU



## Decision makers on coverage policy

- **The Federal Joint Committee**
  - consists of representatives of providers and payers
  - is Responsible for the DRG system
  - defines the benefit catalogue for outpatient benefits
- **The Institute for Quality and Efficiency:**
  - acts as an advisory body to the Federal Joint Committee
- **The Federal Association of Sickness Funds:**
  - defines a positive list for medical aids



<b>Category of medical devices</b>	<b>Reimbursement in Germany</b>
<p style="color: red;"><b>Cat I - Medical aids:</b></p> <p>e.g. incontinence pads, negative pressure therapy</p>	<p><u>For outpatient care:</u> reference prices, public tenders</p> <p><u>For inpatient care:</u> Included in case fees</p>
<p style="color: red;"><b>Cat II - Implants etc.:</b></p> <p>e.g. knee endoprotheses, implantable cardioverter defibrillators, coronary stents</p>	<p>Included in case fees, additional payments for certain technologies</p>
<p style="color: red;"><b>Cat III - Technical equipment for professionals:</b></p> <p>e.g. laparoscope</p>	<p><u>Short-life products:</u> Included in case fees</p> <p><u>Long-life products:</u> Funded as capital by the federal states</p>

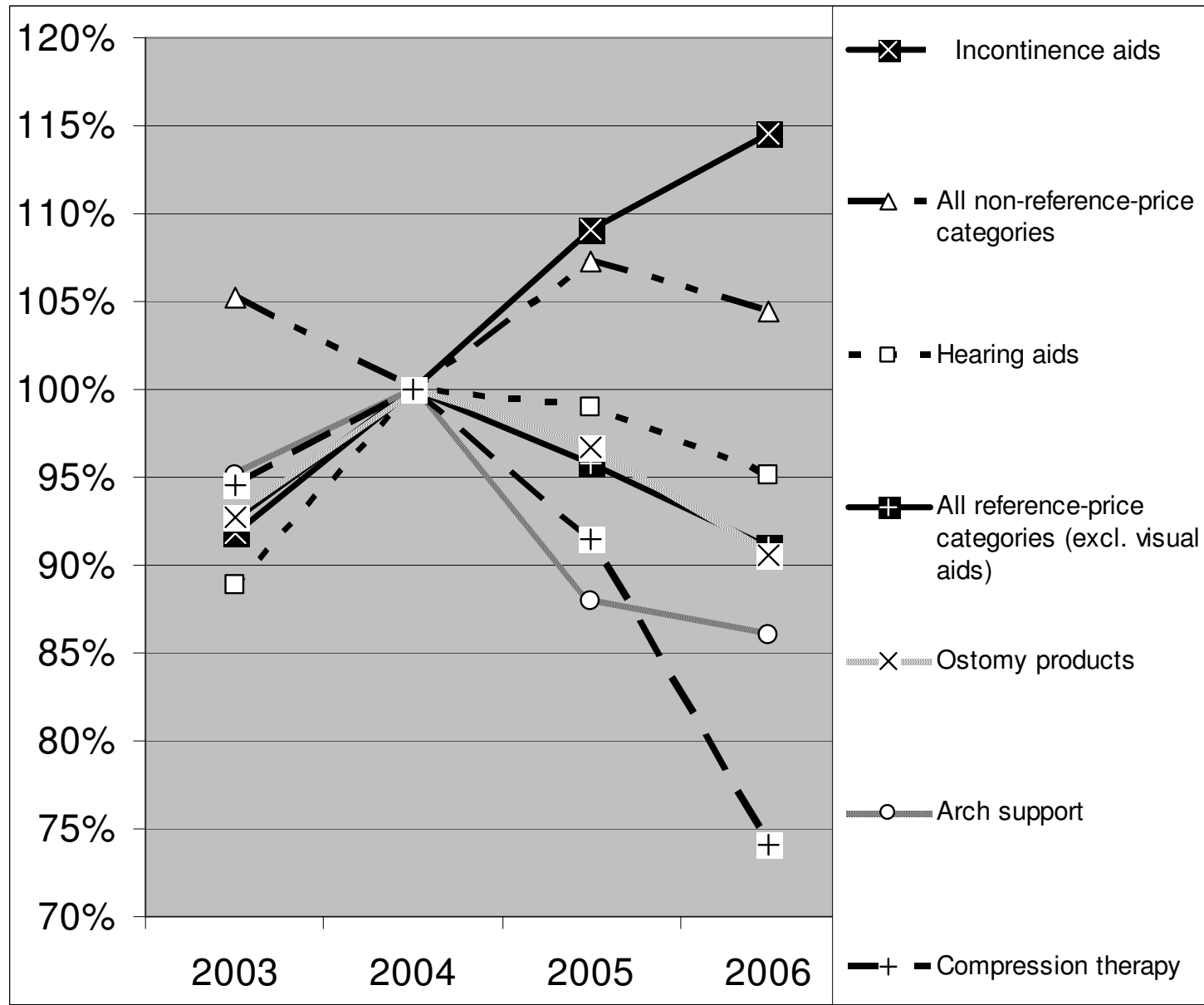
- There are reference prices (RPs) for Incontinence pads
- RPs serve as a reimbursement limit
- Products are grouped in homogeneous classes; for each group, reference prices are set

## Reference prices for Incontinence Pads

Number of position	Term	Reference price [€] [each]
<b>15.25.01</b>	<b>absorptive incontinence pad</b>	
15.25.01.0	Anatomical formed incontinence pad, normal absorptive capacity, size 1	0.29
15.25.01.1	dito., size 2	0.35
15.25.01.2	dito., size 3	0.43
15.25.01.3	rectangular formed incontinence pad, size 1	0.19
15.25.01.4	rectangular formed incontinence pad, size 2	0.23
15.25.01.5	incontinence pad for urinary incontinence	0.21
<b>15.25.03</b>	<b>absorptive incontinence pants</b>	
15.25.03.0	incontinence pants, size 1	0.49
15.25.03.1	incontinence pants, size 2	0.51
15.25.03.2	incontinence pants, size 3	0.69

- There are reference prices (RPs) for Incontinence pads
- RPs serve as a reimbursement limit
- Products are grouped in homogeneous classes; for each group, reference prices are set
- Manufacturers have a voice in this process
- Patients have to make co-payments
- Patients are free to choose any product with a price higher than the RP if they are willing to pay the difference between the actual selling price and the RP

## Medical Aids: Expenditures from public sources under a reference price regime



- In general, all costs for implants are included in the relevant DRGs
- There are additional payments for certain implants
- This includes implants that are not „sufficiently reimbursed“ by the DRG system
- These additional payments may be defined either
  - On national level (national uniform additional payments)
  - By direct negotiations between hospitals and sickness funds

# Knee endoprotheses, ICDs and stents in the G-DRG-System

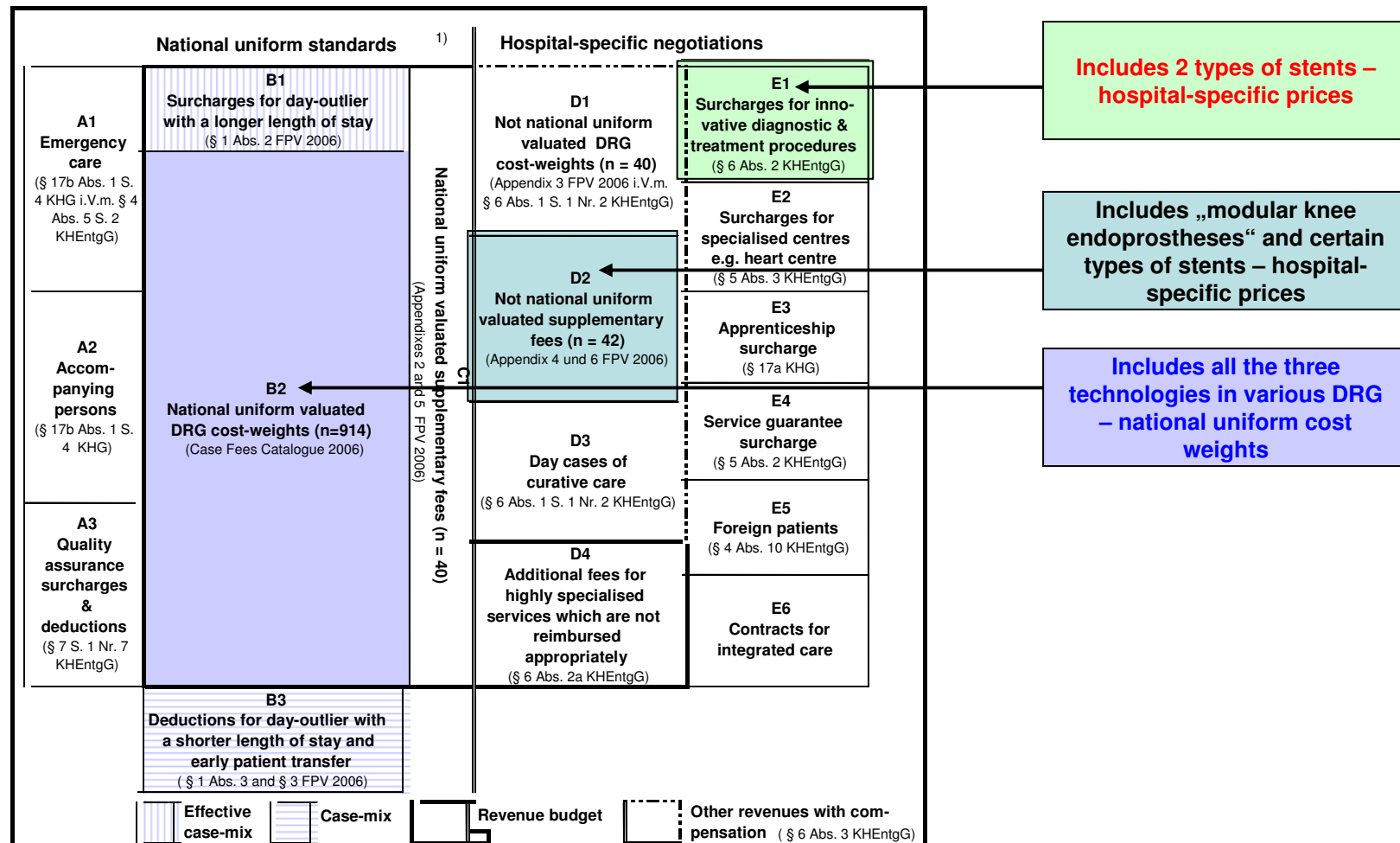
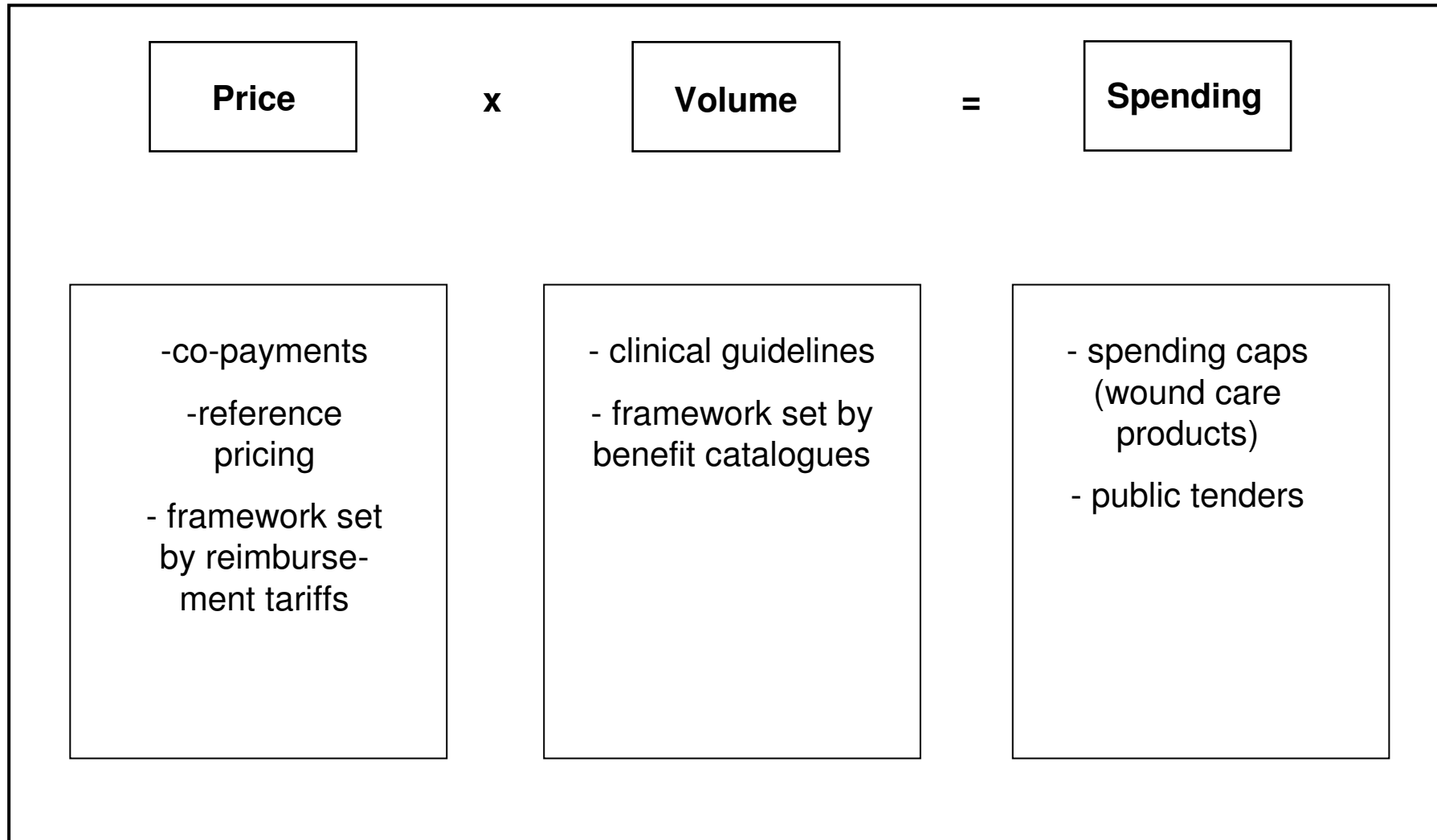


Figure: Reimbursement Components of Inpatient Care in Germany (Schreyögg J, Tiemann O, Busse R (2006) Cost accounting to determine prices: How well do prices reflect costs in the German DRG-system? Health Care Manage Sci 9:269-279. With own adaptations and extensions)

# Market interventions in the German medical devices market





- Most market interventions are intended to reduce spending
  - Spending caps
  - Public tenders
  - DRG-tariffs
- What about balancing?
  - Reference prices
  - Annual revision of the DRG-tariffs and the DRG-Groups
  - Additional payments in the DRG-System
- Measures intended for the diffusion of technologies:
  - Additional payments for new technologies
    - => Further research on the practical relevance is needed