Divestment Technology: Necessity or a result of the crisis?

A German Perspective

Stefan K. Lhachimi, PhD

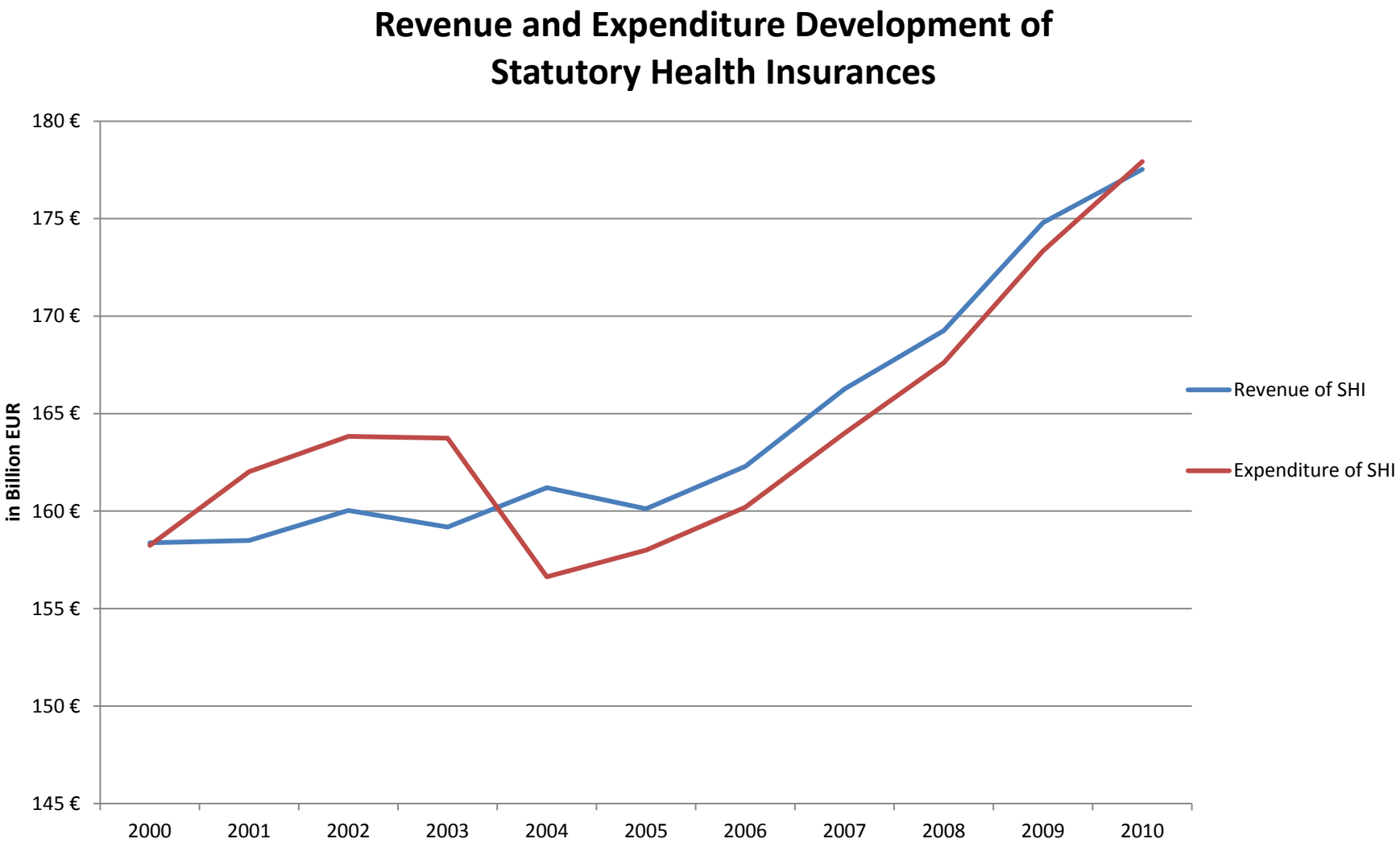
Dept. of Health Economics

Institute for Quality and Efficiency in Health Care (IQWiG)

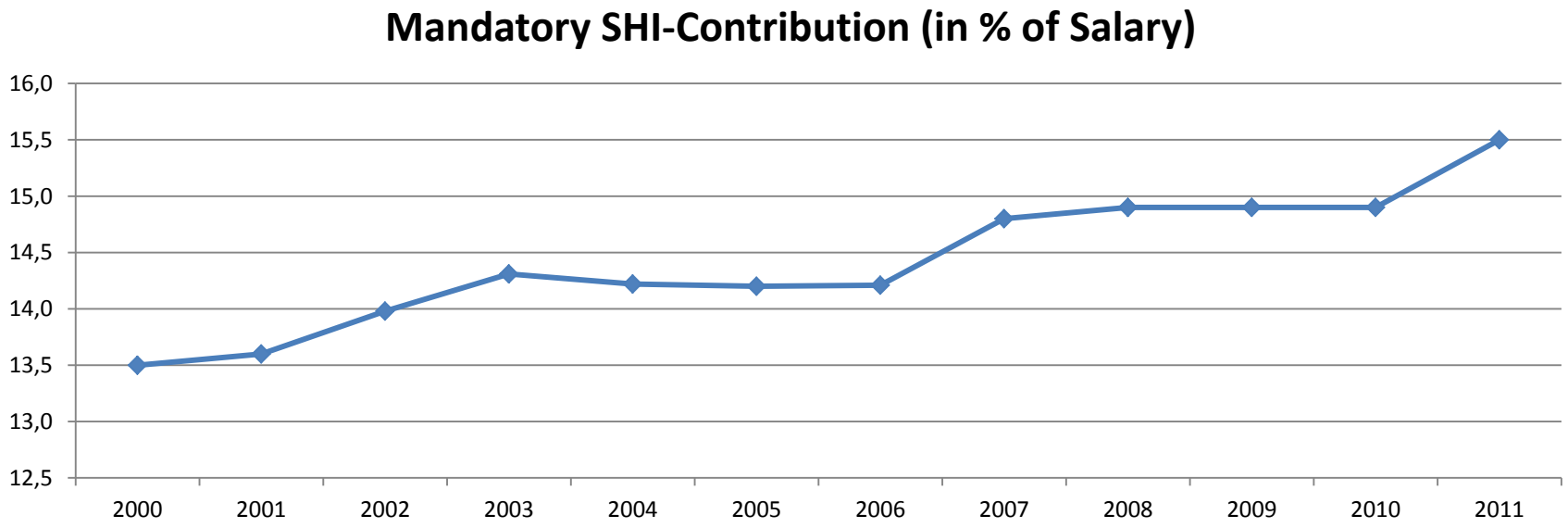
„Crisis? What crisis?“

Attributed to British prime minister James Callaghan during the „winter of discontent“ in 1979

Long Term Increase in Expenditure and Revenue

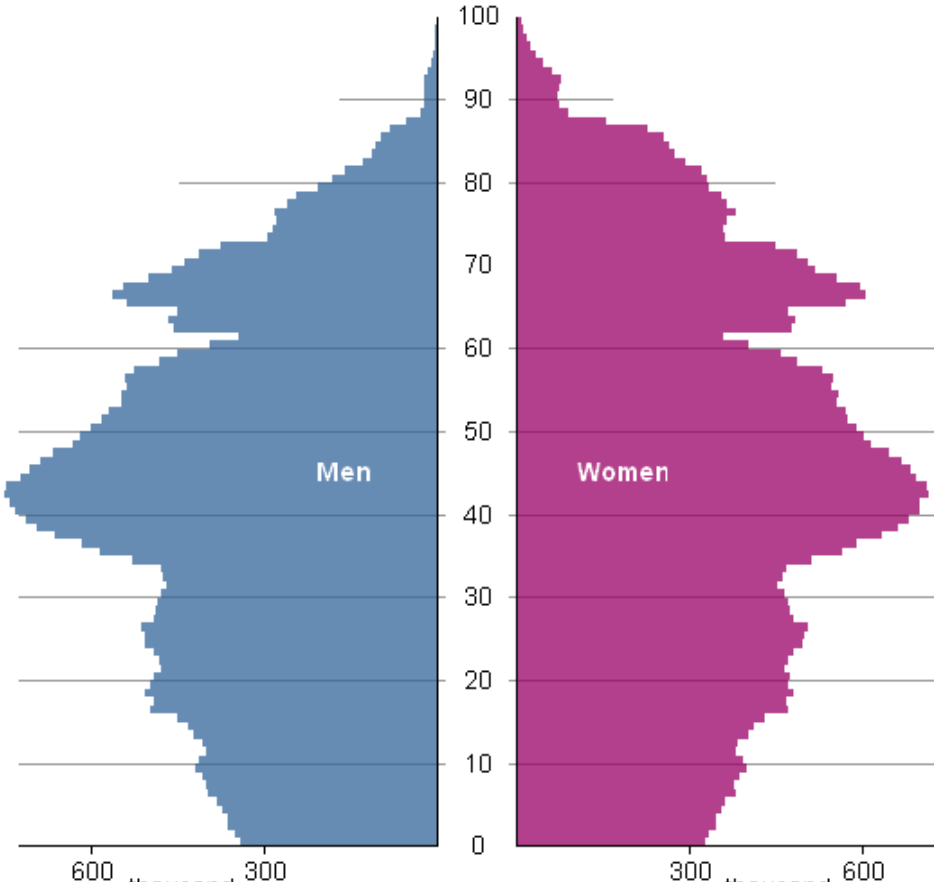


Development of contribution rate and real wages



Germany - Demographic Challenge

31.12.2006
82.3 Mio



0-19	**20%**
20-64	**61%**
65+	**19%**

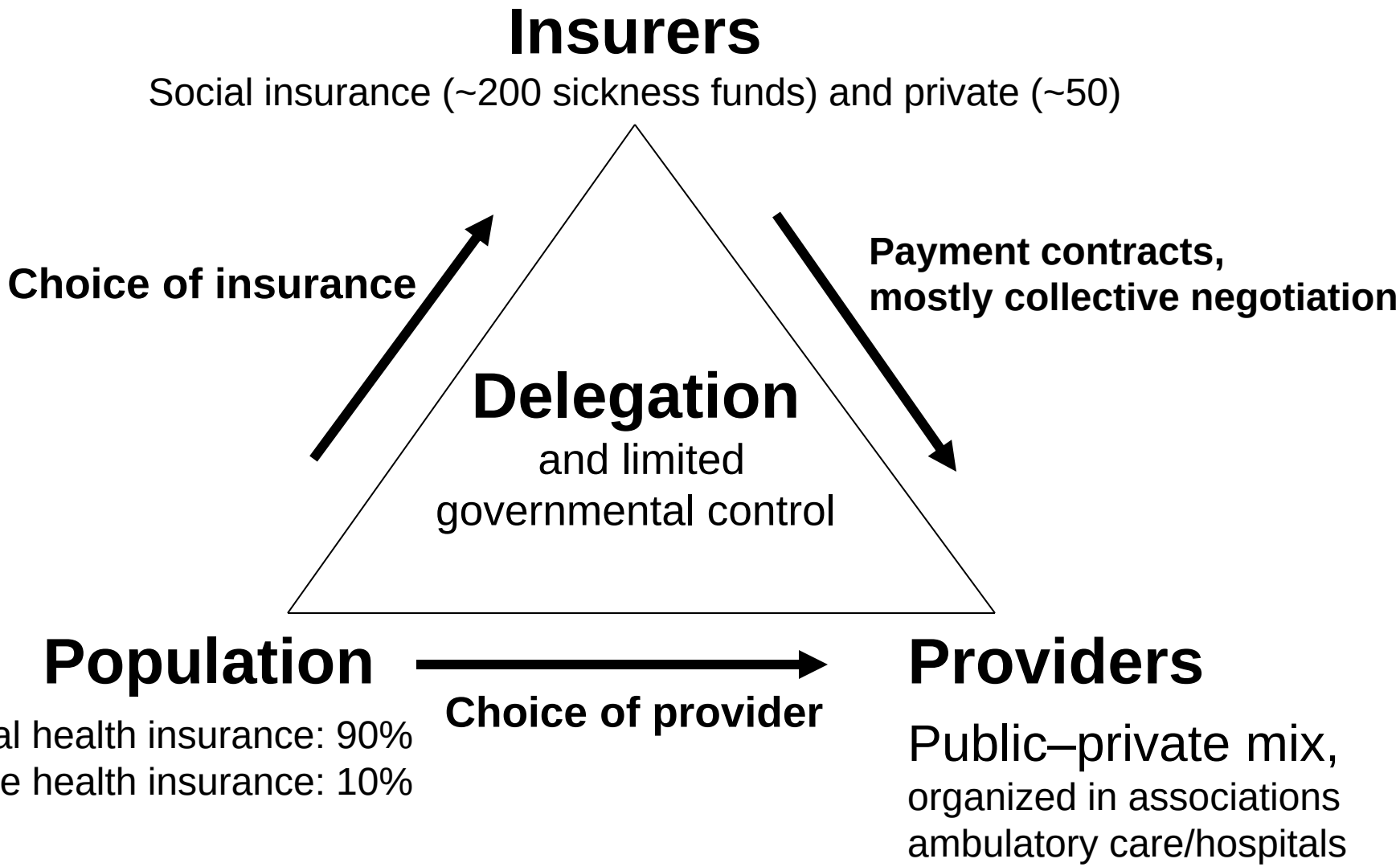
31.12.2050
68.7 Mio

0-19	**15%**
20-64	**52%**
65+	**33%**

Health Care is in a Long Term Crisis

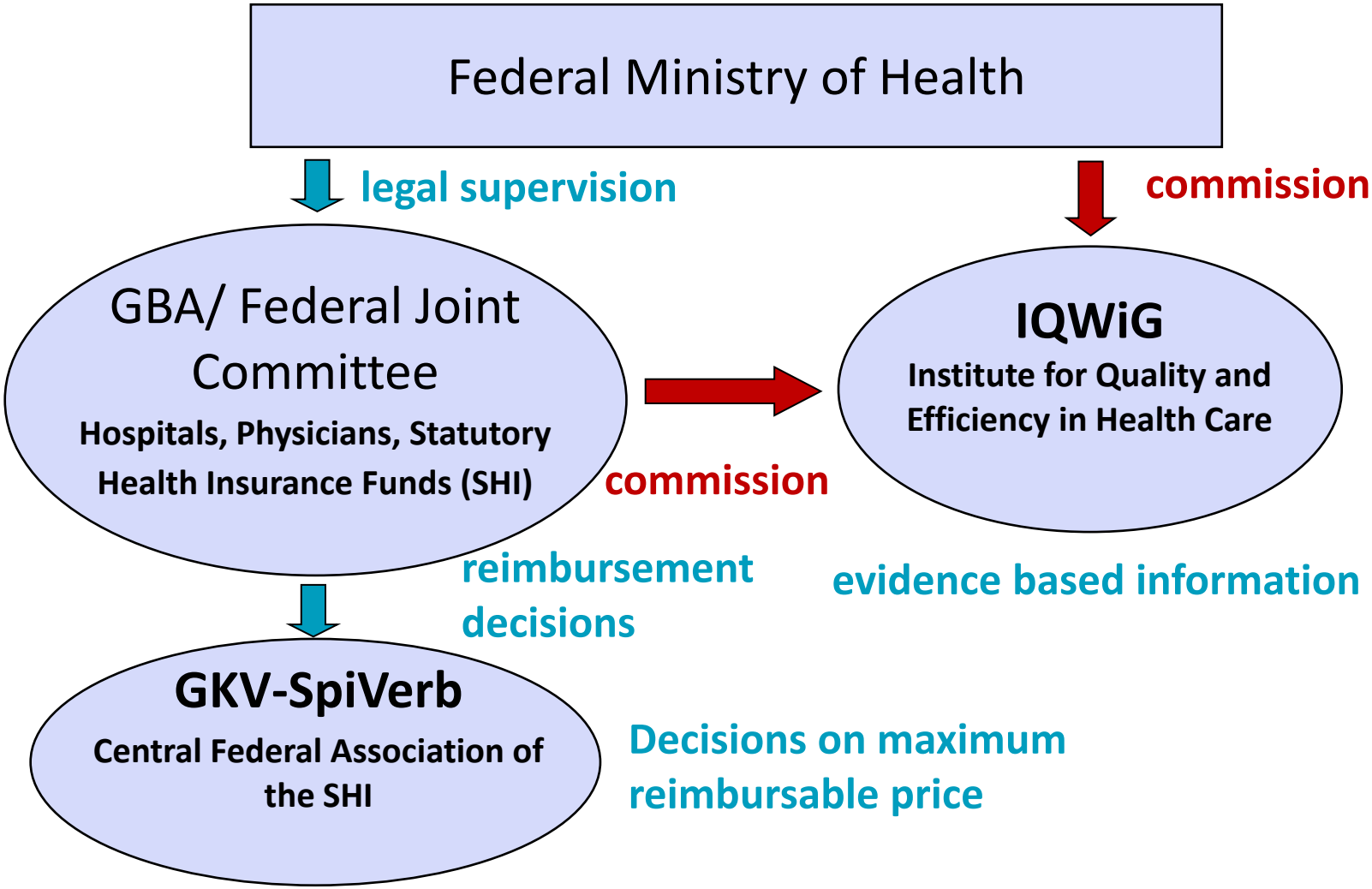
- Two major challenges
  - Constant growth in cost of new technology
  - Aging and rise in chronic disease prevalence
- In the past, budget short-falls lead to an increase in mandatory contributions
- Strong pressure to reduce contributions
- Since 2010, mandatory discount of 16% on drugs

The German Insurance System at a Glance



Source: Reinhard Busse, Berlin University and European Observatory. Presentation to The Commonwealth Fund, 2008.

Self administration in the German SHI



AMNOG Overview

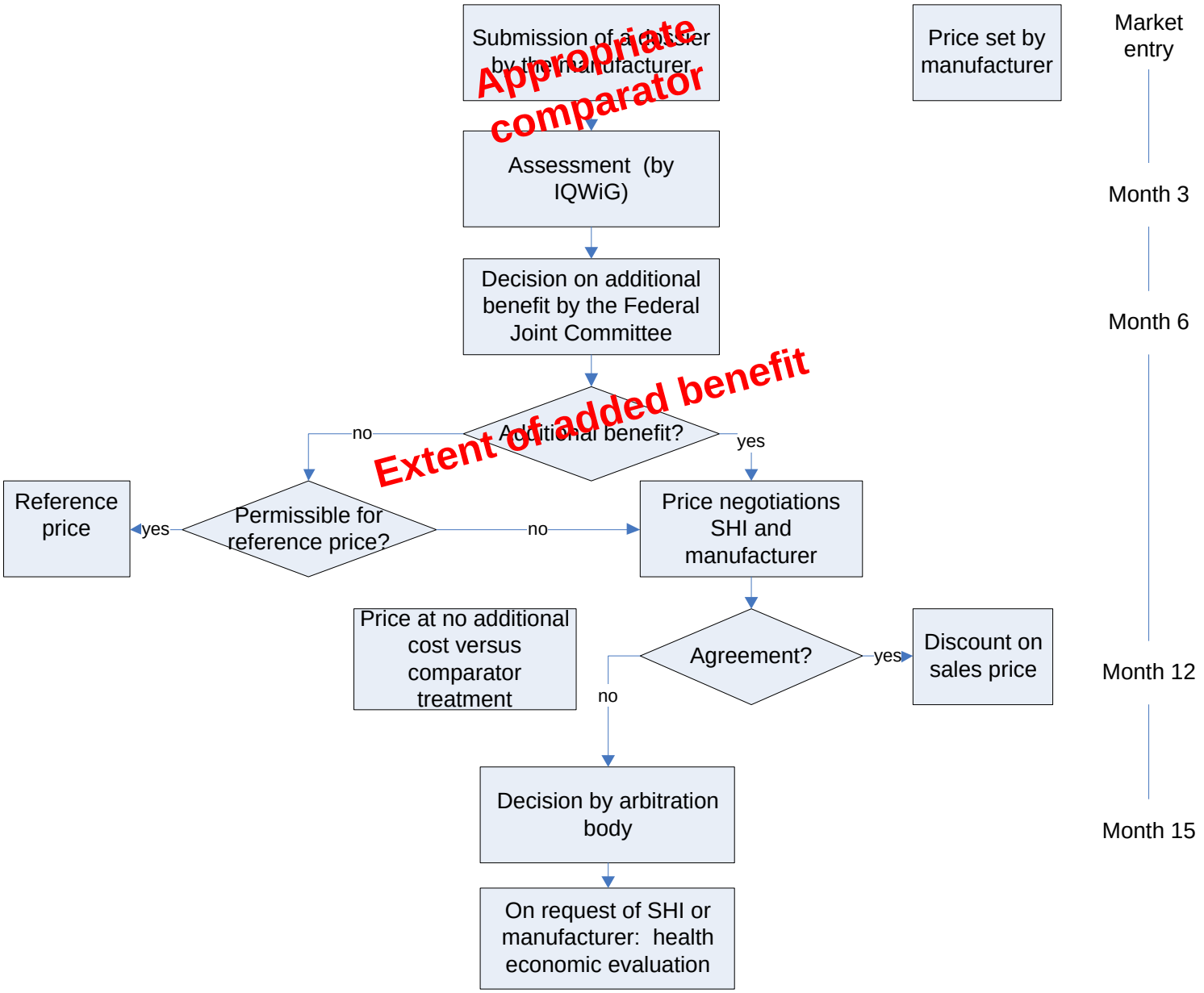
- New law fully in effect since mid 2011
- Governs the Reimbursment of all new Drugs by the SHI
  - The manufacture must demonstrate added benefit
- Submission of dossier document within specified time of market access
- From 2013, gradually all existing medications has to be assessed as well
- Ministry of Health expects approx. 1.5-2 Billion EUR in annual savings

3 Pillars of Early Benefit Assessment

All new Drugs i.e. novel chemical entities / new indications	**With appropriate comparator**	**In terms of additional benefit**
• Exceptions: • Orphan drugs (added Benefit proven through market access; but sill have to submit a dossier)	• Determined by the GBA • Comparator must be in the same area of application • Can be a non-drug treatment • Can be best supportive care.	• major added benefit • considerable added benefit • minor added benefit • added benefit proven, but not quantifiable • no added benefit has been proven • less benefit than that of the appropriate comparator

Demonstrated by the manufacutrer

Drug assessment according to AMNOG



AMNOG Review

- 25 submissions have been reviewed
  - 64% have an added benefit
  - 16% a considerable benefit
  - None have a major benefit

- GBA/JFC can and did differ in the assessment of the added benefit

1st cases of price negotiation

- Ticagrelor (Brilique)
  - Indicitaded for acute coronary syndrom
  - Two endpoints
    - Significant benefit for IA/NSTEMI
    - No additional benefit for STEMI
    - List price was 2.48 EUR per day (but actual price was 2.08 EUR)
    - Actual price after negotiation is now 2.04 EUR per day

1st cases of price negotiation (cont.)

- Pirfenidon (Esbriet)
  - Idiopathic pulmonary fibrosis
  - No additional benefit documented
  - But orphan drug status
  - 11% price discount agreed

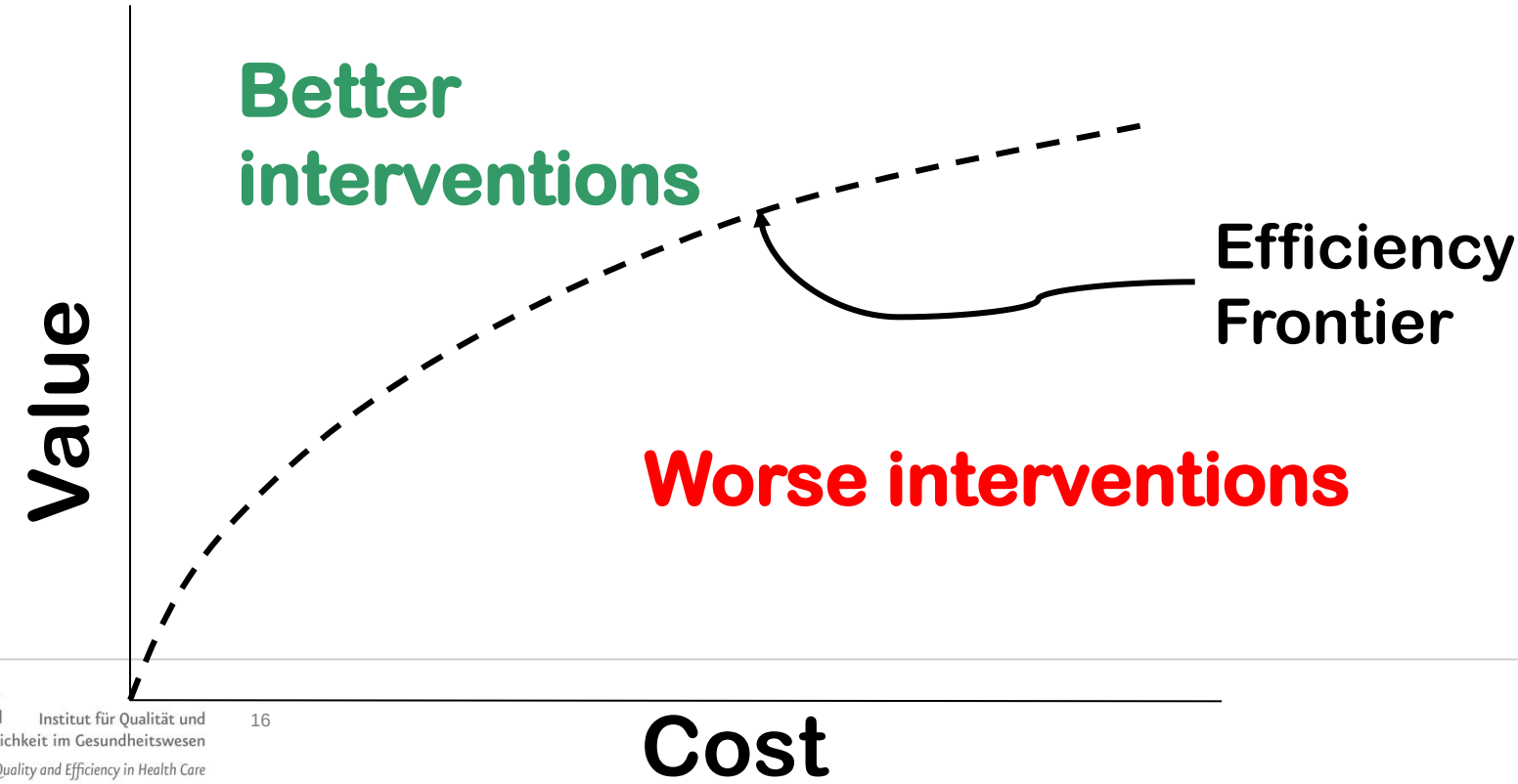
IQWiG‘s method of health economic evaluation

HOW TO DETERMINE A FAIR PRICE?

Efficiency Frontier

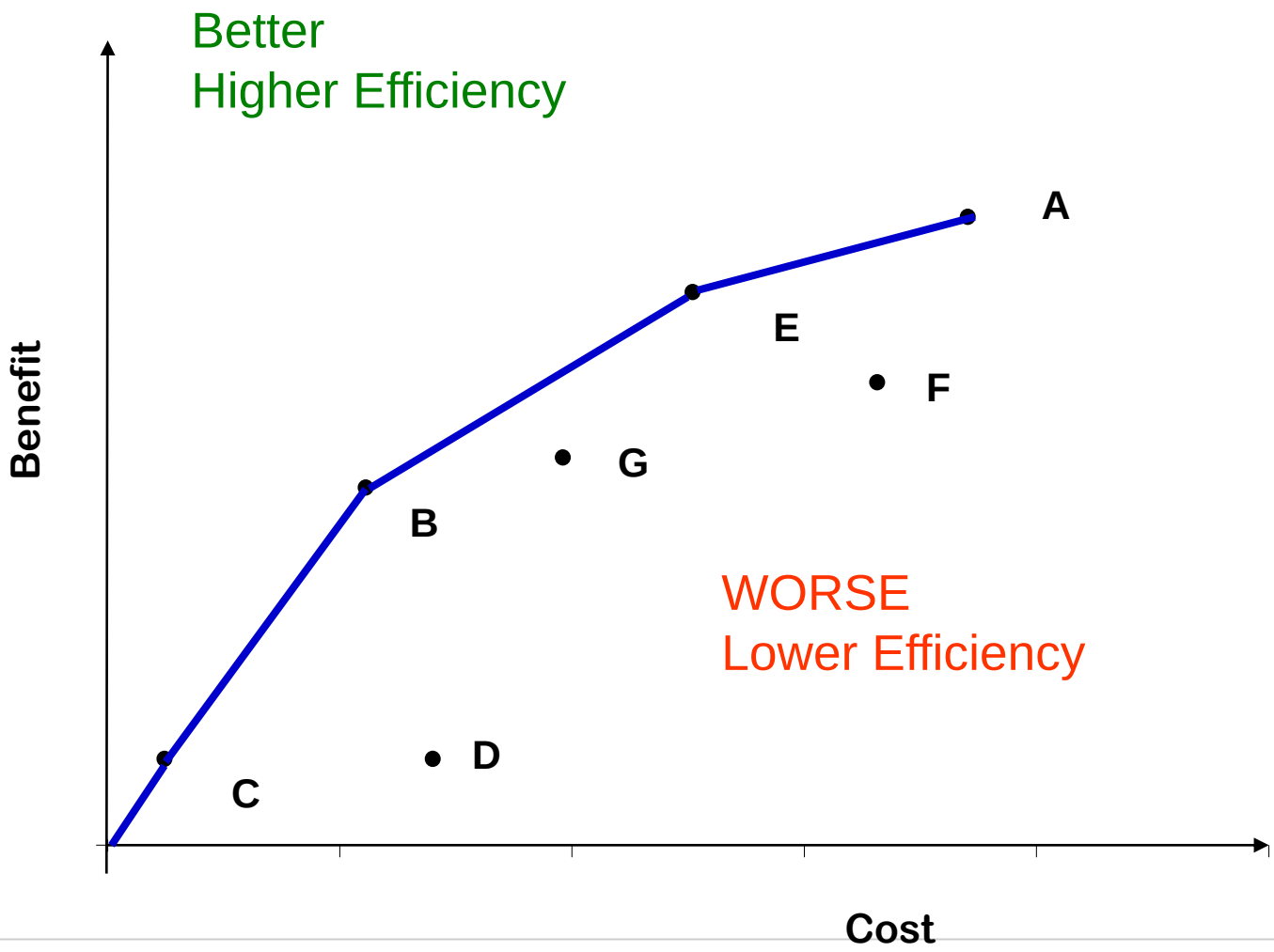
- An efficiency frontier should be constructed for each therapeutic area as the basis for economic evaluation of relevant health technologies

- Reflects the “going rate” for benefits in a specific therapeutic area

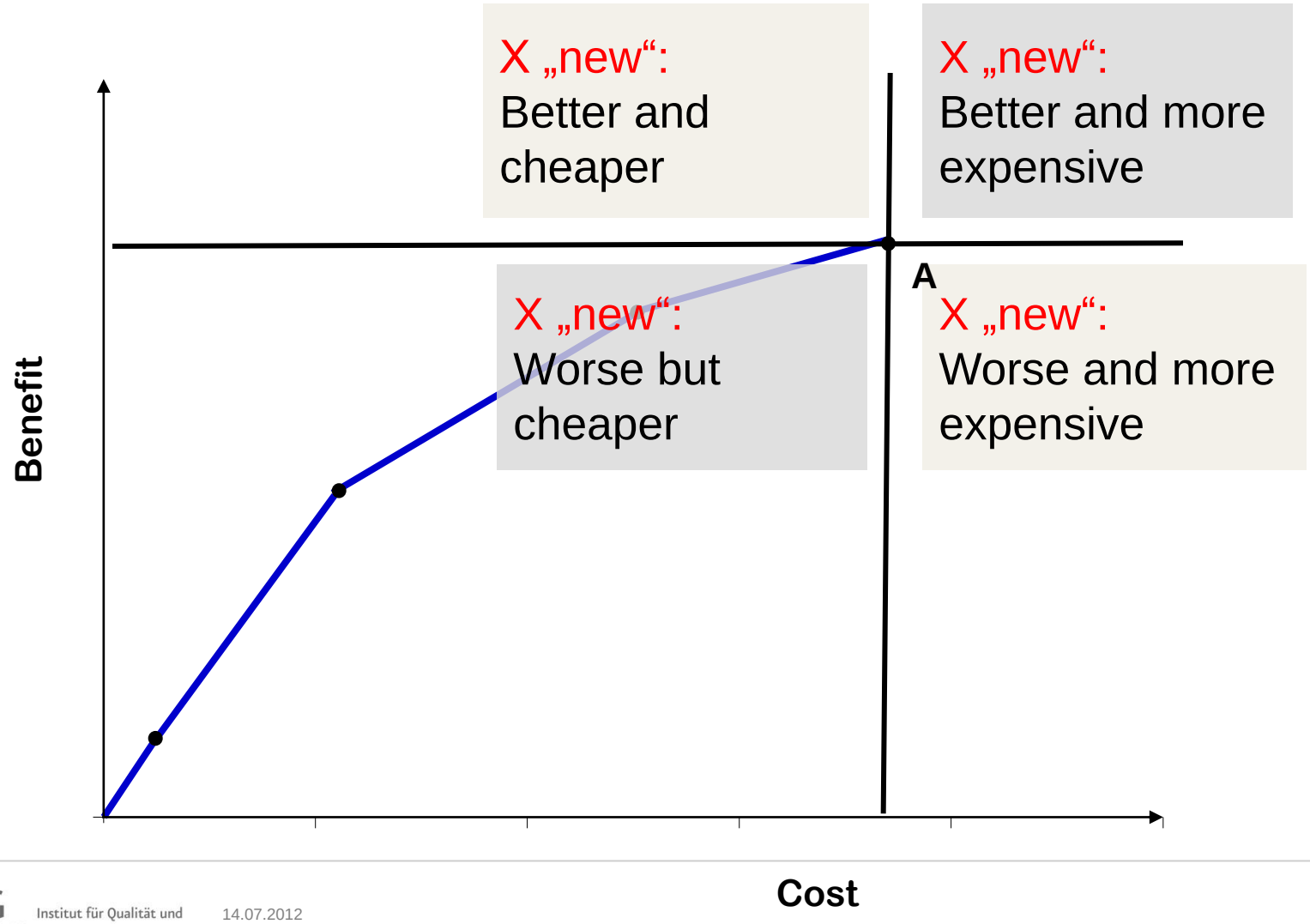


- ✓ The efficiency frontier plot should be constructed so that it reflects the relevant health technologies in a given therapeutic area. This involves:
  - Full, detailed specification of the therapeutic area at issue
  - Scoring existing therapies in terms of cost and how valuable the health improvement (“benefit”) is
  - Locating therapies on a coordinate system with the value of the benefits on the vertical axis and costs on the horizontal
  - Drawing the efficiency frontier.

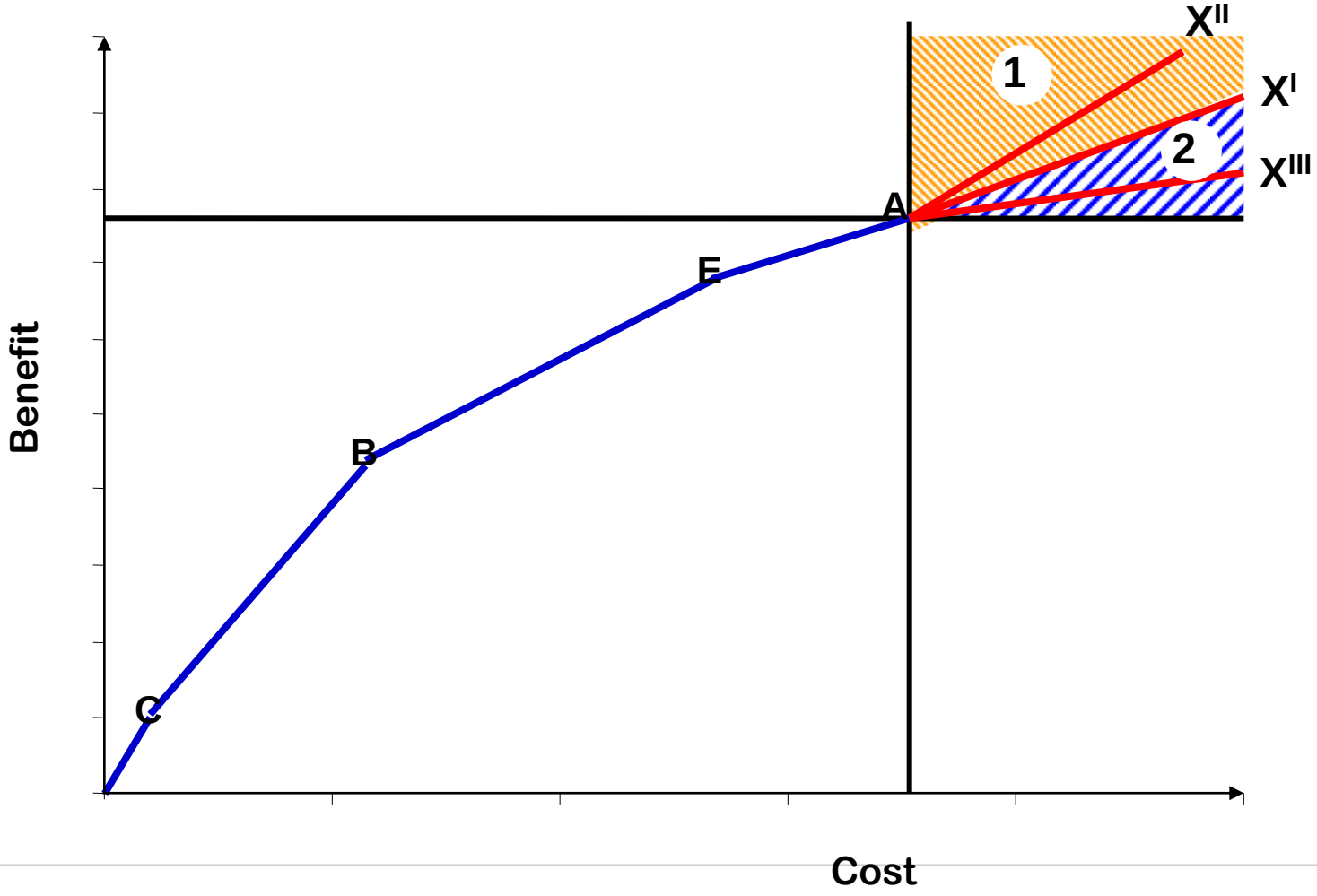
Complete Theoratical Efficiency Frontier



Decision Areas of the Efficiency Frontier



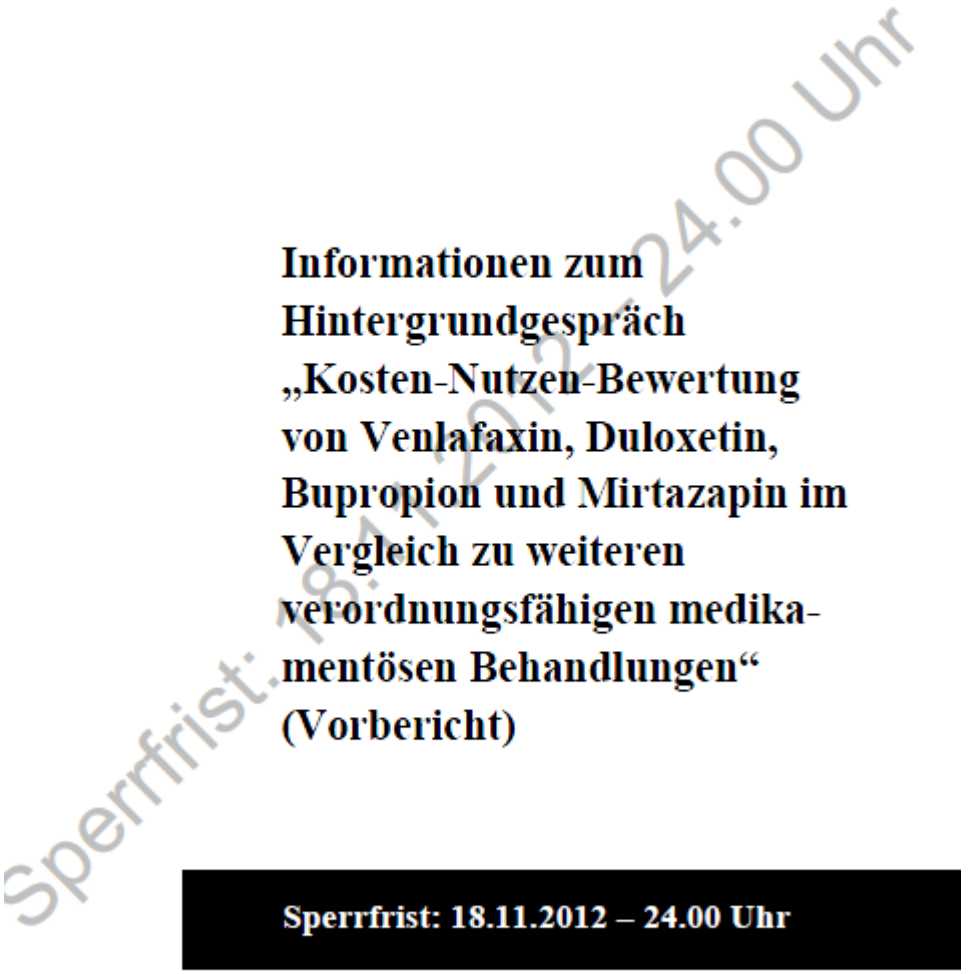
Decision area with higher cost and higher benefit



Discussion Points

- Health Care Sector is in a long term crisis
- Increase in cost for innovation is often not met with corresponding increase in health gains
- Economic evaluation can lead to more value for money
- Significant short-term gains in cost savings may be unlikely

- IQWiG‘s first cost-effectivness will be published coming Monday



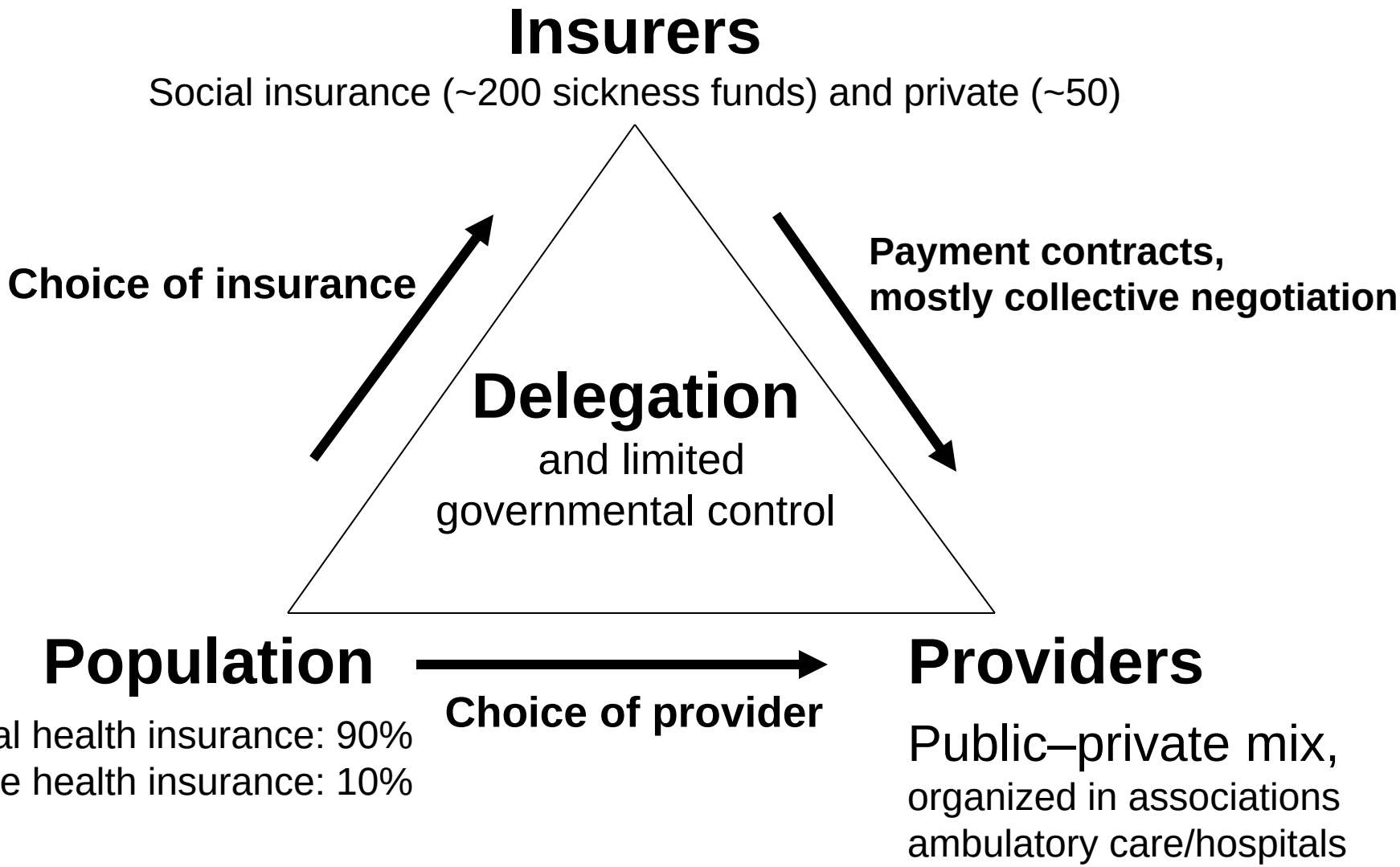
Institute for Quality and Efficiency in Health Care (IQWiG)

- Im Mediapark 8
- D-50670 Köln

- Tel. +49-221/3 56 85-0
- Fax +49-221/3 56 85-1

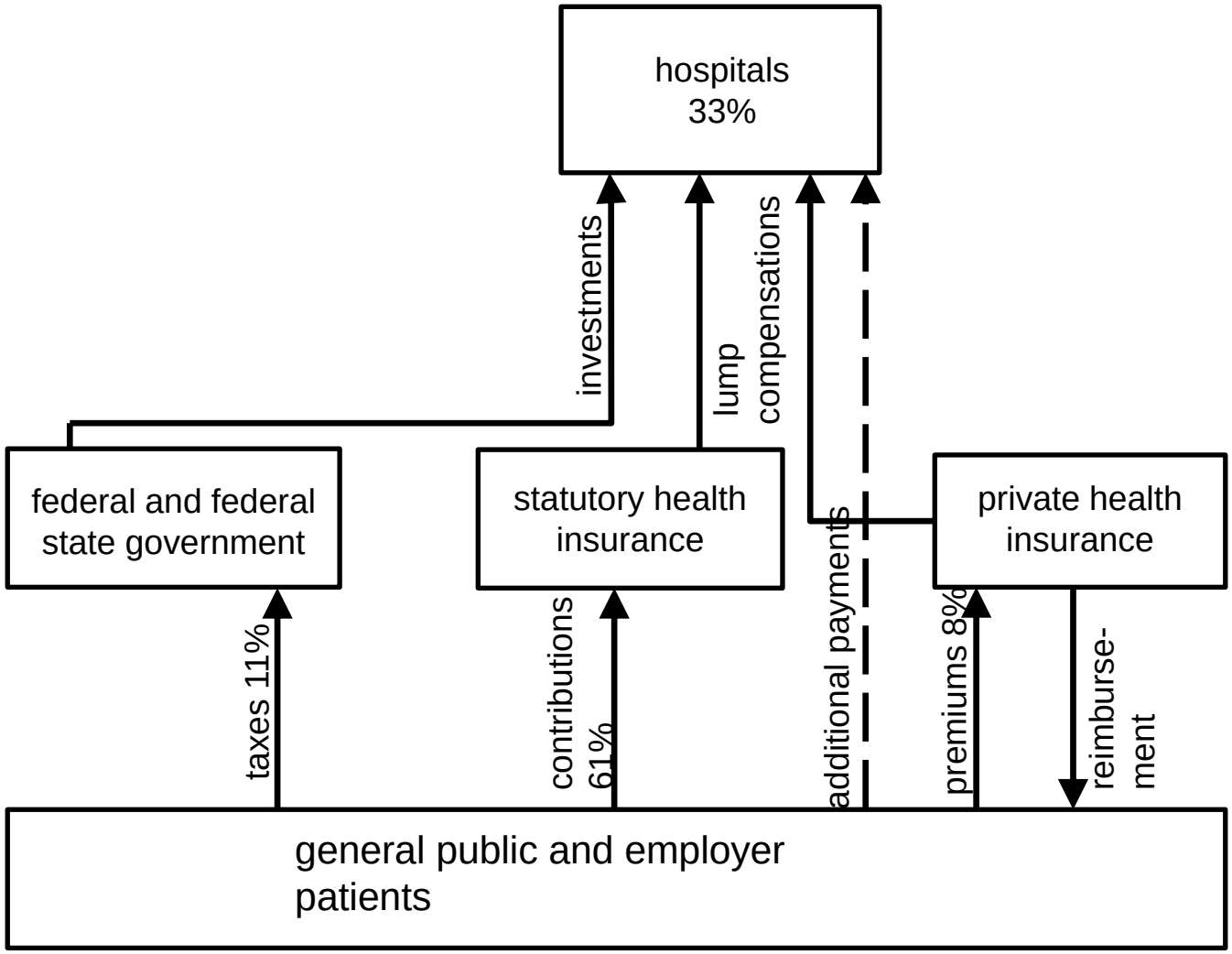
- info@iqwig.de
- www.iqwig.de

The German Insurance System at a Glance



Source: Reinhard Busse, Berlin University and European Observatory. Presentation to The Commonwealth Fund, 2008.

The dual funding



The AMNOG Law

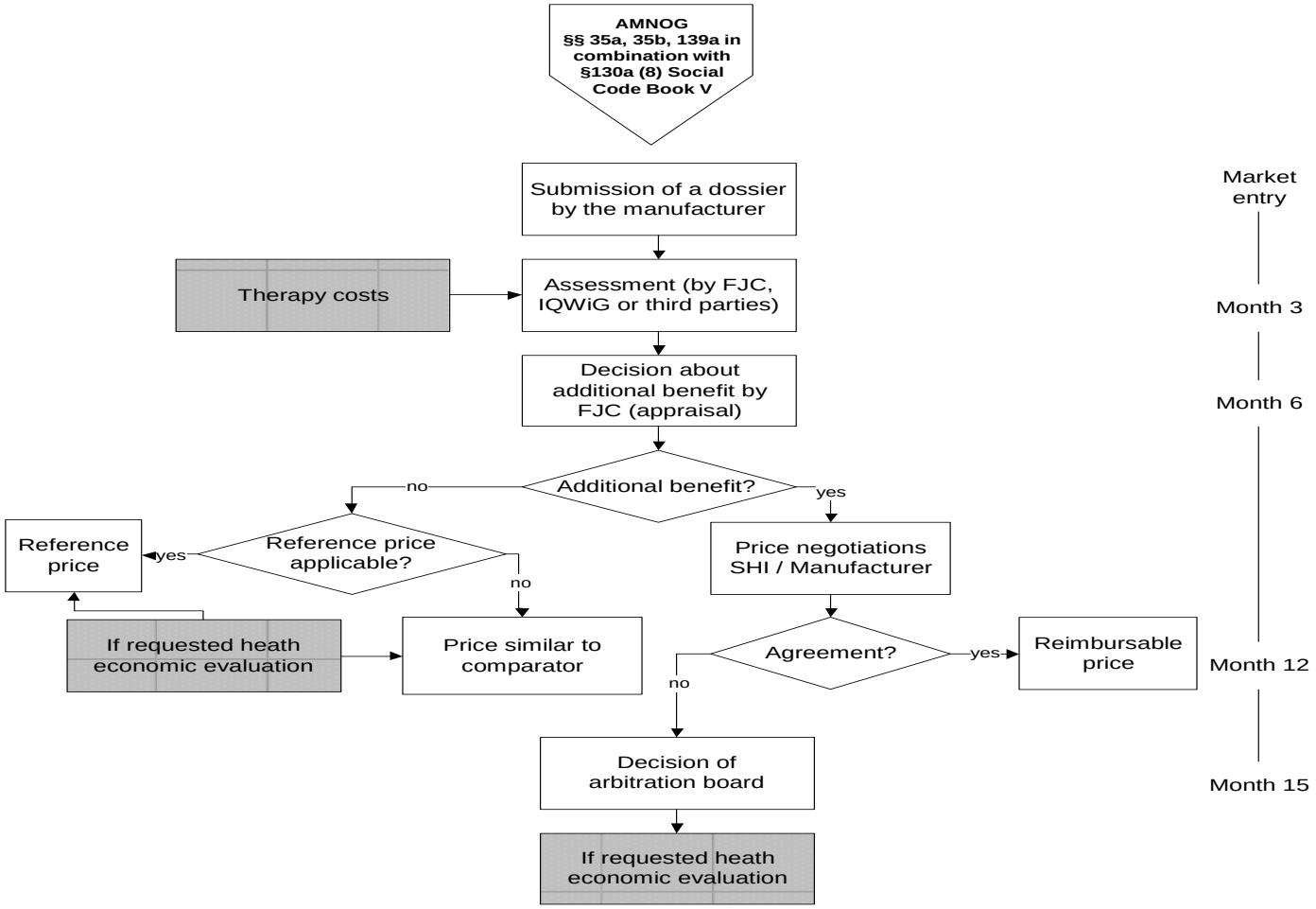
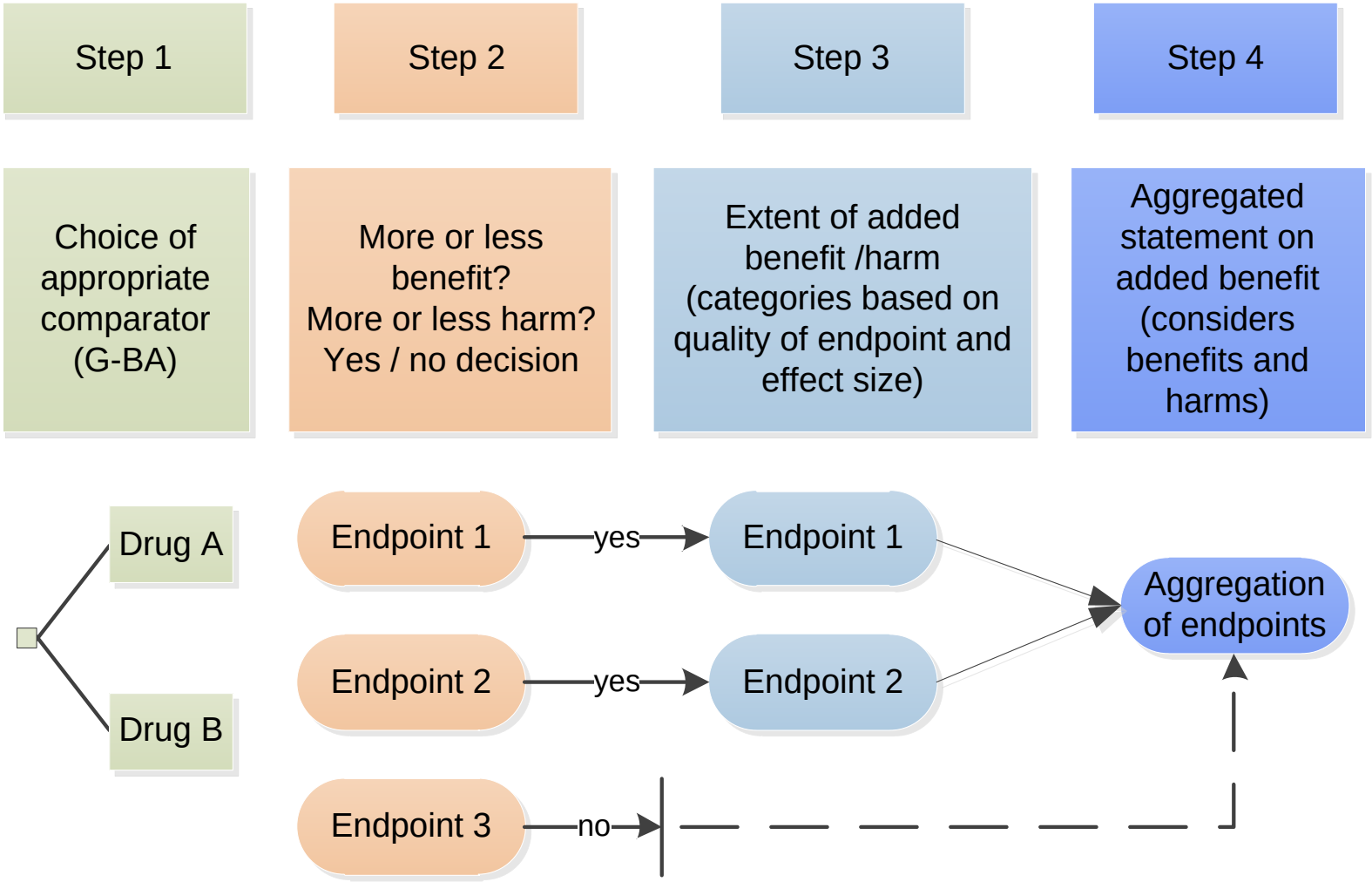


Figure 1: Timeline of the dossier assessment

Legend: Figure 1 illustrates the timeline of the dossier assessment according to the new bill in effect January 1st, 2011. Boxes shaded display where and how IQWiG comes in with regard to health economic criteria in the decision making process on drug prices in Germany.

Process of assessing "added benefit"



Extent of added benefit: six categories, legal basis

major added benefit

considerable added benefit

minor added benefit

added benefit proven, but not quantifiable

no added benefit has been proven

less benefit than that of the appropriate comparator

Criteria in accordance with AM-NutzenV*

sustained and great improvement ^ (cure, major increase in survival time, long-term freedom from serious symptoms, extensive avoidance of serious side effects)

marked improvement ^ (perceptible alleviation of the disease, moderate increase in survival time, alleviation of serious symptoms, relevant avoidance of serious adverse effects, important avoidance of other adverse effects)

moderate and not only marginal improvement ^ (reduction in non-serious symptoms, relevant avoidance of side effects)

*Regulation for Early Benefit Assessment of New Pharmaceuticals

^in the therapy-relevant benefit, which has not previously been achieved versus the appropriate comparator

Criteria in Accordance with AM-NutzenV with Additions

		Outcome Category			
		Survival Time (Mortality)	**Symptoms (Morbidity)**	***Quality of Life***	**Adverse Effects**
Added Benefit	**Major** **sustained great improvement** in the therapy-relevant benefit, which has not previously been achieved versus the appropriate comparator	Major increase in survival time	Long-term freedom from serious (*or severe*) symptoms (*or late complications*)	*Major improvement in quality of life*	Extensive avoidance of serious (*or severe*) adverse effects
	Considerable **marked improvement** in the therapy-relevant benefit, which has not previously been achieved versus the appropriate comparator	Moderate increase in survival time	Alleviation of serious (*or severe*) symptoms (*or late complications*) *Significant reduction in non-serious (or non-severe) symptoms (or late complications)*	*Significant improvement in quality of life*	Relevant avoidance of serious *(or severe)* adverse effects Significant avoidance of other (*non-serious or non-severe*) adverse effects
	Minor **moderate and not only marginal improvement** in the therapy-relevant benefit, which has not previously been achieved versus the appropriate comparator	*Any increase in survival time*	*Any reduction in serious (or severe) symptoms (or late complications)* Reduction in non-serious *(or non-severe)* symptoms *(or late complications)*	*Relevant improvement in quality of life*	*Any reduction in serious (or severe) adverse effects* Relevant avoidance of *(other, non-serious or non-severe)* adverse effects

italics: additions to the AM-NutzenV.

Determination of the Degree of Added Benefit - Quantitative Operationalization

		Outcome Category			
		Survival Time (Mortality)	**Serious *(or Severe)*** Symptoms *(or Late Complications)* and Adverse Effects	***Quality of Life***	**Non-Serious *(or Non-Severe)*** Symptoms *(or Late complications)* and Adverse Effects
Added Benefit	**Major** **sustained and great improvement** in the therapy-relevant benefit, which has not previously been achieved versus the appropriate comparator	Major increase in survival time **CI_S: 0.85** (RR_1 = 0.50)	Long-term freedom or extensive avoidance **CI_S: 0.75** (RR_1 = 0.17) **and risk ≥ 5%**[2]	*Major improvement* [1] **CI_S: 0.75** (RR_1 = 0,17) **and risk ≥ 5%**[2]	Not applicable
	Considerable **marked improvement** in the therapy-relevant benefit, which has not previously been achieved versus the appropriate comparator	Moderate increase in survival time **CI_S: 0.95** (RR_1 = 0.83)	Alleviation or relevant avoidance **CI_S: 0.90** (RR_1 = 0.67)	*Significant improvement*[1] **CI_S: 0.90** (RR_1 = 0.67)	Significant avoidance **CI_S: 0.80** (RR_1 = 0.33)
	Minor **moderate and not only marginal improvement** in the therapy-relevant benefit, which has not previously been achieved versus the appropriate comparator	*Any (statistically significant) increase in survival time* **CI_S: 1.00**	*Any (statistically significant) reduction* **CI_S: 1.00**	*Relevant improvement*[1] **CI_S: 1.00**	Relevant avoidance **CI_S: 0.90** (RR_1 = 0.67)