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RECHTSANWALTSSOCIETÄT

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German & American Healthcare Conference

Comparative Effectiveness Research / HTA

Minneapolis, April 29th 2009

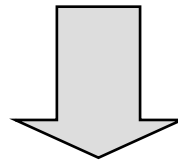
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Agenda

- Introduction
- Bottom Line in Germany
- Main Principle for Reimbursement of Medicines in Germany:
Wirtschaftlichkeitsgebot (efficiency principle)
- Pricing in Germany in the out-patient sector:
 - *Lauer Taxe* (Official Pharmacists Price Schedule)
 - *Festbetragsregelung* (Reference Price System)
 - *Höchstbetragsregelung* (Maximum Price System).
- German Institute for Quality and Efficiency in the Healthcare Sector (“IQWiG”).
- Joint Federal Committee (“G-BA”).
- The IQWiG – HTA Procedure
- Conclusion

Introduction

- Increasing costs for medicines in all Health Care systems
- Revenues do not increase equally
- P: affordability of Health Care System



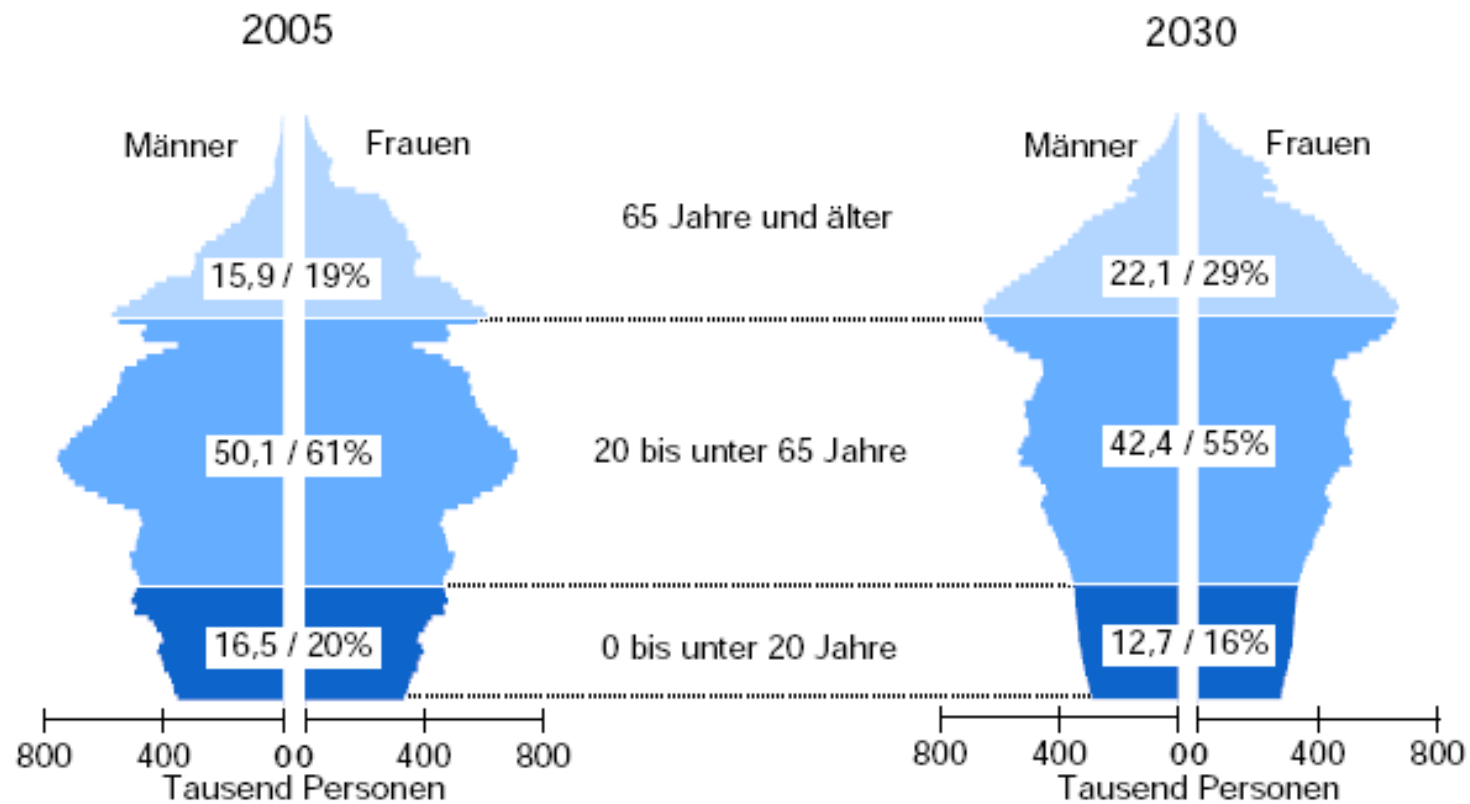
Pertinence of HTA

Bottom Line

In Germany:

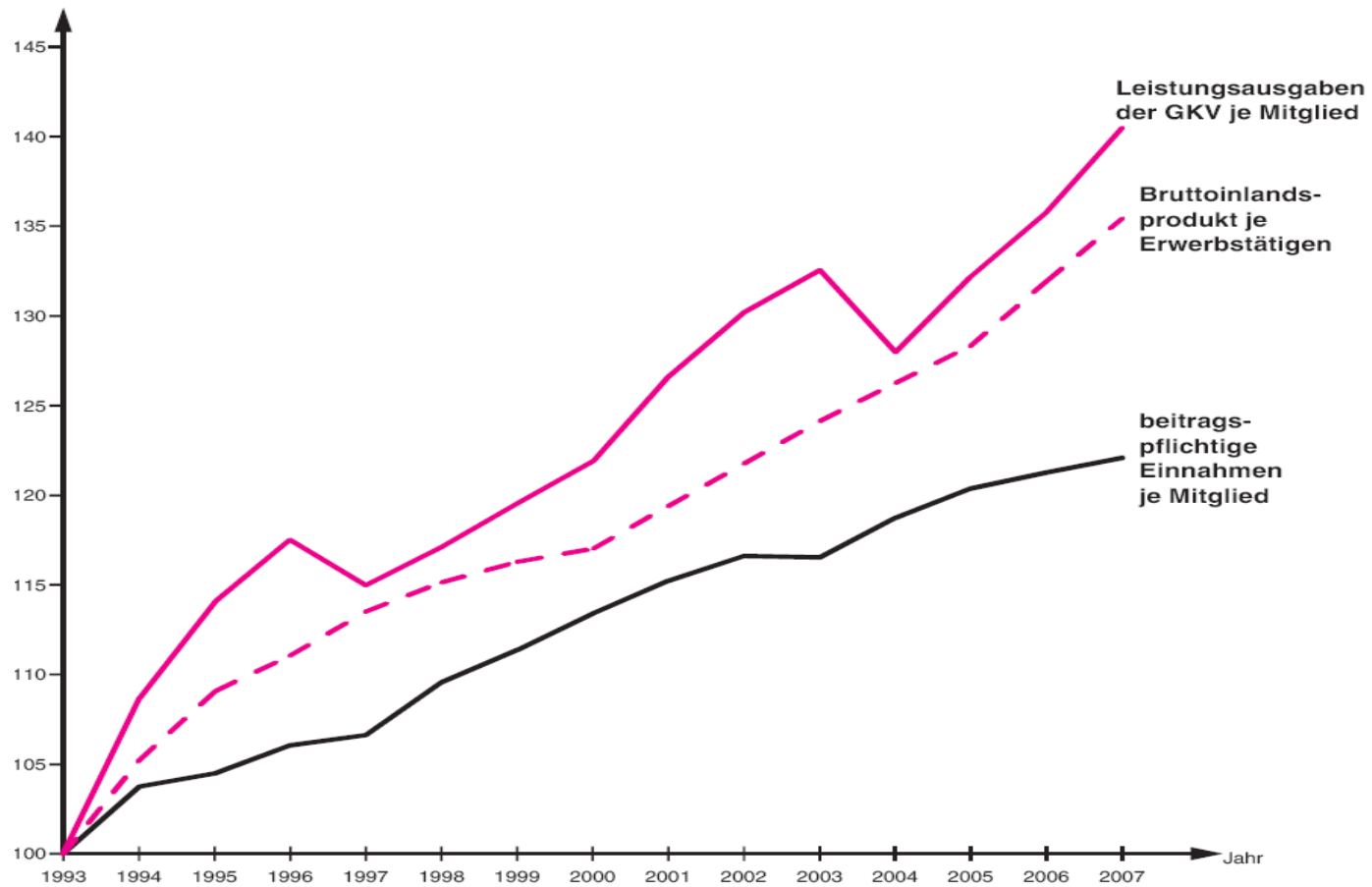
- High expenditures for Health Care System, esp. medicines.
- High rises in expenses for the Health Care System not only due to the actual demographic trend but also cost-intensive high innovative medicines.
- Frequently questionable value and therapeutically benefit of medicines.
- No direct regulatory restrictions do exist in Germany regarding the pricing of medicines: Pharmaceutical companies in Germany are free and change their prices at will.
- *Principle:* Each approved medicine has to be reimbursed within the system of the SHI.
- **BUT: Highly complex system of reimbursement resp. reimburse-ability of medicines (inter alia Wirtschaftlichkeitsgebot (Efficiency Principle)).**

Demographic trend in Germany



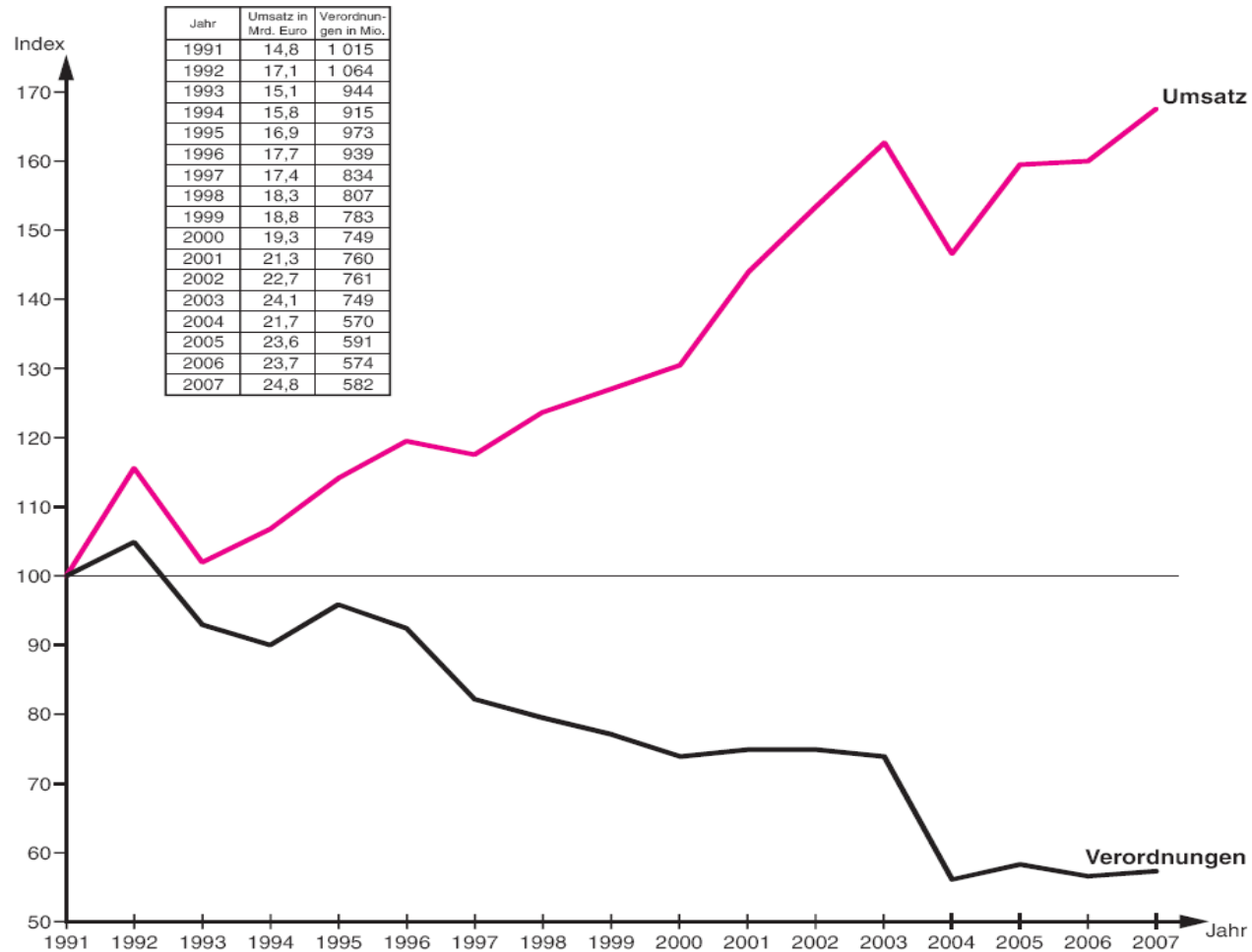
Source:  STATISTISCHE ÄMTER
DES BUNDES UND DER LÄNDER

Cost-revenue relation



Quelle: Statistisches Bundesamt, BMG (KJ 1, KV 45)

Turnover and sales of medicines in Germany



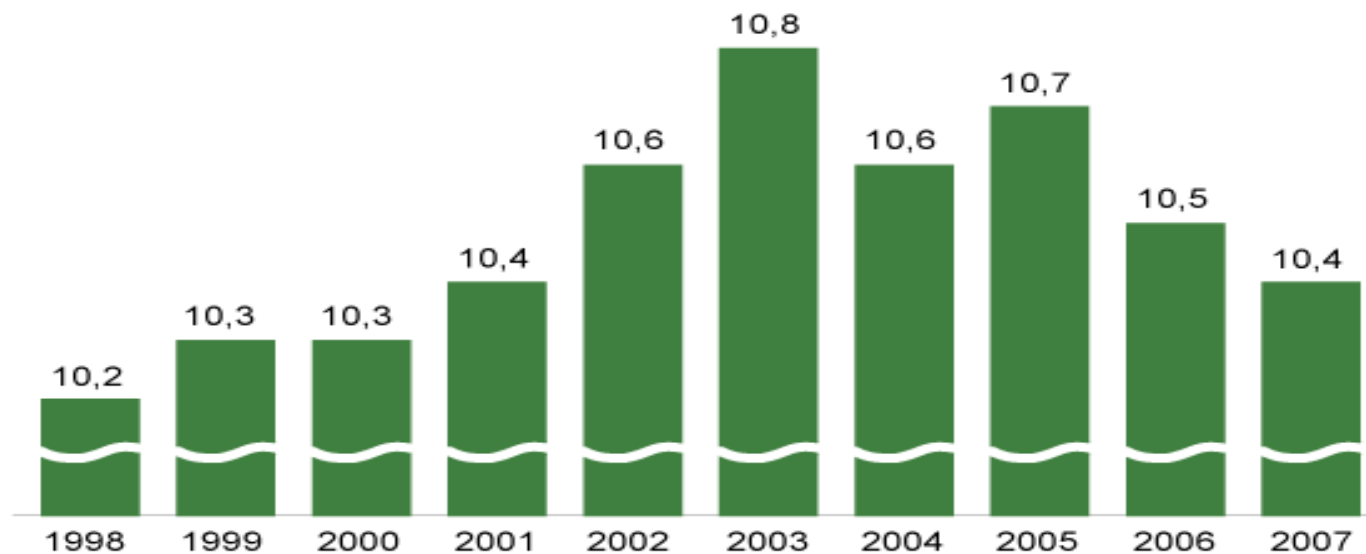
Quelle: Arzneiverordnungs-Report

Health expenditures in Germany in relation to GDP

Entwicklung der Gesundheitsausgaben

Anteil am Bruttoinlandsprodukt (BIP)

%



Quelle: Statistisches Bundesamt, Wiesbaden

Wirtschaftlichkeitsgebot (Efficiency Principle)

- The prescription of medicines within the system of the *Gesetzliche Krankenversicherung* (Statutory Health Insurance, “SHI”) must be in line with the efficiency principle.
- I.e. the physicians’ prescribing a medicine must consider whether the treatment is
 - *sufficient,*
 - *appropriate,*
 - *economically efficient and*
 - *must not exceed the extent of the medically-necessary.*
- In case the SHI challenges the compliance with the efficiency principle, the physicians prescribing medications must, in particular, ensure that it can be proven that such prescription is medically necessary.

Pricing in Germany: *Lauer Taxe* (Official Pharmacists Price Schedule)

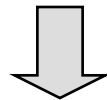
- Incorporation is requirement for the reimbursement of medicines within the system of the Statutory Health Insurance Funds (SHI).
- Nationwide used identification key for medicines distributed by pharmacies, cf. Section 300 Social Code Book V (“SGB V”).
- Information includes:
 - Central Pharmaceutical Number (*PZN*, to be labeled on the package)
 - Product Characteristics
 - Form of Administration
 - Package Size and Price (!)
- Conclusion: No inclusion in the *Lauer-Taxe* without price!
- However: an application re: preliminary *PZN* can be submitted without a price has been set.

Pricing in Germany: *Festbetragsregelung* (Reference Price System)

- *Festbetragsregelung* does apply to medicines with
 - The same active substances
 - Pharmacologically and therapeutically comparable active substances
 - Therapeutically comparable effects, in particular combination medicines
- If a drug falls within one category, reimbursement is limited to the maximum amount constituted for the medicines within this category.
- The reference price is not mandatory for pharmaceutical companies, it solely states the benchmark for reimbursement within the SHI.
- However, no reference price should be set for patent medicines based on a new principle and deemed to represent a significant therapeutic advance.

Pricing in Germany: *Höchstbetragsregelung* (Maximum Price System)

- For cost-intensive medicines: Cost-benefit calculation of the *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (Institute for Quality and Efficiency in Health Care, “IQWiG”), cf. Section 35b SGB V.
- Consequence: *Höchstbetragsregelung*, sets a maximum amount for Medicines to be reimbursed within the SHI.
- Decision making body: *Spitzenverband Bund* (Central Federal Association of the Health Insurance Fund).



Basis: HTA

- Note: Innovative medicines, i.e. no alternative treatment is available, are statutorily excluded from any *Höchstbetragsregelung*.

G-BA: Joint Federal Committee

- The so called “little Legislator“ in the German Healthcare Sector.
- Decisions are taken by the Sub-Committee Medicines.
- Reimbursement of cost-intensive medicines may be subject of a *Therapiehinweis* (therapeutical information).
- Newly issued for cost-intensive medicines:
Zweitmeinungsverfahren (Second Opinion Procedure).
- Scientific support from the German Institute for Quality and Efficiency in the Healthcare Sector (IQWiG).

IQWiG: German Institute for Quality and Efficiency in Health Care



- Is responsible for the scientific evaluation of the benefits and harms.
- Evaluation of quality and efficiency of health care services.
- Since April 2007: new cost-benefit-assessment

- The responsibilities include:

evaluation of clinical practice guidelines, submission of recommendations on disease management programs, evaluation of the benefits, harms and a cost-benefit-ratio of pharmaceuticals, and publication of health information for patients and consumers.

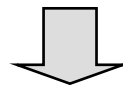
The IQWiG - HTA Procedure

HTA: is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner.

IQWiG-Procedure:

- covers all parts of the HTA definition
- established by lawmaker

Note: IQWiG-Procedure is non-exclusive!



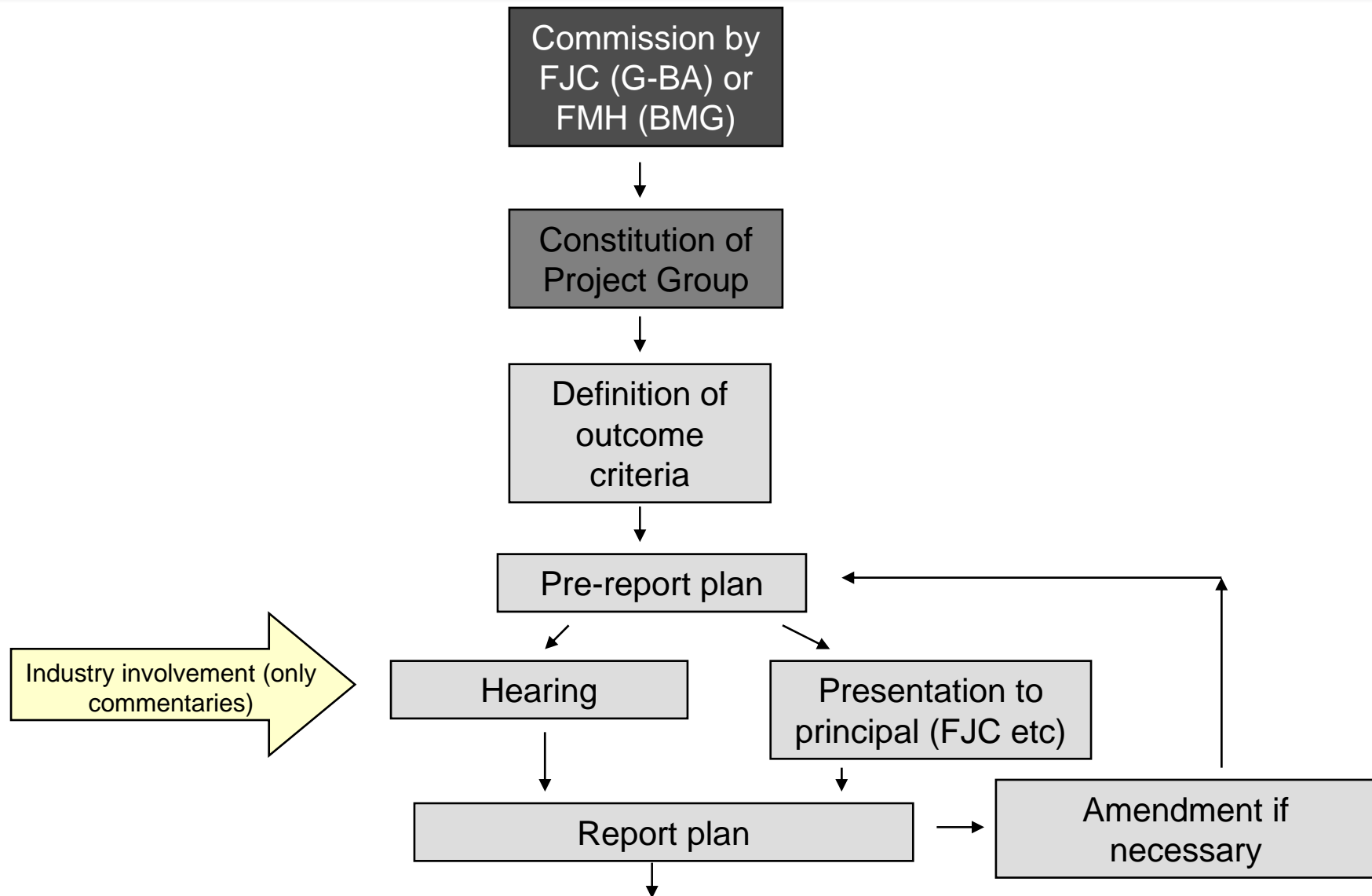
(additional) HTA by other institutes can make sense in order to influence e.g. the decision of G-BA actively.

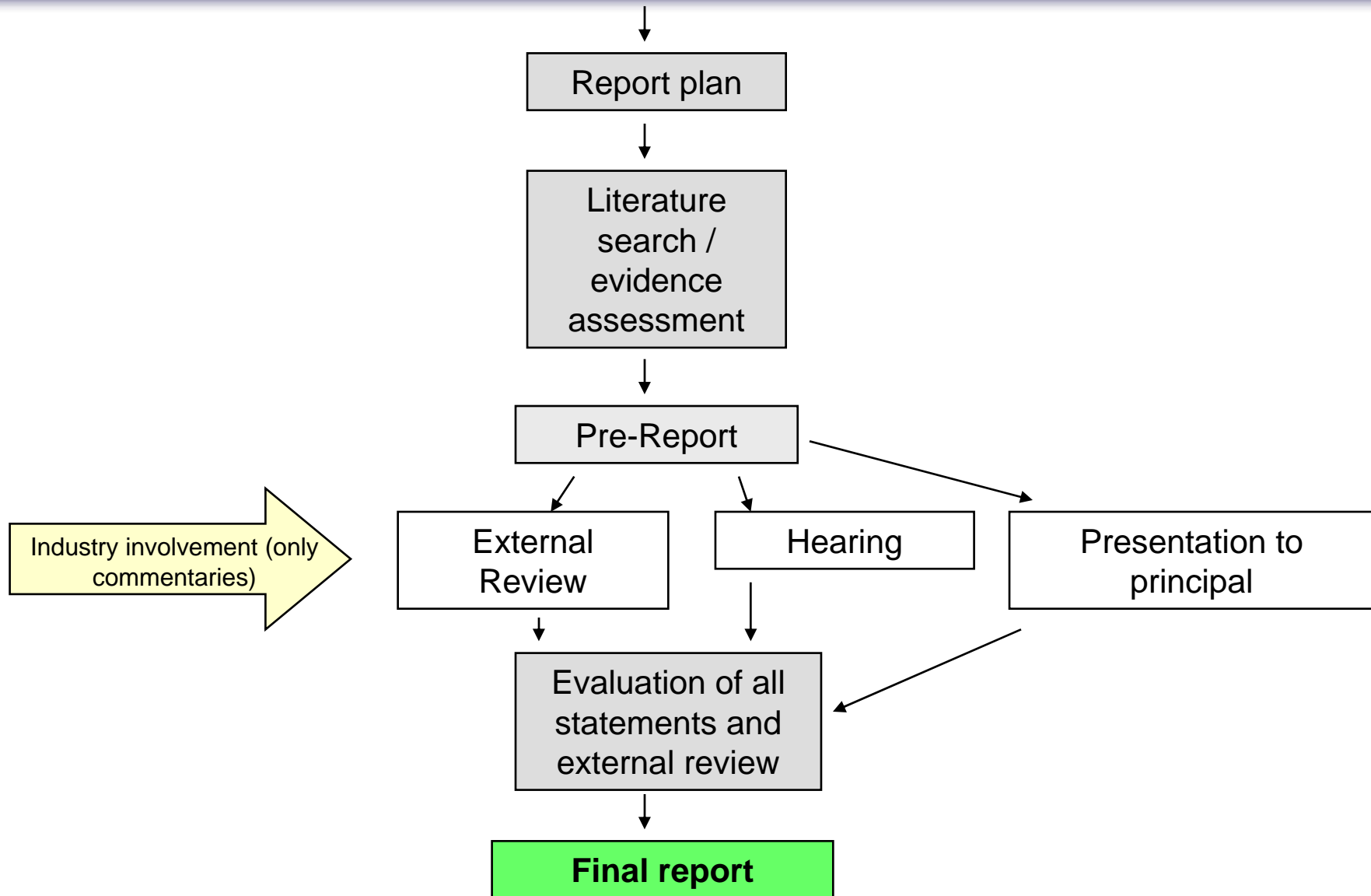


Public Policy
Advisory!

Assessment Procedure IQWiG

- G-BA instructs the IQWiG to give scientific advice regarding the cost-benefit assessment.
- The advice is legally classified as recommendation.
- However, the G-BA mostly adopts the (pre-) decision of the IQWiG.
- Important: Actively participation in the decision-taking process of the IQWiG.

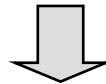




Specifics of IQWiG-HTA

- In contrast to other HTA agencies the IQWiG does not use the incremental-cost-effectiveness-ratio (ICER) approach.
- IQWiG introduced a different methodological instrument:

Efficiency Frontier.

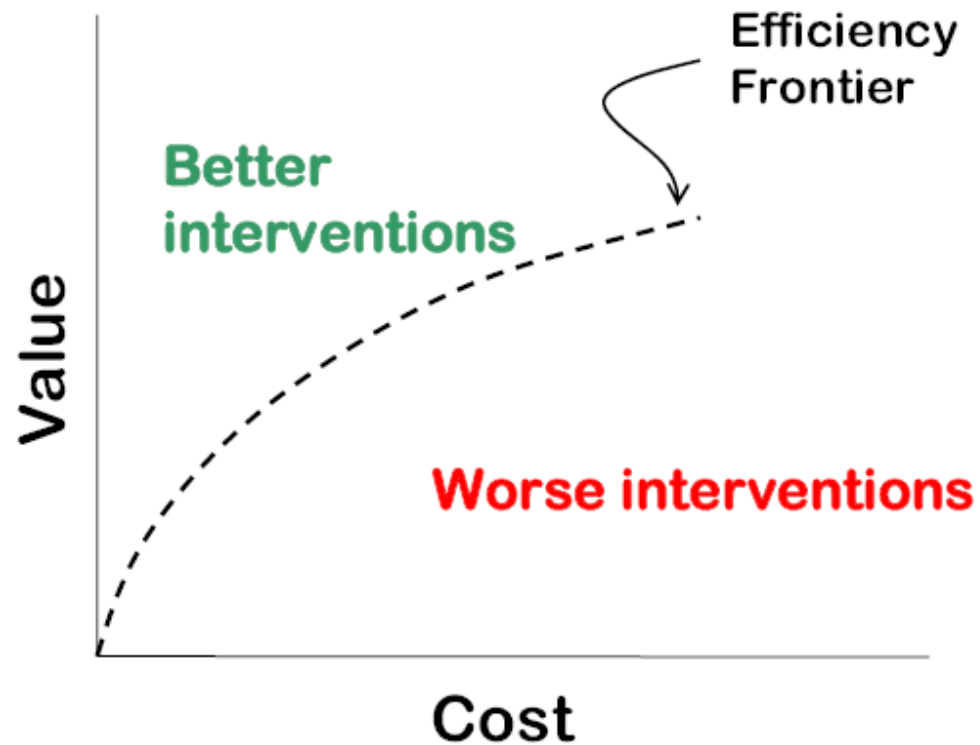


all available compounds / agents have to be compared using their total value in relation to their total costs.

New agents:

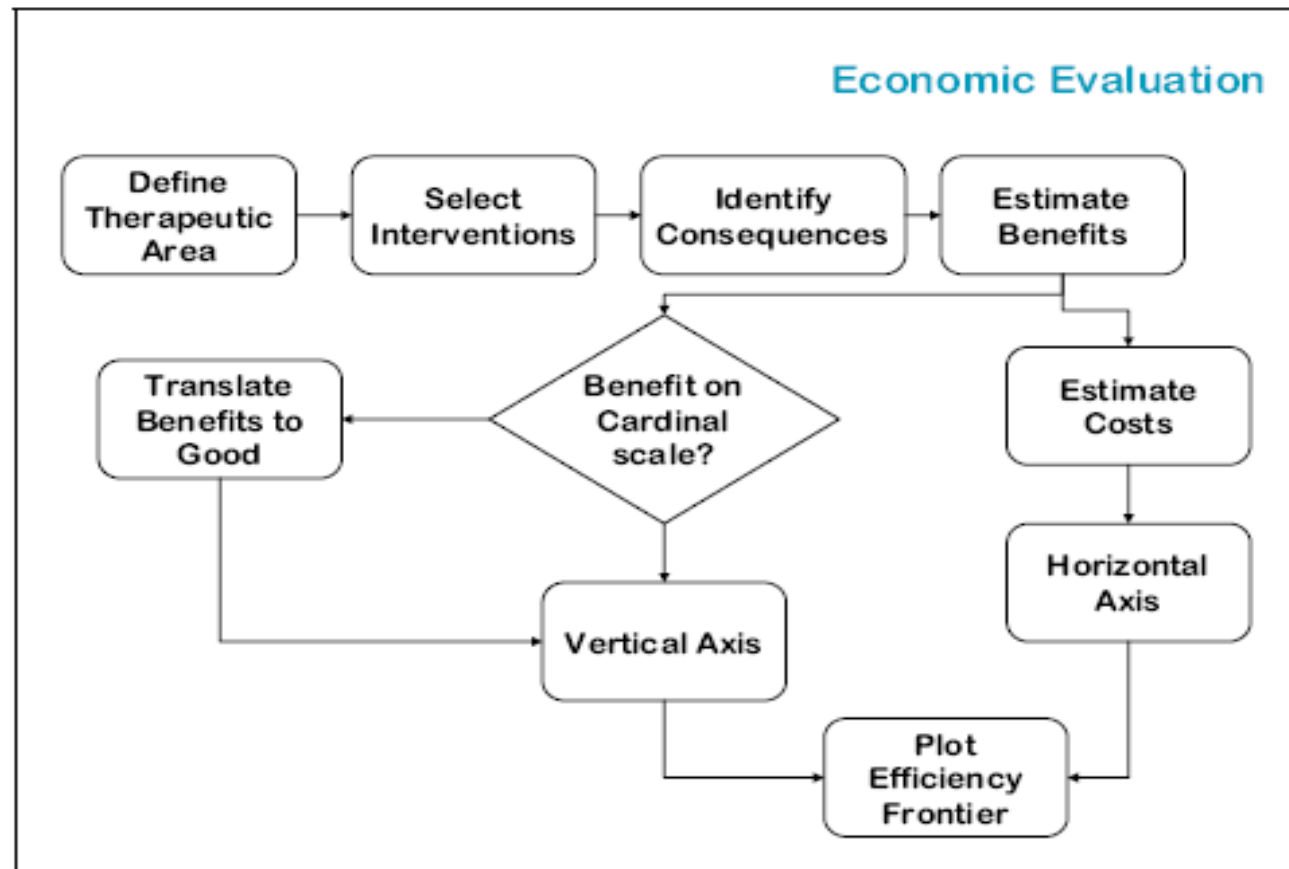
have to show comparable efficiency, compared to (a) the best available cost-benefit-ratio, (b) compared to the mean cost-benefit-ratio, or (c) compared to the last accepted cost-benefit-ratio.

Efficiency Frontier



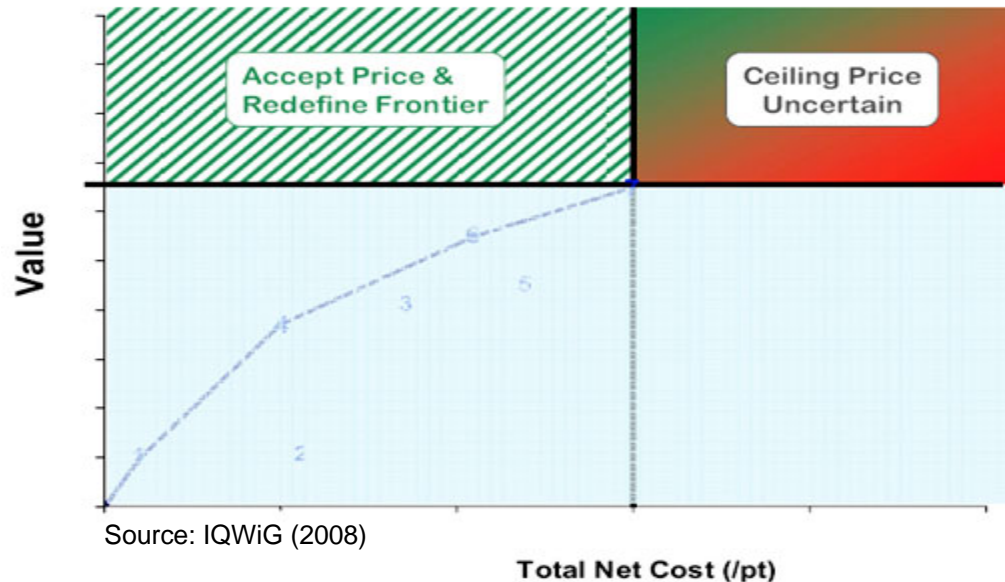
Source: IQWiG (2008)

(Proposed) process of economic evaluation



Source: IQWiG

New Superior Interventions



- The area of **superiority** is demarcated by the horizontal line intersecting the point of the intervention that gives the most value.
- The area of **higher costs** is demarcated by the vertical line that intersects the most expensive therapy.

Methods for Assessment of the Relation of Benefits to Costs in the German Statutory Health Care System

- 1st version in 2008
- Ongoing discussion in Germany whether the new methods are consistent with federal social law (§ 35b social code book)
- It is highly controversial whether the efficiency frontline approach is appropriate to use.

P: No example in real life of the usage of the efficiency frontier approach exists

- **In 2009:** publication of the second draft of their methods and the technical annex with necessary details how to evaluate values and costs.

IQWiG commissioned pilot studies for demonstrating the appropriateness of the efficiency frontier.

Pro and Contra of the Cost-Benefit Assessment

Pro:

- Established procedure for economic disciplines.
- High certainty for the physician while providing the healthcare service.

Contra:

- Lack of transparency.
- Cost-benefit assessment is not always practice orientated.
- Costs are an economic factor which may not always meet healthcare needs.

Conclusion

Thank you very much for your attention.

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