# Pharmaceutical Benefits and the Economic Crisis in European Countries:

## The case of Germany

Peter Kolominsky-Rabas, MD, PhD, MBA
Director
Interdisciplinary Centre for Health Technology Assessment and Public Health
University of Erlangen-Nurnberg
Bavaria, Germany

# Basic principles of the German health care system

- Statutory health insurance (GKV)
  - SHI dates back to 1883 (Chancellor Otto von Bismarck)

  - covers 85% of the population with 166 sickness funds with non-profit status

- Substitutive private health insurance (PKV)
  covers 10% of the population with 46 insurance companies

- Complemtary private health insurance
  - reimburses health services NOT covered by the GKV or co-payments

# Basic principles of the German health care system (II.)

- SHI characteristics - working solidarity principle i.e.

  - no surcharge for age or risk
  - low salary = low payment
  - contributions for unemployed & welfare recipients paid by public funds

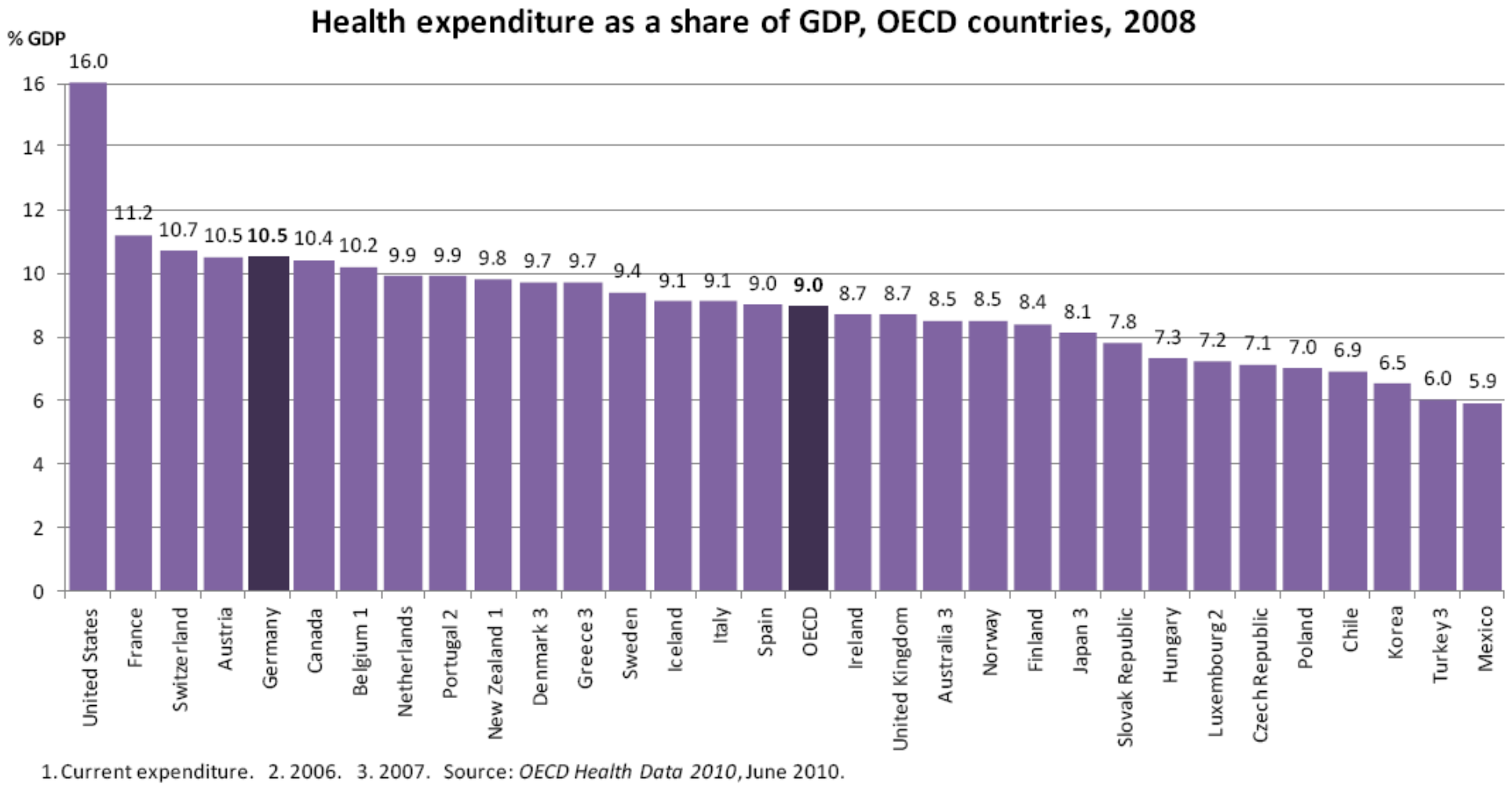
- Highly developed infrastructure

- Free access, no waiting lists

# Basic principles of the German health care system (III.)

- SHI enrolment compulsary for non-public sector employees earning less than 49,950 Euro a year (in 2010)
- GKV-members 2010: 69.970.000 m
- Free coinsurance for family members: 7.7 m
- Since 2009 uniform contribution rate 14.9% (2011: 15.5%)
  employer: 7% (2011: 7.3%)
  employee: 7.9% (2011: 8.2%)

# Health expenditures as a share of GDP - OECD comparison




1. Current expenditure. 2. 2006. 3. 2007. Source: *OECD Health Data 2010*, June 2010.

# Health expenditures as a share of GDP - Germany 1999-2008

# Political Framework

**IQWiG**

**G-BA**

**GKV-Spitzenverband**
(Federal Assoc. of SHI)

# The Social Code Book V

- Social Code Book V is
  THE cornerstone of German health insurance legislation

- The legal foundations of **G-BA, IQWIG & GKV-Spitzenverband** are anchored in the German Social Code Book V (SGB V), where its brief, the carrying out of its responsibilities, and its funding basis are laid down

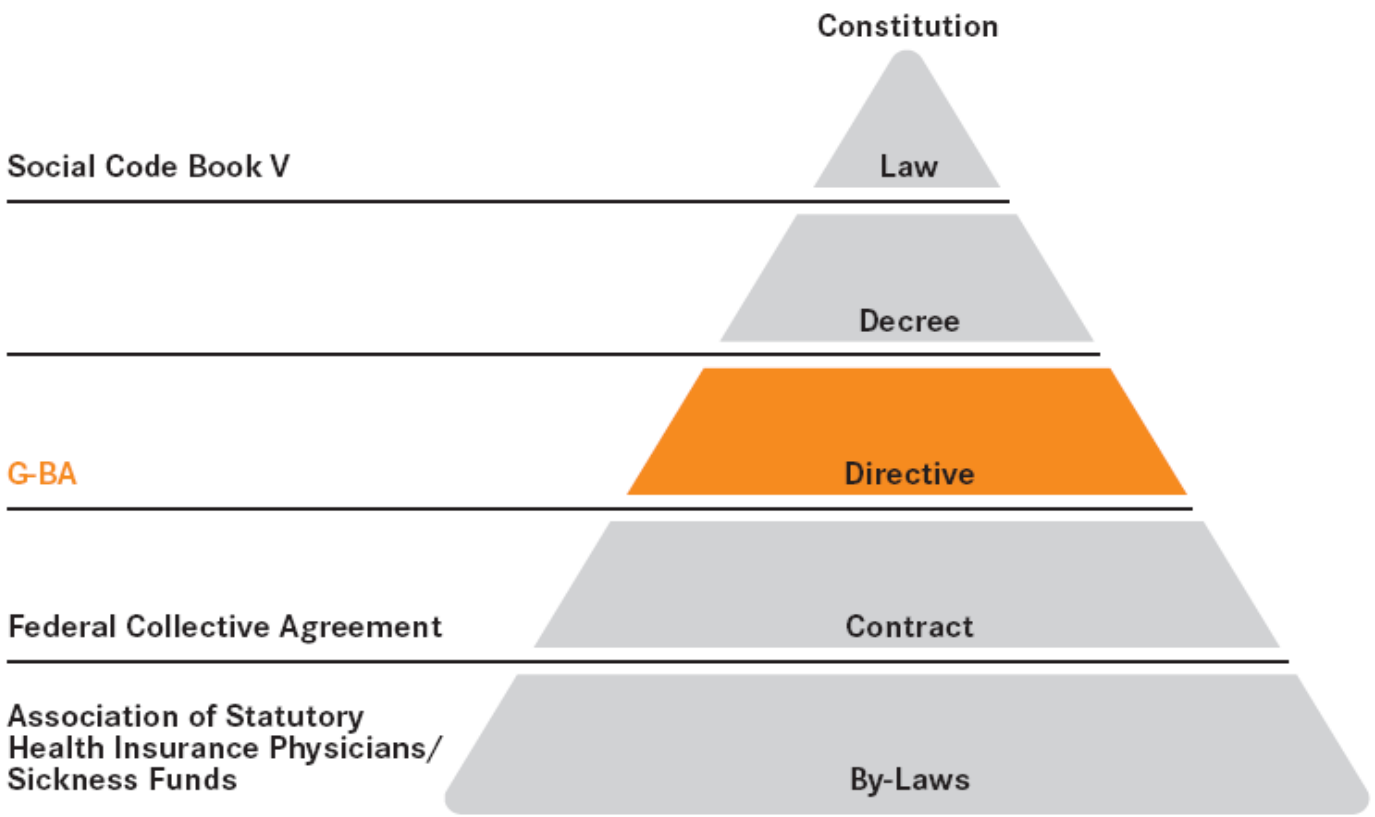
- No 'cart blanche' in this field
  Health care delivery is not a privilege but a civil right

# Gemeinsame Bundesausschuss (G-BA)
# Federal Joint Committee

## G-BA

- is the supreme decision-making body of the so-called self-governing system in Germany
- represents physicians, psychotherapists, dentists, hospitals, sickness funds and patients
- issues directives and thus determines the benefit package of the SHI covering about 70 million people
- is responsible for reimbursement decisions in the SHI system

# Gemeinsame Bundesausschuss (G-BA)
# Legal status



# Institute for Quality & Efficiency in Health Care (IQWiG)

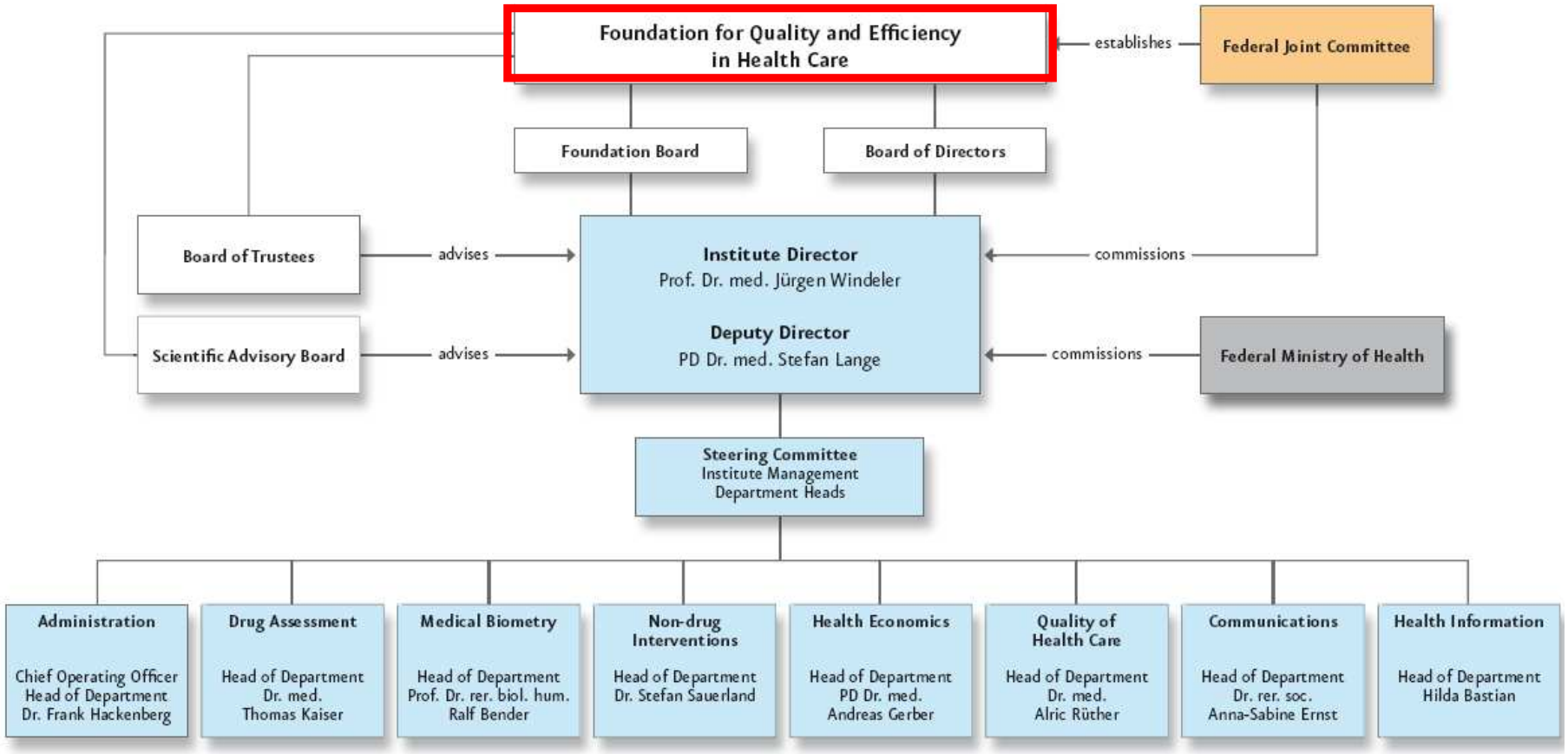
- main scientific advisory body in the German SHI system
- assessing pharmaceuticals, surgical procedures, diagnostic tests, clinical practice guidelines and aspects of disease management programmes, following the principles of evidence-based medicine
- sole contracting agencies are the G-BA and the Federal Ministry of Health (BMG)
- IQWiG can also tackle topics on its own initiative (general commission)
- neither political authorities, nor health insurance funds, nor industry have influence on IQWiG‘s evaluations

# Legal Foundation and Supervision

- Legal basis of the G-BA & IQWIG is the Social Code Book V (SGB V)
- G-BA & IQWIG were established on January 1st, 2004 as mandated by a federal health reform law (GKV Modernisation Act – GMG)
- The work of the G-BA is under the legal review of the Federal Ministry of Health, but it is not a subordinate authority
- IQWIG is a private foundation and indendent

# Independent institute

Organisation Chart of the Institute for Quality and Efficiency in Health Care



# Funding

## G-BA & IQWIG funded

- to 50% by a fee on every hospital case to be invoiced
- to 50% by a fee for medical and dental outpatient services reimbursed by statutory health insurance (SHI) [§85 and §87a.]
- fee for each hospital case, the proportions contributed by the associations of SHI physicians and dentists, as well as details on the forwarding of these funds are determined by the G-BA.

# Pharmaceuticals: Free Pricing and Access in Germany

New pharmaceuticals after approval

Full reimbursement* by SHI

Price is set by pharmaceutical company

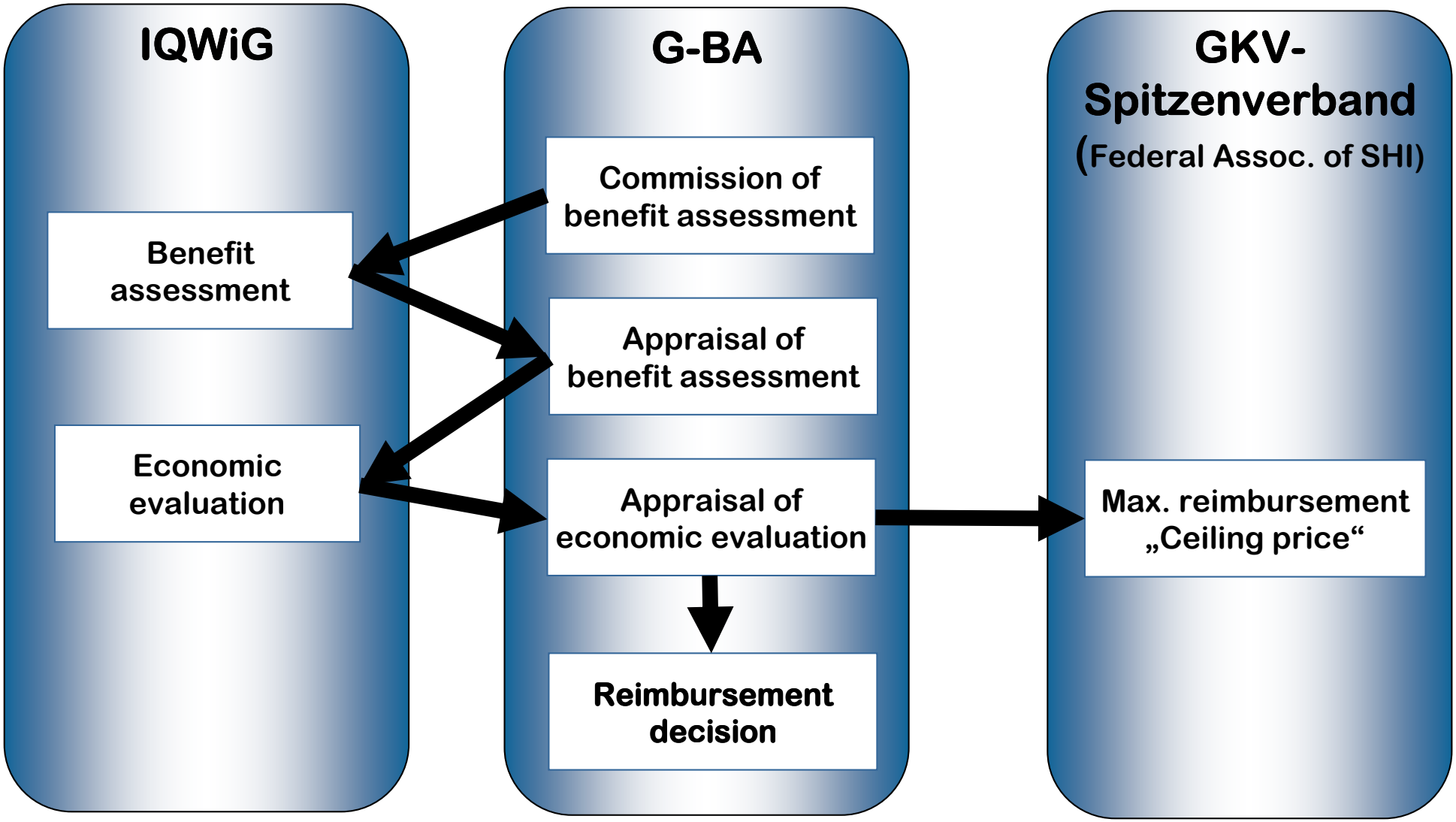
**Pharmaceuticals generally excluded from reimbursement:**

- OTC, only reimbursed as therapy-standard in severe diseases
- Drugs for trivial diseases
- Life-Style-Drugs“ (eg hair loss, smoking cessation, weight loss)

# Pharmaceuticals: Regulatory tools by the G-BA

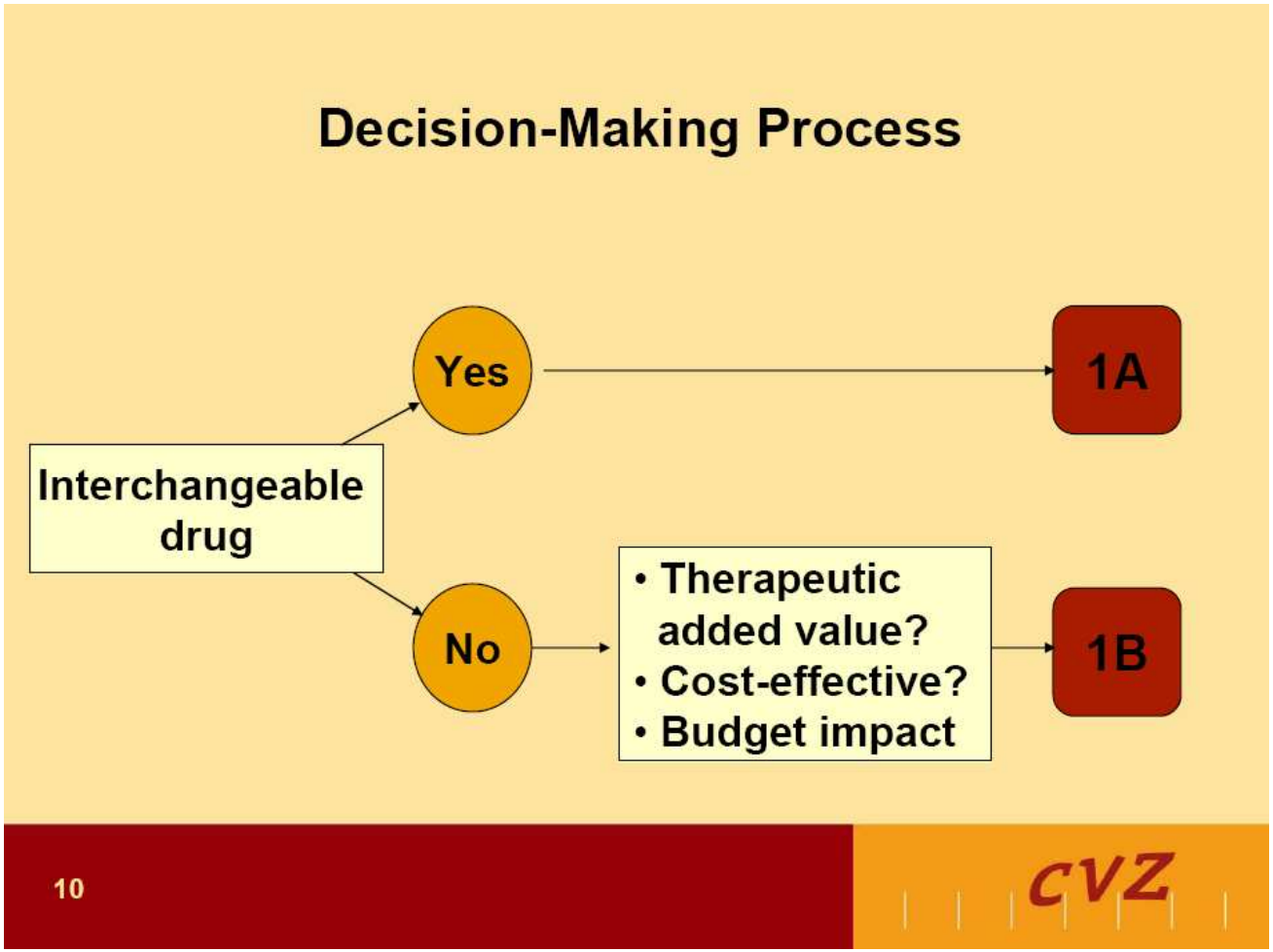
- Reference price groups („Festbeträge“)
- Restriction or exclusion or drugs (Benefit-Assessment)
  - Example: restriction of Clopidogrel to subgroup of stroke patients
- Therapy advice for economical prescribing
- Co-signing procedure for pharmaceuticals („second opinion“)
- Application procedures for medical devices with CE-certification
- Economic evaluation with maximum reimbursement („ceiling price“) (Cost-Benefit-Assessment)

# Political Framework

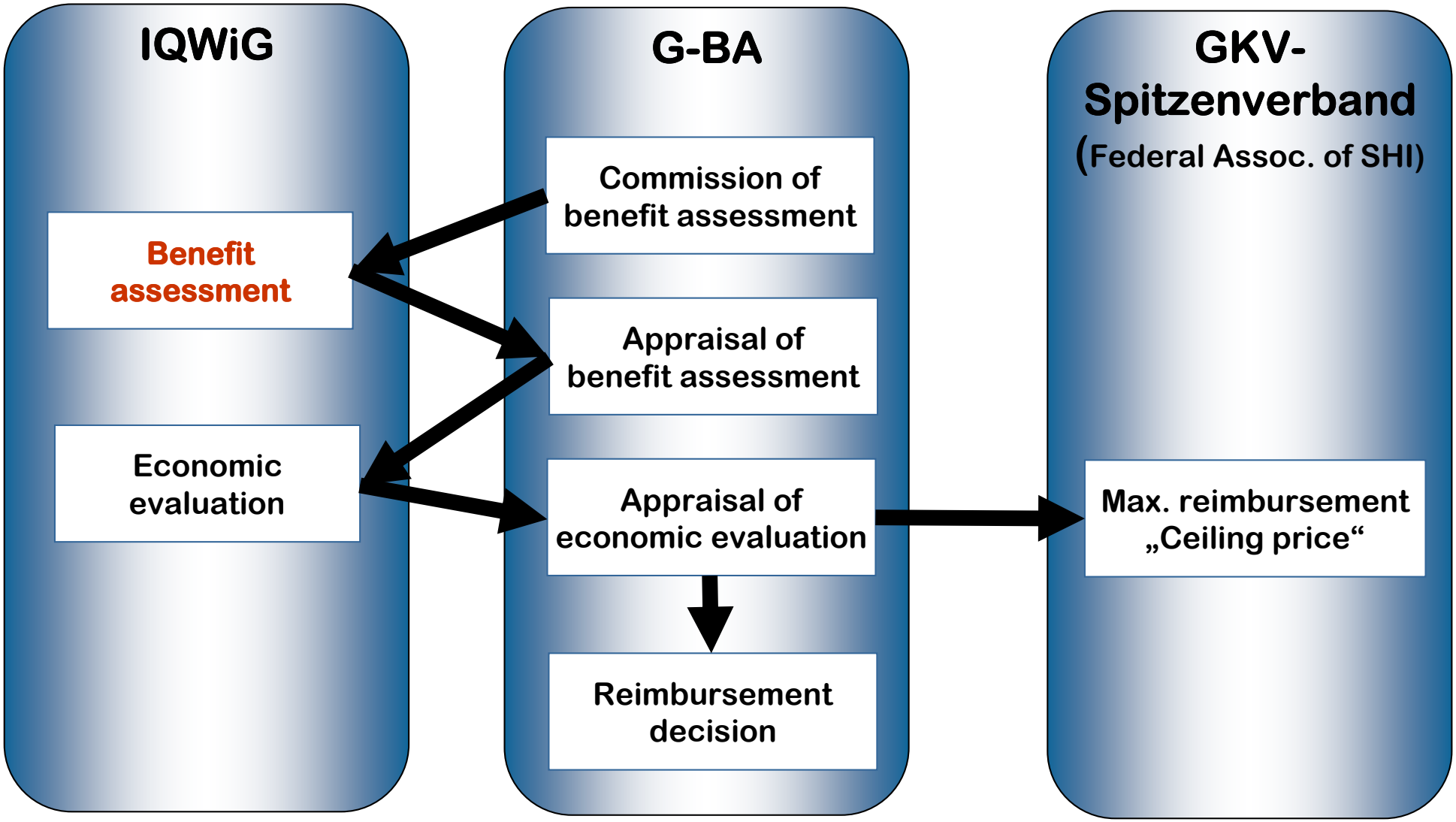


# Preceding benefit assessment

## Example: The Netherlands
## College voor zorgverzekeringen (CVZ) (Health Insurance Board)



# Political Framework



# Benefit Assessment of Drugs by IQWiG and G-BA

- Exclusion of **Insulin analogues** if price is higher than standard Insulin
- Exclusion of **Clopidogrel** monotherapy for Coronary Heart Disease and Cerebrovascular Disease
- Exclusion of **Reboxetin** in treatment of depression (16.09.2010)
- Exclusion of **Glinides, Glitazones** in DM II (oral anti-diabetic drugs) Exception: patients with renal dyfunction (16.09.2010)
- **Work in progress**: Biosimilars in Rheumatoid Arthritis, Anticholinergic drugs in Alzheimer Dementia

# Assessments by IQWiG

- The benefit assessment has to follow the standards of evidence based medicine (§139a SGB V)
- Fair comparison of alternatives in prospective controlled trials
- Based on published and unpublished data
- Focus on patient-relevant outcomes

# Patient-Relevant Outcomes (Benefit and Harm)

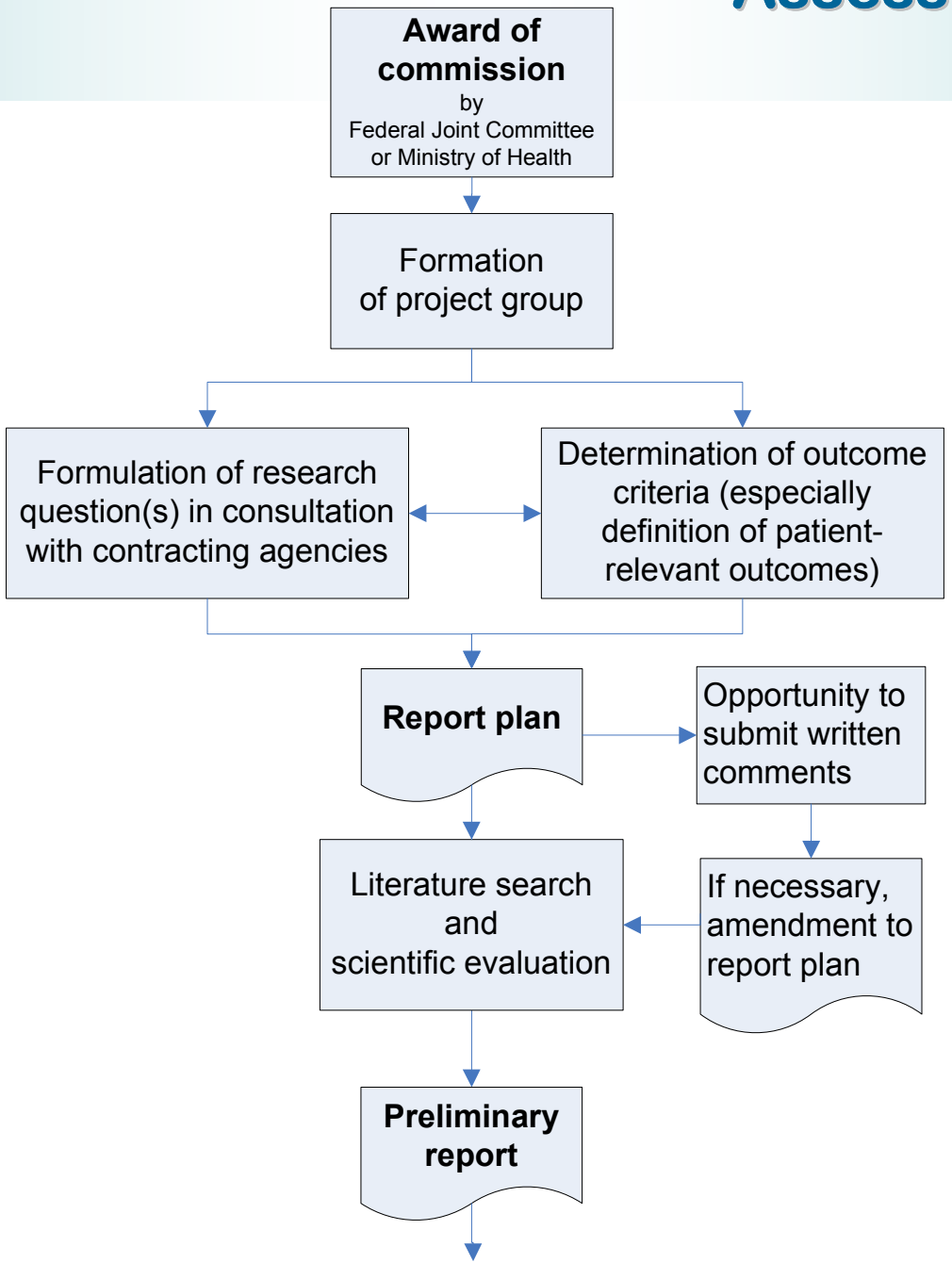
- Improvement in health status
- Reduction disease duration
- Increase in life expectancy
- Reduction of adverse effects
- Increase in health related quality of life

➲ Codified by law (Social Code Book V)

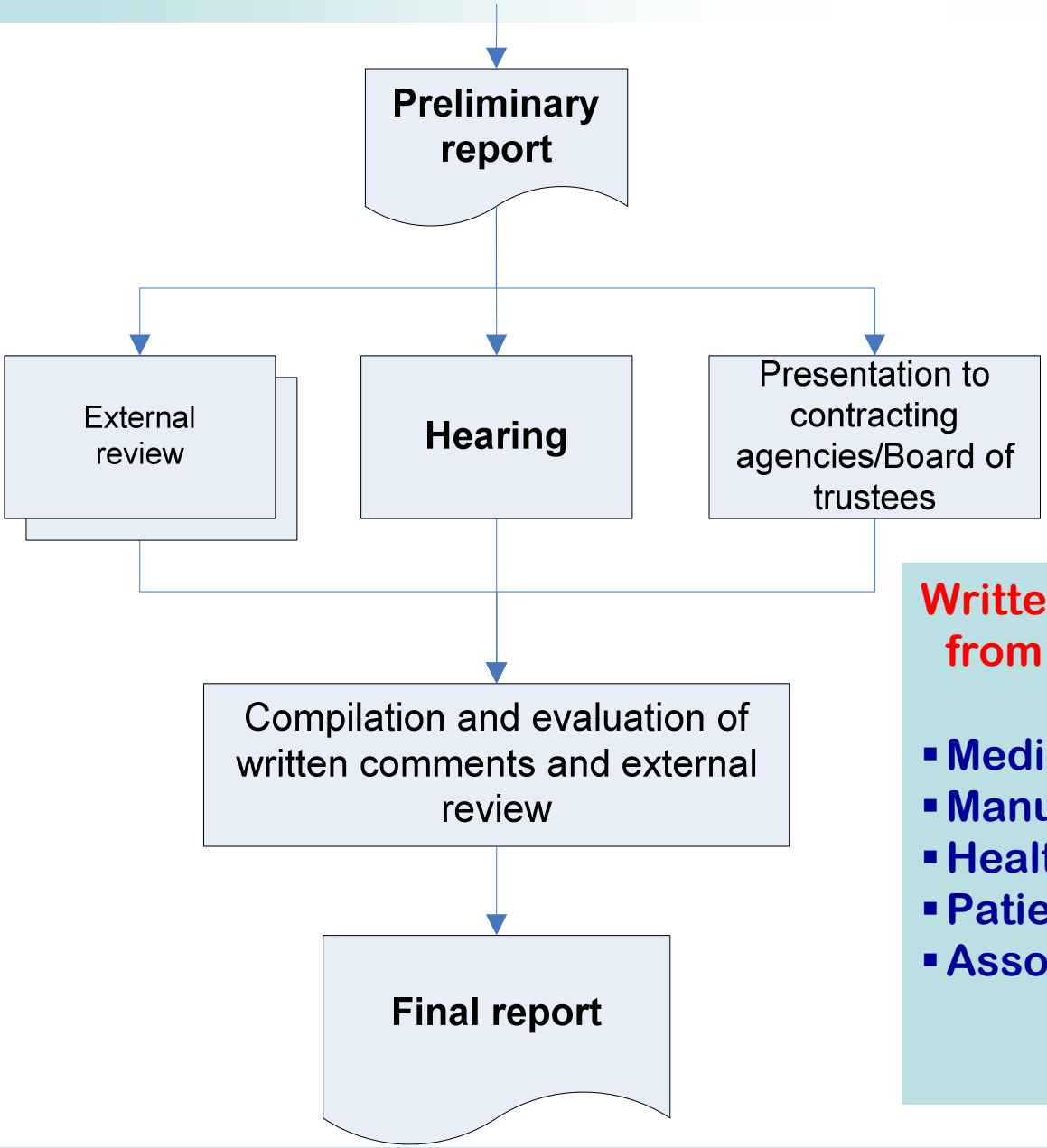
**§ 35b Bewertung des Nutzens und der Kosten von Arzneimitteln**

(1) Das Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen kann nach § 139b Abs. 1 und 2 beauftragt werden, den Nutzen oder das Kosten-Nutzen-Verhältnis von Arzneimitteln zu bewerten. Bewertungen nach Satz 1 können für jedes erstmals verordnungsfähige Arzneimittel mit patentgeschützten Wirkstoffen sowie für andere Arzneimittel, die von Bedeutung sind, erstellt werden. Die Bewertung erfolgt durch Vergleich mit anderen Arzneimitteln und Behandlungsformen unter Berücksichtigung des therapeutischen Zusatznutzens für die Patienten im Verhältnis zu den Kosten. Beim Patienten-Nutzen sollen insbesondere die Verbesserung des Gesundheitszustandes, eine Verkürzung der Krankheitsdauer, eine Verlängerung der Lebensdauer, eine Verringerung der Nebenwirkungen sowie eine Verbesserung der Lebensqualität, bei der wirtschaftlichen Bewertung auch die Angemessenheit und Zumutbarkeit einer Kostenübernahme durch

# Assessment process (I.)



# Assessment process (II.)




**Written comments from stakeholders from different areas:**

- **Medicine**
- **Manufacturers**
- **Health Economics**
- **Patient representatives**
- **Association of pharm. manufacturers**

# Example ‚Clopidogrel'


**Clopidogrel versus acetylsalicylic acid**

**for the secondary prevention of vascular diseases[1]**

**- Final report -**

**[Commission No. A04-01A]**

# Example ‚Clopidogrel'
# G-BA Assignment to IQWiG

## Patient-relevant outcomes

- all cause mortality and vascular death
- vascular morbidity
- health-related quality of life
- adverse events

# Example ‚Clopidogrel' IQWiG's conclusion

- CLEAR evidence of additional benefit of clopidogrel vs. ASA in patients with symptomatic peripheral arterial disease (PAD) with regard to vascular events

- NO evidence of additional benefit of clopidogrel vs. ASA in patients with ischaemic heart disease or ischaemic cerebrovascular disease

# Example ‚Clopidogrel‘ G-BA‘s decision

## Indication-specific exclusion of reimbursement

**Exclusion of clopidogrel monotherapy except for patients with:**

- **PAD-related amputation or intervention or**
- **unambiguously diagnosed typical intermittent claudication with pain regression < 10 min of resting or**
- **ASA intolerability**

# Example ‚Glinides‘

IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports – Commission No. A05-05C

**Glinides in the treatment of diabetes mellitus type 2**[1]

**Executive Summary**

[1] Translation of the executive summary of the final report "Glinide zur Behandlung des Diabetes mellitus Typ 2" (Version 1.0; Status: 06.04.2009). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

# Example ‚Glinides'
# IQWIG's assessment

| | |
|---|---|
| GBA-task | benefit of long-term use of glinides |
| Substance | Repaglinid (NovoNorm® - NovoNordisk)<br>Nateglinid (Starlix® - Novartis) |
| Studies included | 8 on Repaglinide<br>2 on Nateglinide |
| Duration | minimum duration of 24 weeks<br>*none of the trials lasted longer than 14 months* |
| Recommendation | Benefit of glinides in the treatment of type 2 diabetes NOT proven |

# Example ‚Glinides'
# G-BA's decision

**Beschluss**

**des Gemeinsamen Bundesausschusses**

**über eine Änderung der Arzneimittel-Richtlinie (AM-RL):**

**Anlage III – Übersicht der Verordnungseinschränkungen und -ausschlüsse**

**Glinide zur Behandlung des Diabetes mellitus Typ 2**

Vom 17. Juni 2010

Der [redacted] Bundesausschuss hat in seiner Sitzung am 17. Juni 2010 beschlo[redacted]linie über die Verordnung von Arzneimitteln in der vertragsärztlic[redacted] (Arzneimittel-Richtlinie) in der Fassung vom 18. Dezember 200[redacted]09 (BAnz. Nr. 49a), zuletzt geändert am [ ] (BAnz. [ ] [ ]), wie folgt [redacted]

EXCLUDED

Vorbehaltlich der Prüfung durch das BMG und Veröffentlichung im Bundesanzeiger gem. § 94 SGB V

I. Die Anlage III wird um eine Nummer [redacted]

| Arzneimittel | Re[redacted]lagen und Hinweis[redacted] |
|---|---|
| 50. Glinide zur Behandlung des Diabetes mellitus Typ 2. Hierzu zählen:<br>- Nateglinid<br>- Repaglinid<br>Ausgenommen ist die Behandlung von niereninsuffizienten Patienten mit einer Kreatinin-Clearance < 25 ml / min mit Repaglinid, soweit keine anderen oralen Antidiabetika in Frage kommen und eine Insulintherapie nicht angezeigt ist. | Verordnungseins[redacted]ng verschreibungspflichtiger Arzneimittel nach dieser Richtlinie. [4] |

# Economic Assessment of Drugs

1. IQWiG gives a proposal to G-BA („efficiency frontier“)

2. Criteria of G-BA for appraisal and decision (exclusion, partial or full reimbursement)

- Consideration of quality and quantity of benefit
- Proposal of IQWiG
- Situation of care and patients (severity of disease, access)
- Budget impact

# Economic Assessment of Drugs (II.)

3. If G-BA appraisal decides that the actual price of a new drug is not „appropriate and reasonable“,

- the Federal Association of the Statutory Health Insurances (GKV-Spitzenverband) can set a „ceiling price“ (maximum reimbursement) with taking into account development costs

# Economic Assessment of Drugs (III.)

First 2 commissions for cost-benefit assessment given by G-BA to the IQWiG (December 2009):

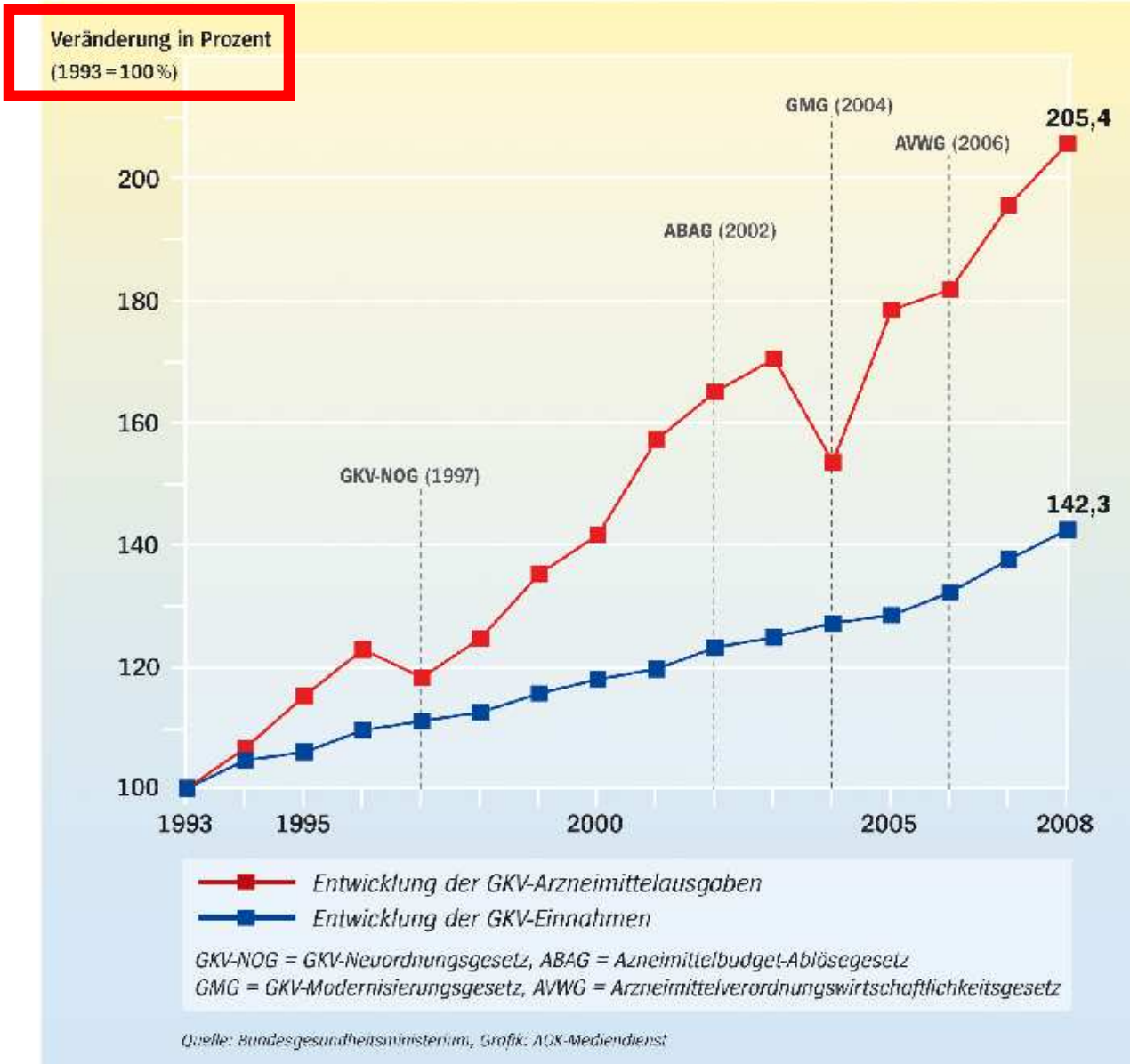
1. Venflaxin, Duloxetin, Buprion, Mirtazapin compared to other pharmaceuticals in depression

2. Clopidogrel in acute coronary syndrome and
in peripheral vascular diesease

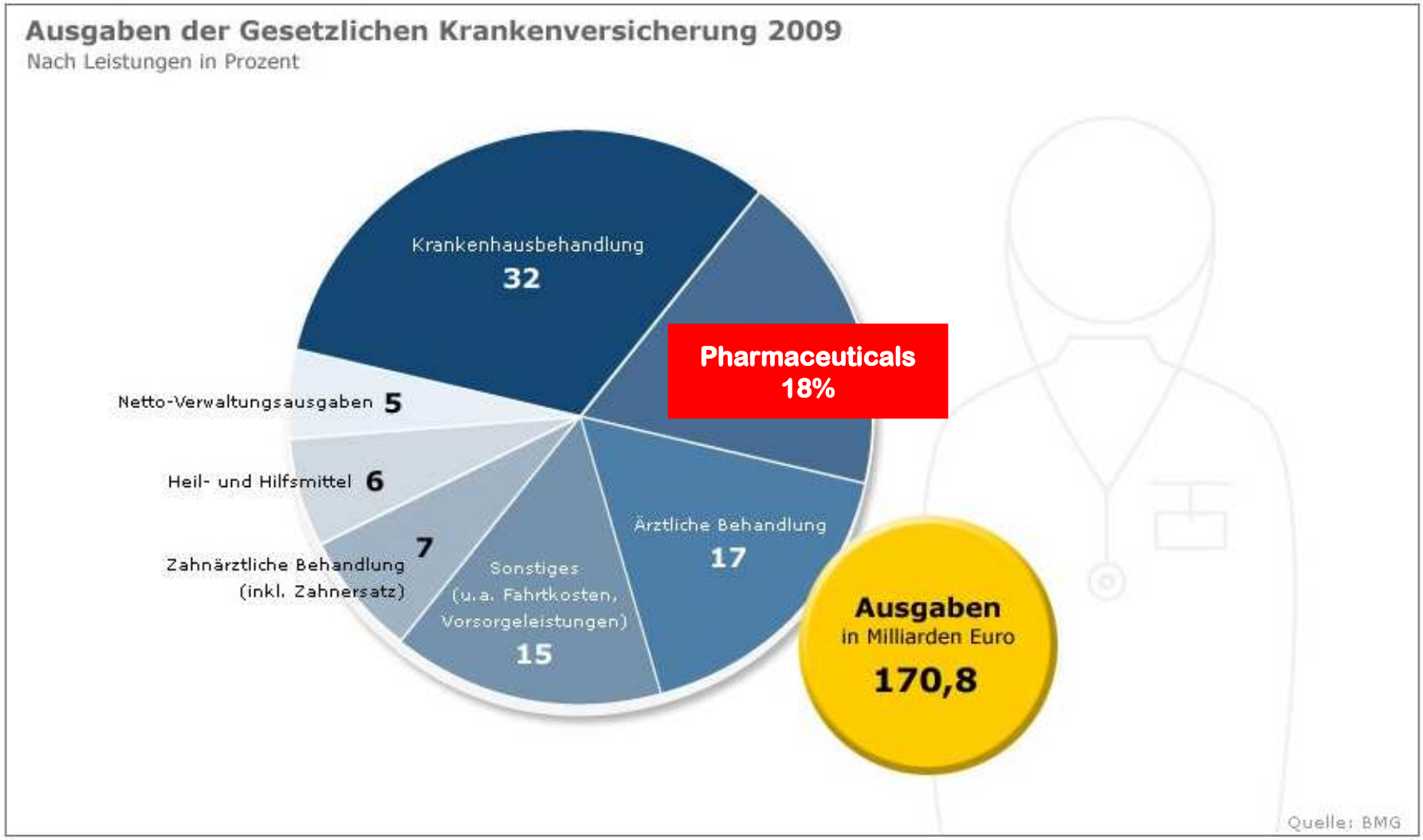
Problems:

- Benefit and economic evaluation take approx. 18-24 months
- Time lag with free pricing and free market access
- No cooperation incentive for companies for evaluation process

# German Statutory Health Insurance System
# Pharmaceutical expenditures 1993-2008



# German Statutory Health Insurance System Expenditures in 2009



# Arzneimittelmarktneuordnungsgesetz (AMNOG)
## New Health Act in Preparation

- Evaluation of every new drug by G-BA immediately after market access
- Drug company obliged to present a „value dossier“ on additional benefit
- If not suitable for reference-price-group, free pricing for 1 year
- Contracts between manufacturers and single SHI are possible after 1 year, ceiling price is set
- If suitable for reference-price-group, G-BA sets a reference price

# Consequences for HTA in Germany

- Increasing urgency demonstrating 'process innovation' vs. pure 'product innovation'
- Necessity for post-launch evidence and evaluation
  What is the value for the system?
  - public health impact
  - comparative effectiveness
- Increasing importance of private-public-partnership between SHI and industry
- Shift from classical HTA (desk research) to New HTA (field research):

# New HTA in Germany

- Importance of post-launch evaluation for private & public stakeholders
- Real-life studies with selective products
- Greater focus on
  - specific (limited) subgroups
  - specific care scenarios
  - patient-related outcomes (PRO)
  - comparative effectiveness

## Thank You !

**More information:**

**www.public-health.de**

**peter.kolominsky@uk-erlangen.de**