Gemeinsamer
Bundesausschuss

Pricing and Reimbursement Decisions in Germany

CDDF MULTI-STAKEHOLDER WORKSHOP

Access to Innovative Oncology Drugs in Europe

Madrid, 7 September 2017

Florian Jantschak
Scientific Advisor, Pharmaceuticals Department
Federal Joint Committee (G-BA)

- The Federal Joint Committee (G-BA)
- The AMNOG procedure
- Price negotiation and arbitration process
- Recent social court decision on pricing
- Amount of AMNOG-savings
- Summary

- **The Federal Joint Committee (G-BA)**
- The AMNOG procedure
- Price negotiation and arbitration process
- Recent social court decision on pricing
- Amount of AMNOG-savings
- Summary

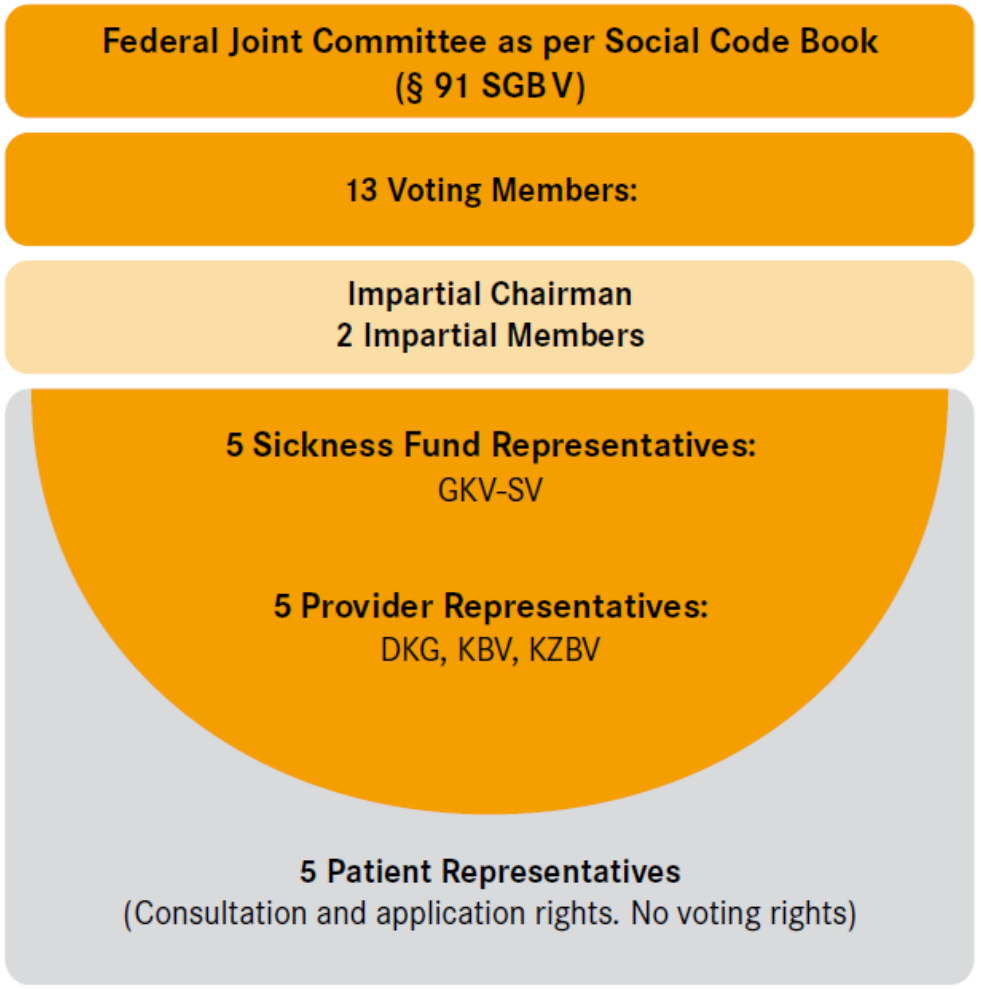
The Federal Joint Committee (G-BA)

Highest decision-making body of the statutory health insurance system

- Established in 2004
- Binding decisions for healthcare providers, the insured and sickness funds
- Ministry of Health: control of legality

Gemeinsamer Bundesausschuss

The Federal Joint Committee (G-BA)



Impartial members appointed by Parliament (Bundestag)

GKV-SV: sickness funds umbrella organization

DKG: German hospital organization

KBV: German doctor association

KZBV: German dentist association

Subcommittees (total 9)
Office / Academic Staff
Academic & Methodological Institutes (IQWIG, IQTIQ)

- The Federal Joint Committee (G-BA)
- **The AMNOG procedure**
- Price negotiation and arbitration process
- Recent social court decision on pricing
- Amount of AMNOG-savings
- Summary

Act on the Reform of the Market for Medicinal Products (AMNOG)

Free pricing of new drugs until 2010

Patented drugs: 13% share in volume but 45% share in sales in 2009

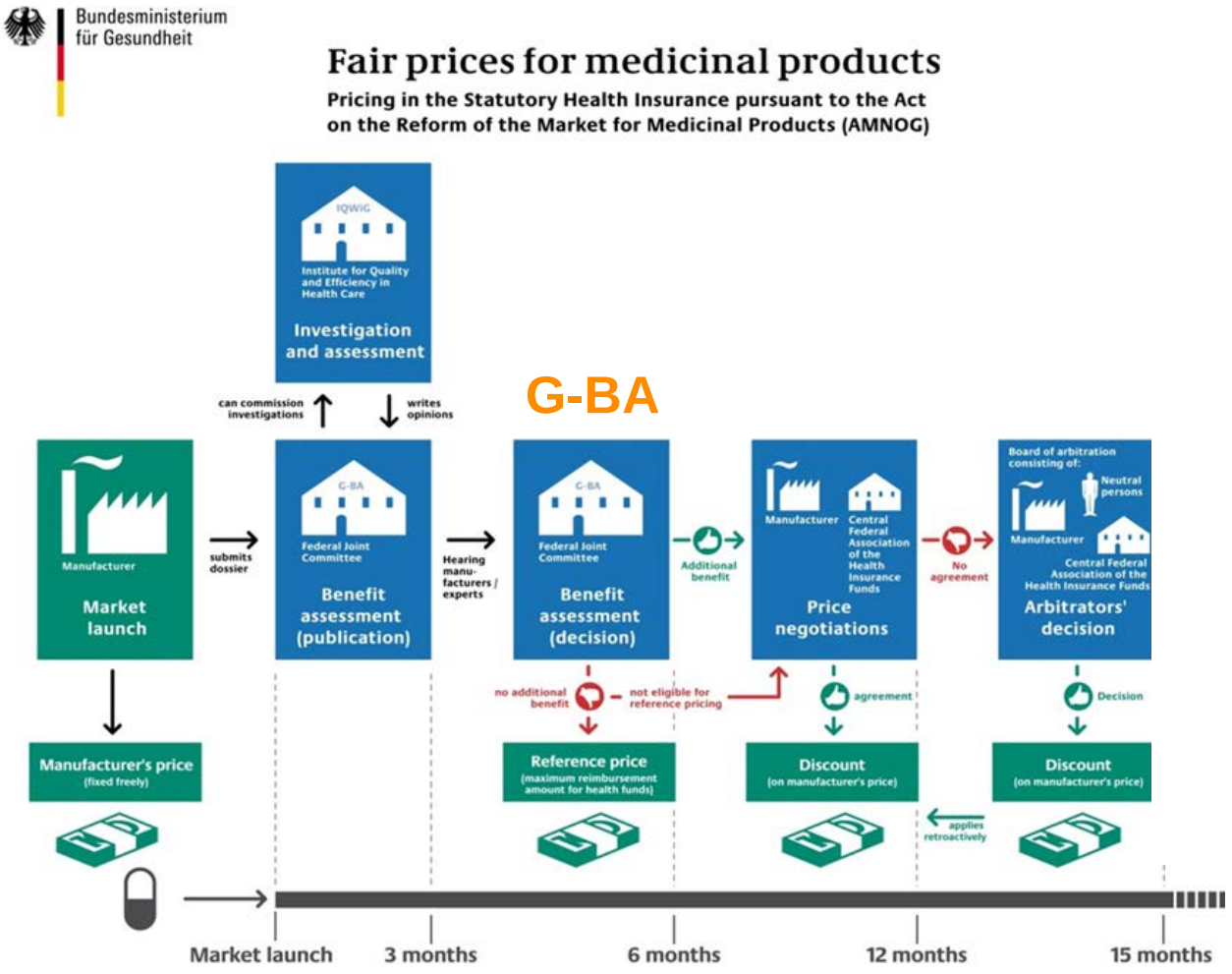
Increase in sales from 18.8 bn (€) in 1999 to 28.5 bn (€) in 2009

➢ **Need for action**

AMNOG-law on drug pricing and HTA in 2011

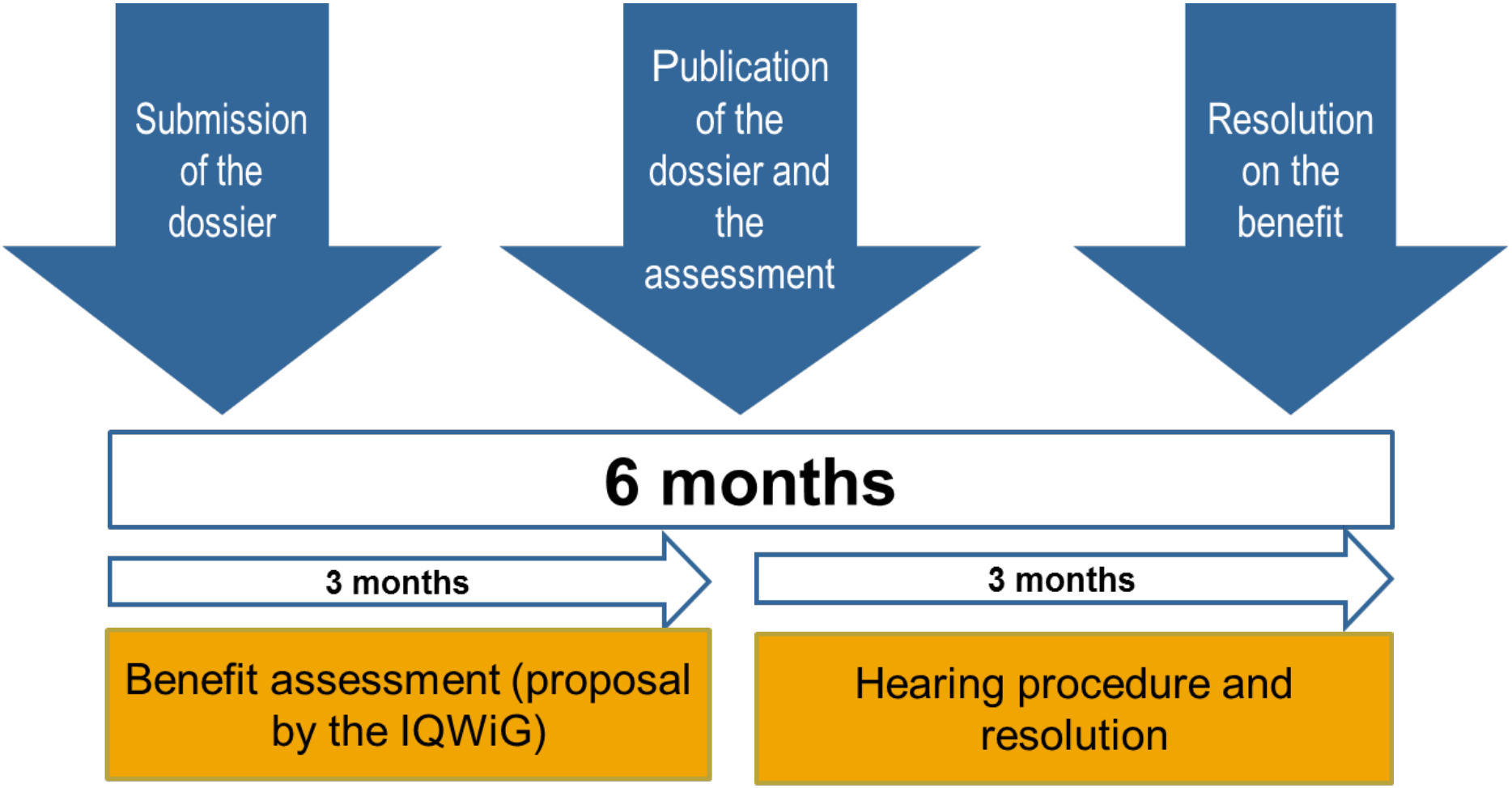
- Assessment of drugs on additional benefits compared to the benefits of an appropriate comparator by the Federal Joint Committee (G-BA)
- Free pricing was replaced by negotiation between manufacturer and National Association of Statutory Health Insurance Funds (GKV-SV)

Reform of the Market for Medicinal Products (AMNOG)



Gemeinsamer Bundesausschuss

The early benefit assessment - sequence



Resolution on the additional benefit

Resolution is part of the Pharmaceutical Directive and includes

- Additional benefit over an appropriate comparator
- Number of patients
- Requirements for quality-assured administration
- Costs of treatment, also in comparison to the appropriate comparator

…for each therapeutic indication

Resolution on the additional benefit

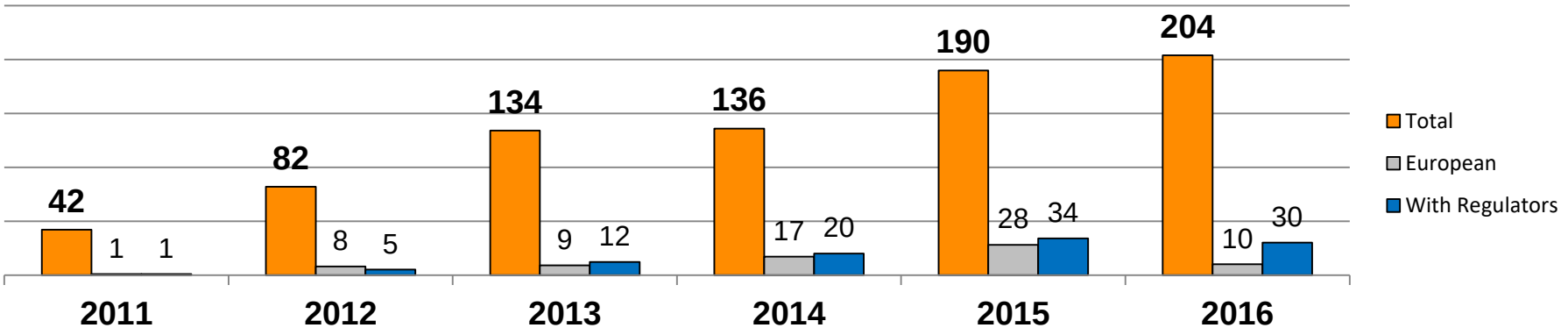
Transparency: Resolution is published same-day on the G-BAs website

Gemeinsamer Bundesausschuss

Appropriate comparator

Appropriate comparator is determined by the GBA

- Defined criteria per law:
  - Licensed (off-label-use is not allowed)
  - Standard of care
  - Best evidence
- Can differ from the comparator used in a study
- Can be requested within a consultation with the G-BA



Gemeinsamer Bundesausschuss

Extent of the additional benefit

Differences in patient-relevant endpoints are crucial

- Mortality
- Morbidity
- Quality of life
- Adverse events

The primary endpoint is not the focus of interest!

Asymptomatic findings (PFS, ORR…) are not per se patient-relevant!

IQWiG: The upper limit of confidence interval defines the additional benefit

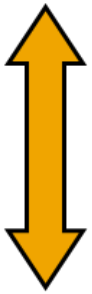
G-BA: Balanced decision-making

Extent of the additional benefit

The extent of the additional benefit over the appropriate comparator taking into account **statistical significance, clinical relevance** and the **severity of the disease**:

1) Major additional benefit----------

2) Considerable additional benefit

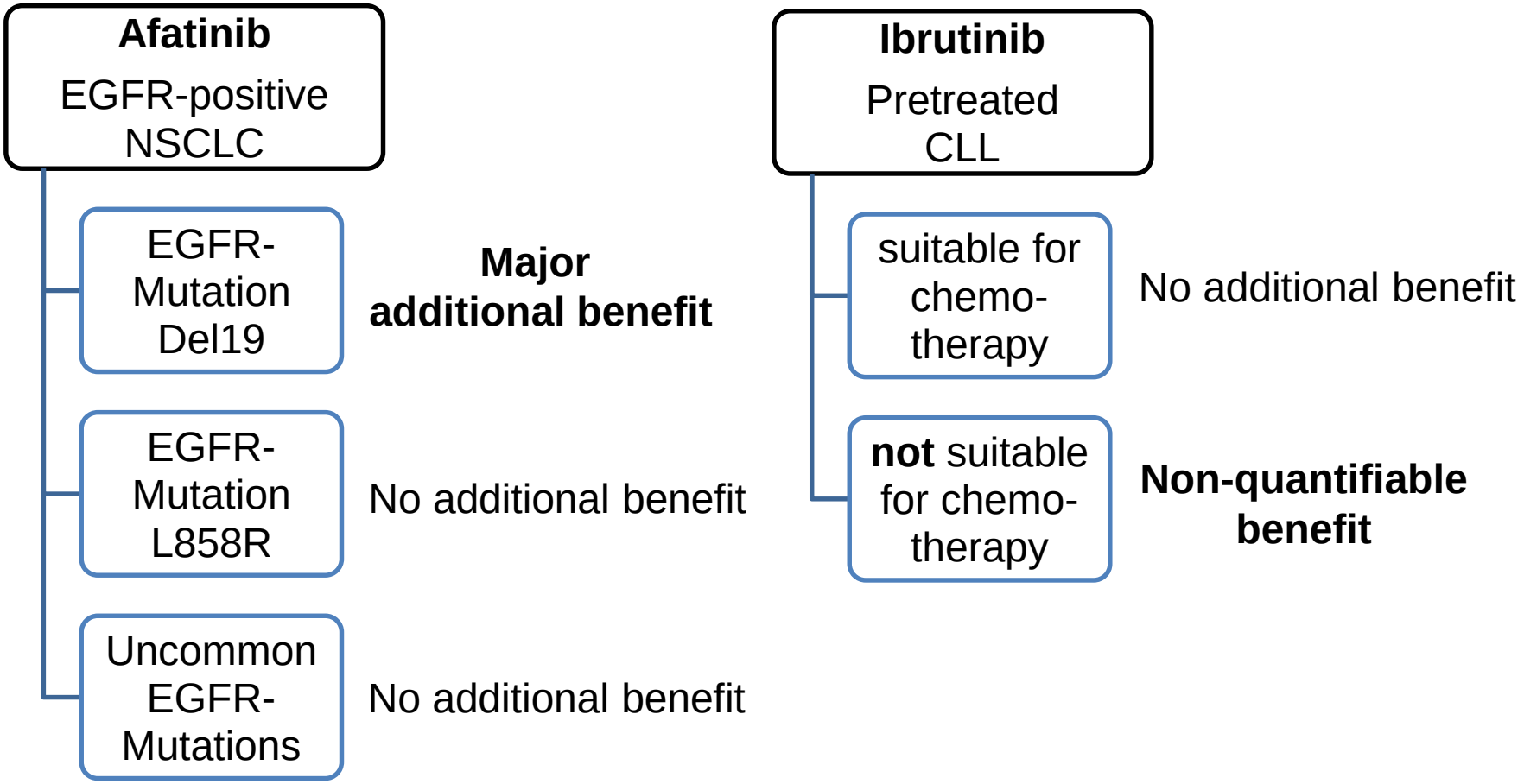


6) Non-quantifiable

3) Minor additional benefit----------

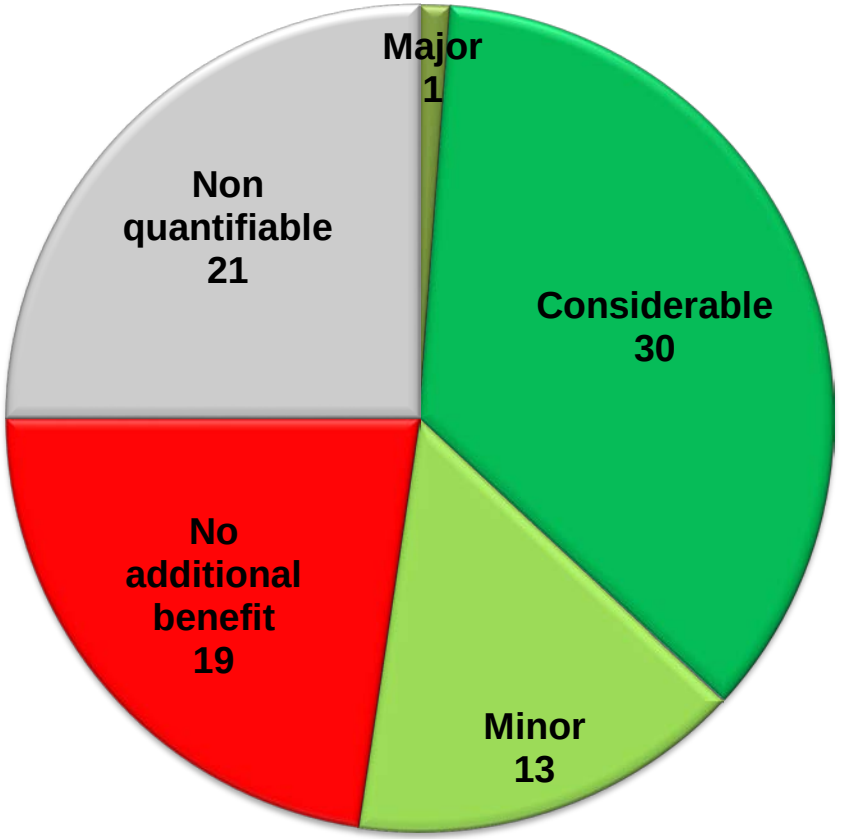
4) No additional benefit

Subgroup-specific decisions

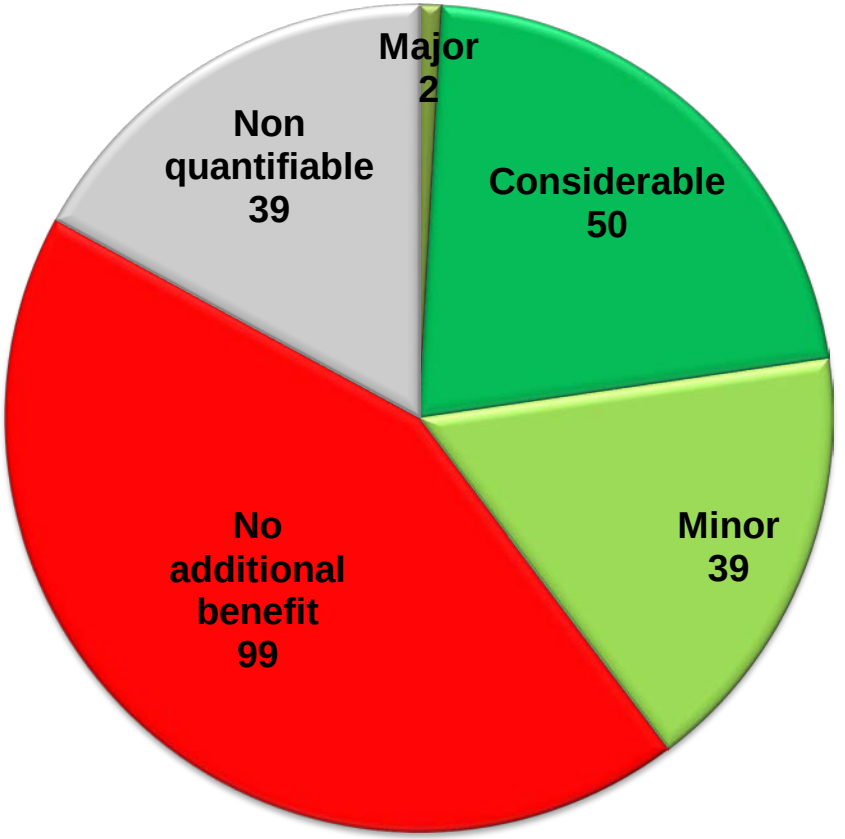


Extent of the Additional Benefit
Highest Category per Active Ingredient

Cancer drugs (84)



All assessments (229)



Effective: 3 August 2017

Gemeinsamer
Bundesausschuss

- The Federal Joint Committee (G-BA)
- The AMNOG procedure
- **Price negotiation and arbitration process**
- Recent social court decision on pricing
- Amount of AMNOG-savings
- Summary

Price negotiation and arbitration process

Price negotiations between manufacturer and National Association of Statutory Health Insurance Funds take place **on the basis of the G-BA resolutions** (period of 6 months after G-BA resolution):

Legal framework

§ 130b SGB V

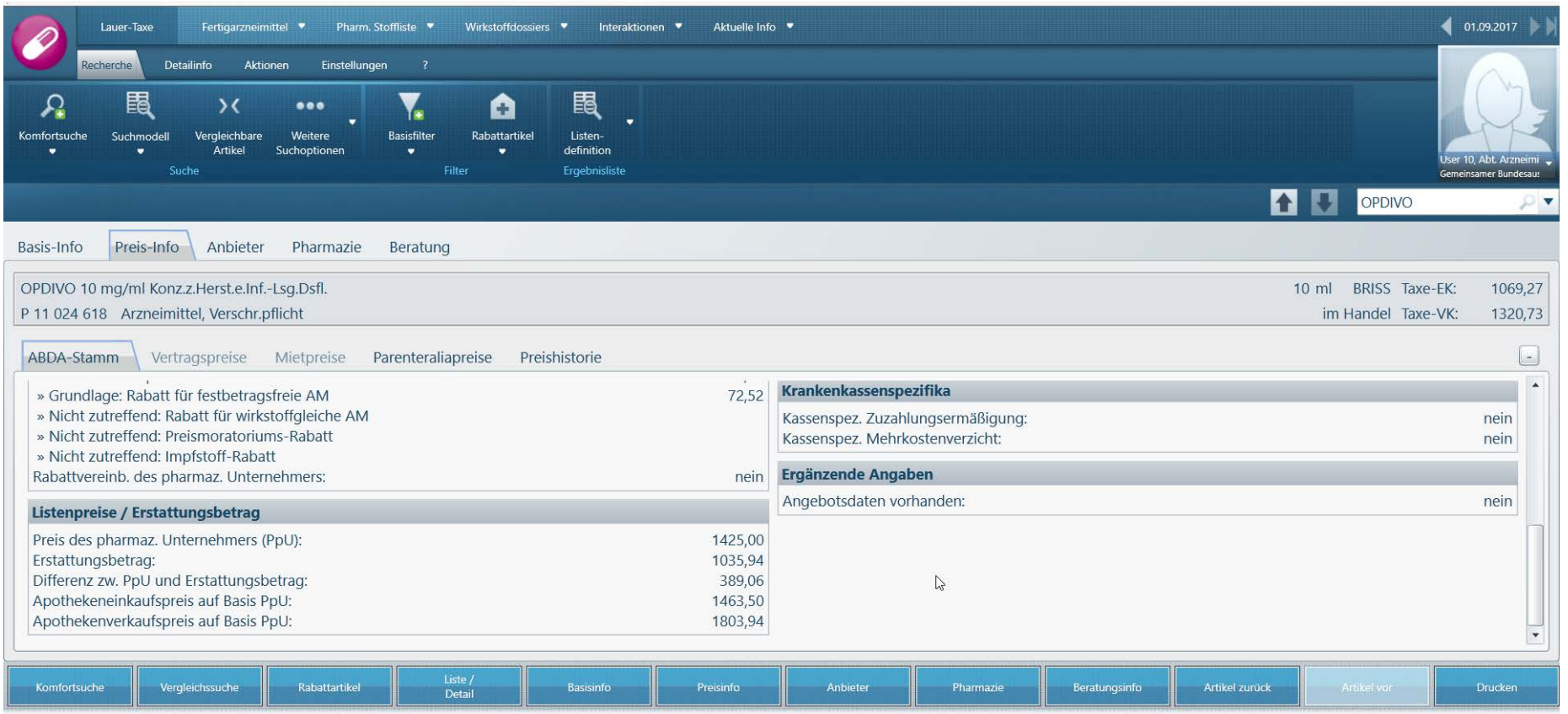
- Cost of appropriate comparator therapy should be the **upper limit** for the price of the new drug if it has **no additional benefit**

Rahmenvereinbarung nach § 130b Abs. 9 SGB V („general agreement“)

- If an additional benefit is proven, **a supplement on top** of the price of the **appropriate comparative therapy** is negotiated
- *“Real”* sales price in other European countries is incorporated
- Price-volume agreements are possible

Price negotiation and arbitration process

Cost transparency: post-AMNOG rebate is published publicly available



Gemeinsamer Bundesausschuss

Price negotiation and arbitration process

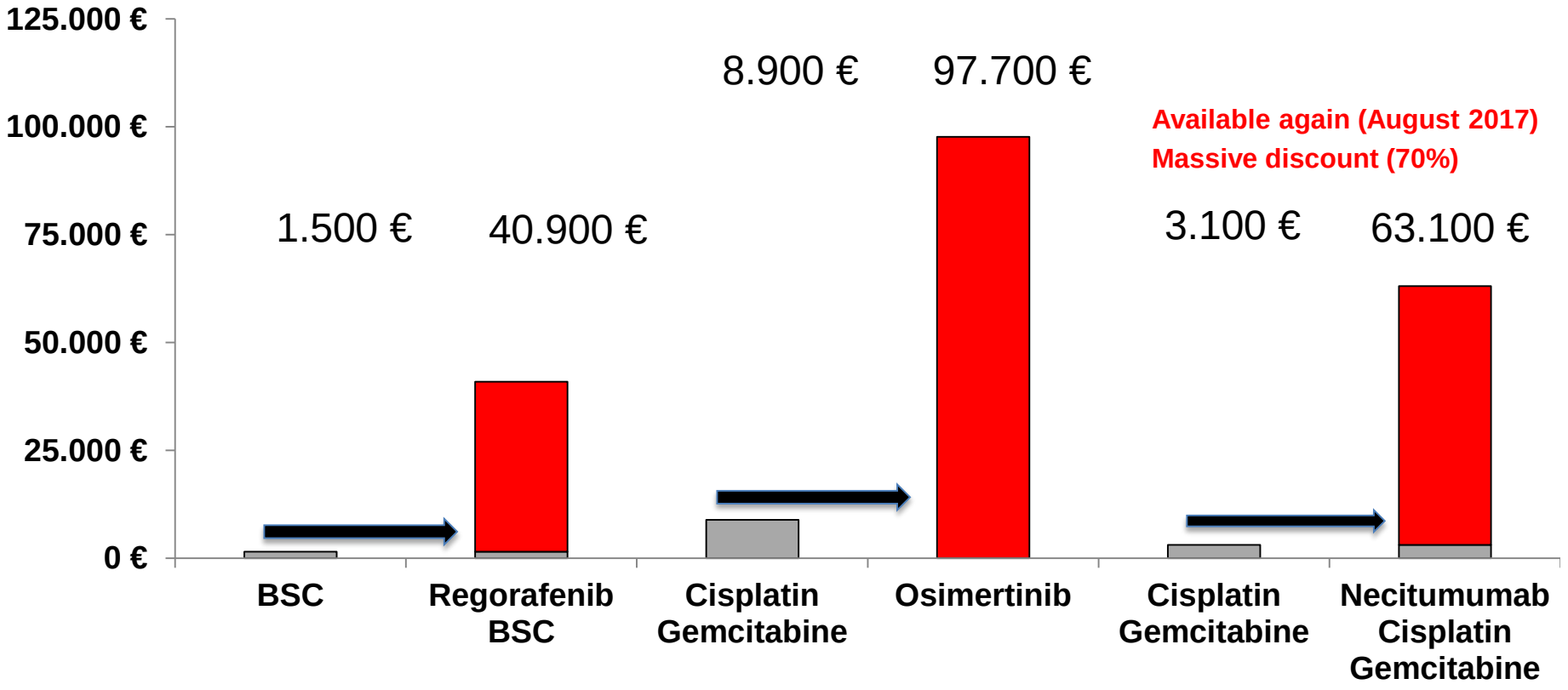
Decisions by 24 August 2017

- Completed price negotiations: 122
- Arbitration decisions: 26
- Market exit: 19

Only three oncology drugs are (currently) not available in Germany		
Regorafenib *(Stivarga®)*	CRC	No additional benefit
Osimertinib *(Tagrisso®)*	NSCLC	No additional benefit
~~Necitumumab~~ *(~~Portrazza~~®)*	NSCLC	No additional benefit

Price negotiation and arbitration process

Market exits most likely if there is no additional benefit and annual therapy costs of the appropriate comparator are low



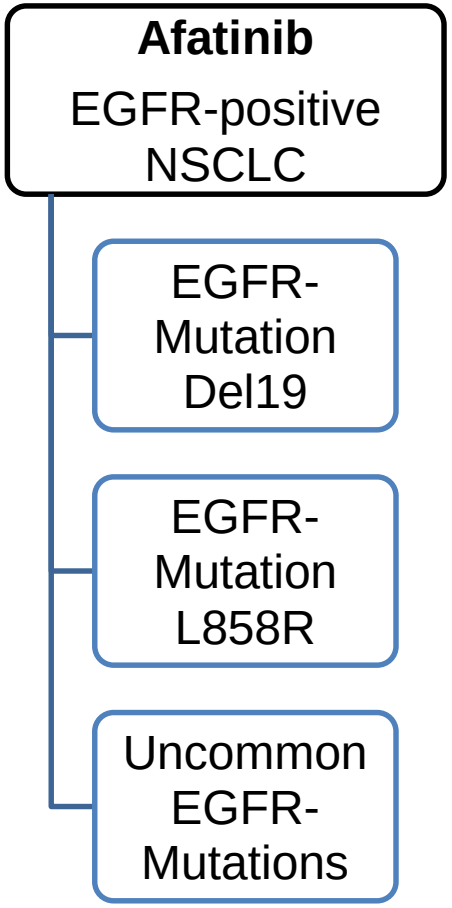
Gemeinsamer Bundesausschuss

- The Federal Joint Committee (G-BA)
- The AMNOG procedure
- Price negotiation and arbitration process
- **Recent social court decision on pricing**
- Amount of AMNOG-savings
- Summary

Recent social court decision on pricing

Guiding principle: One drug – One benefit-based-price

Problem: How to integrate different levels of additional benefit into one price per drug? A controversial concept: calculation of a „mixed price“



Price negotiations completed
Price per unit: **3.050 € > 2.690 €**
Annual costs: **39.700 € > 35.000 €**

Major additional benefit
Patients: 1.530 – 3.590

No additional benefit
Lowest annual costs: **8.960 €**
Patients: 850 – 1.980

No additional benefit
Lowest annual costs: **8.960 €**
Patients: 360 – 840

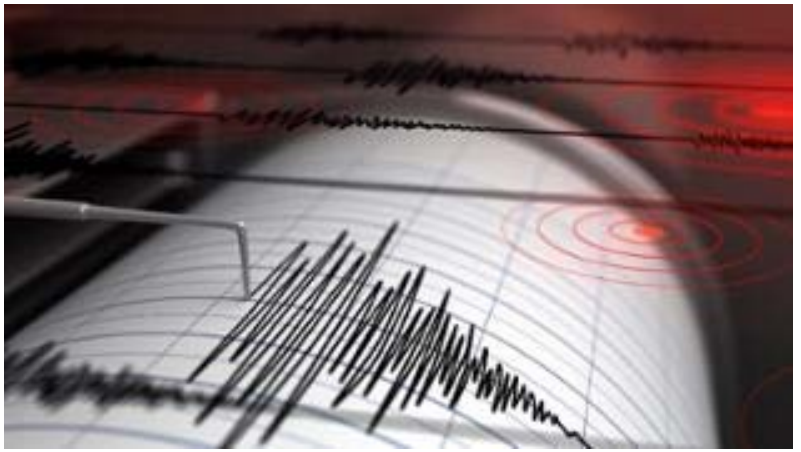
Recent social court decision on pricing: Problem of “mixed price” - concept

Social court decision (March 2017):

Cost of appropriate comparator therapy should be the **upper limit** for the price of the new drug if it has no additional benefit:

- „Mixed price“ is not cost-effective in subgroups with no additional benefit
- „Mixed price“ is too low in subgroups with an additional benefit

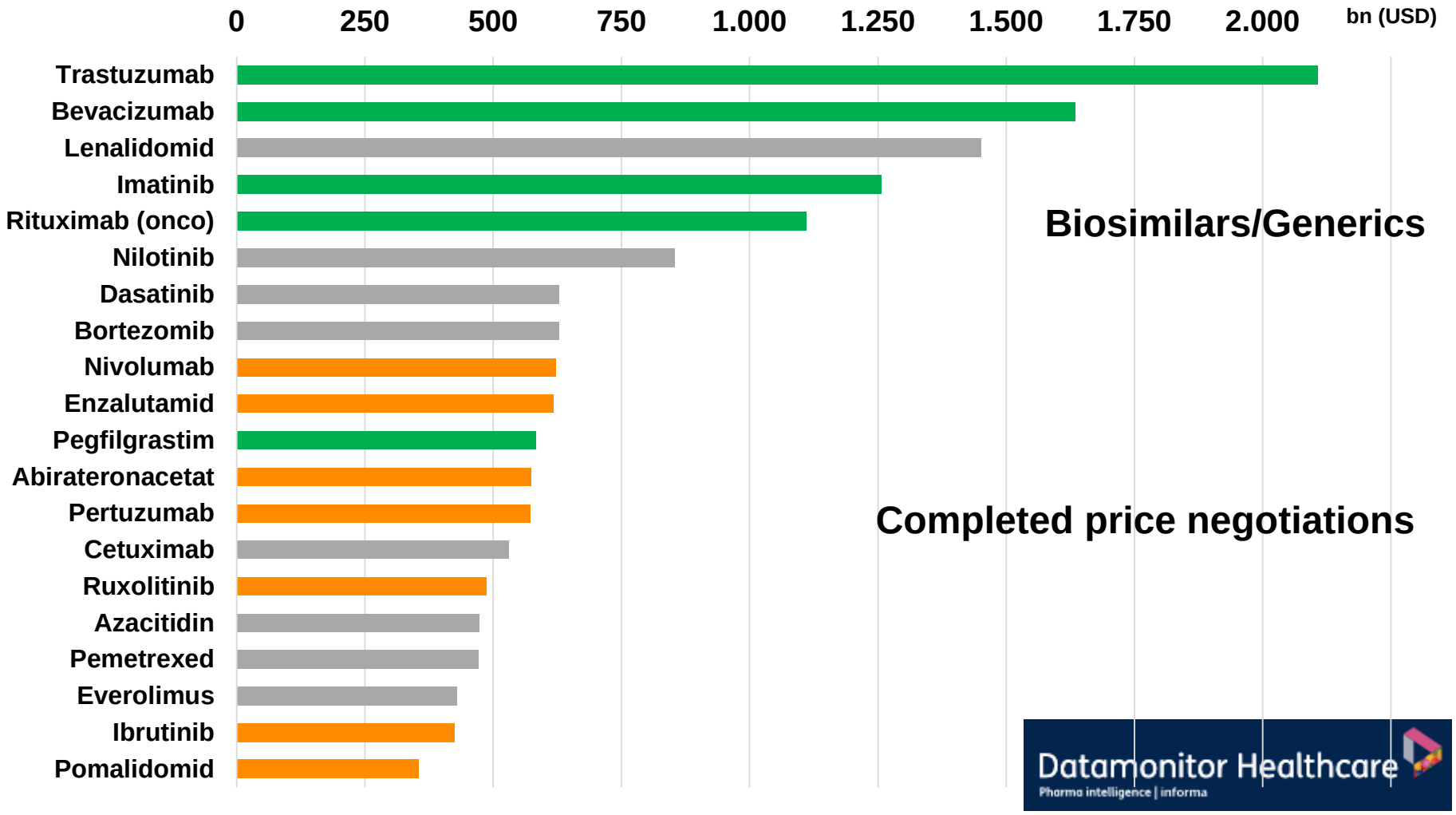
Prescribing drugs in subgroups without additional benefit is not per se cost-effective!



- The Federal Joint Committee (G-BA)
- The AMNOG procedure
- Price negotiations / Arbitrations / Market exits
- Recent social court decision on pricing
- **Amount of AMNOG-savings**
- Summary

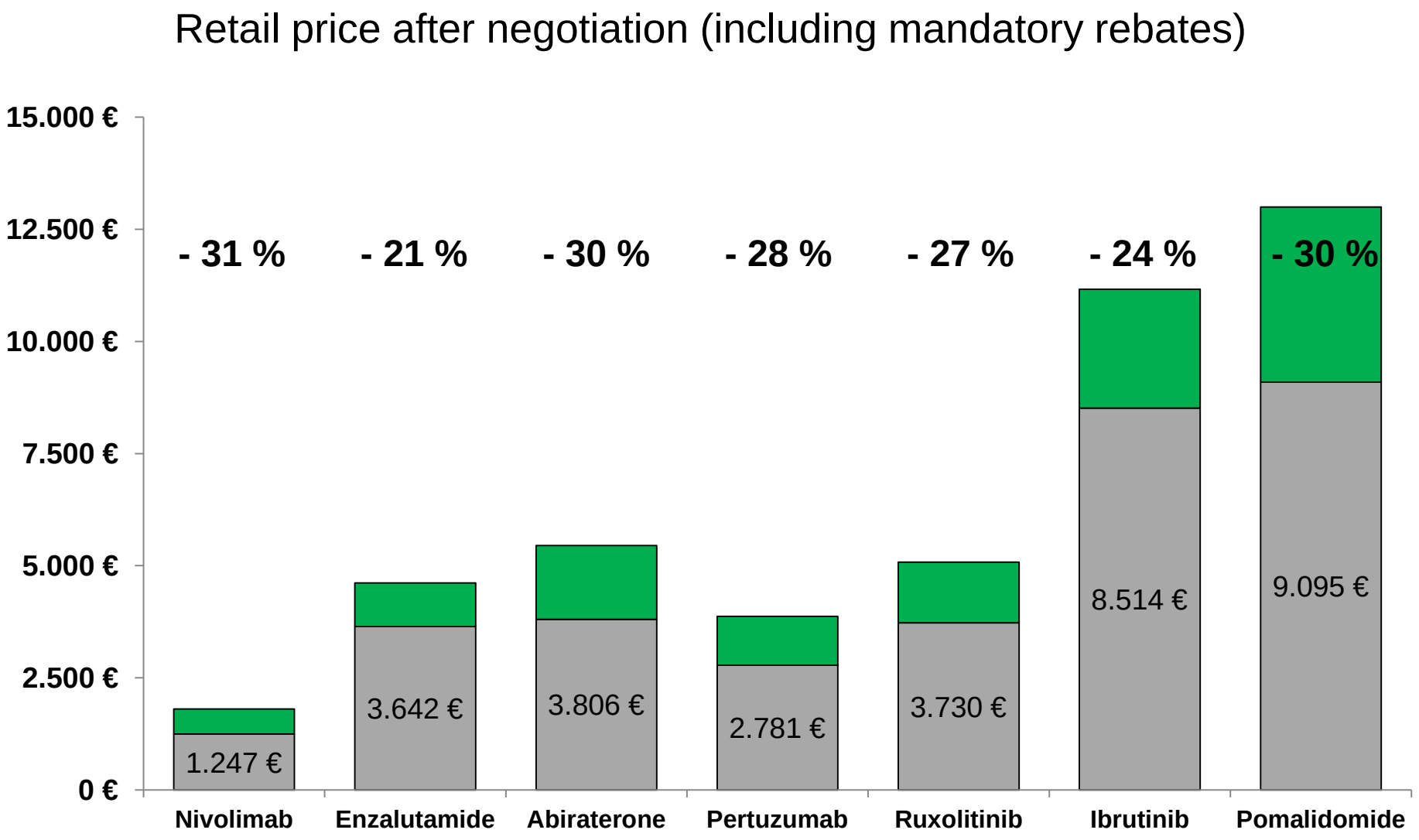
Top 20 Cancer Drugs in EU5 2016 by Sales

(France, Germany, Italy, Spain and UK)



Gemeinsamer Bundesausschuss

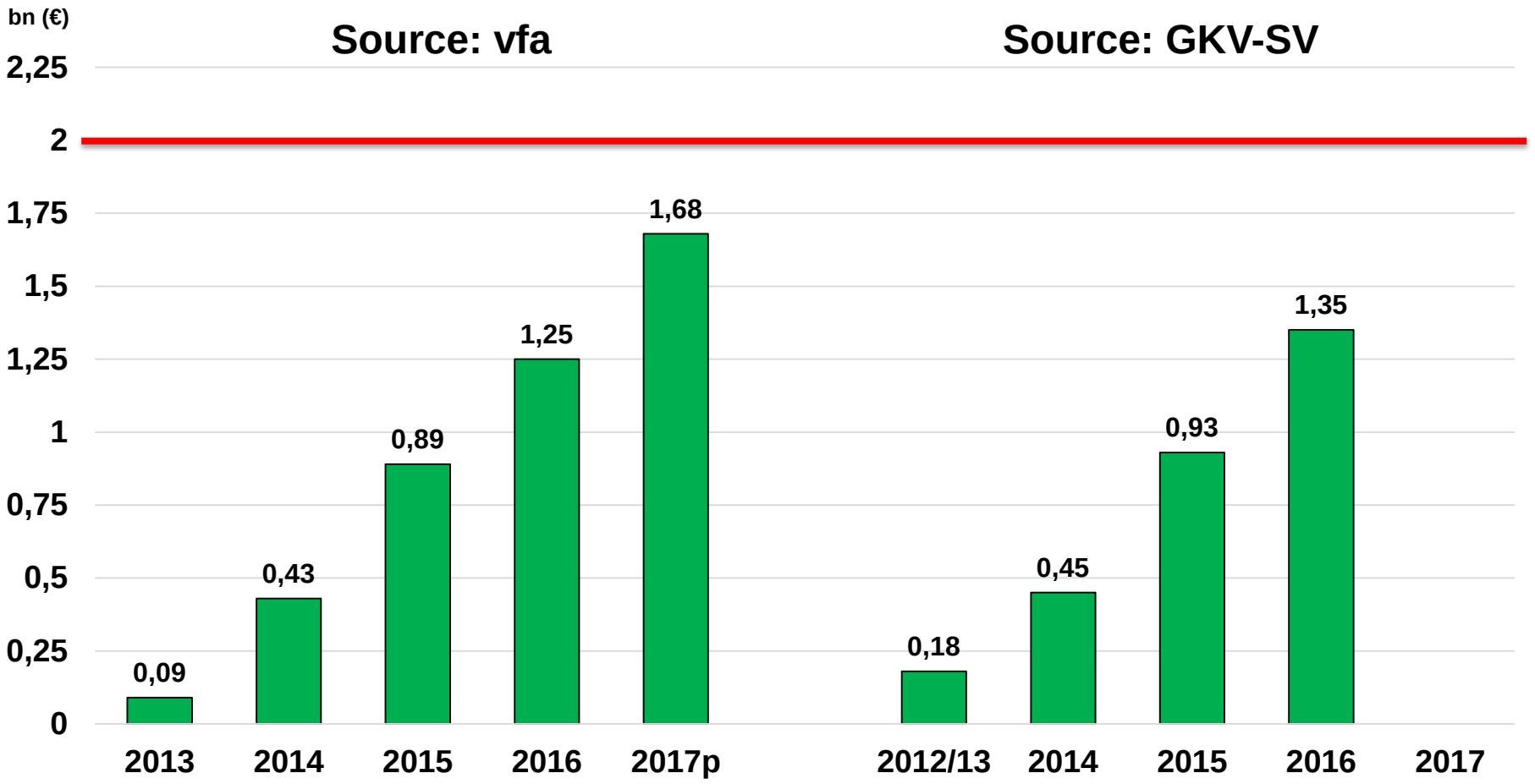
Amount of AMNOG-savings



Gemeinsamer Bundesausschuss

Effective: 15 August 2017
(biggest package, highest dose)

Amount of AMNOG-savings



The impact of indirect savings is unclear…

Gemeinsamer Bundesausschuss

- The Federal Joint Committee (G-BA)
- The AMNOG procedure
- Price negotiation and arbitration process
- Recent social court decision on pricing
- Amount of AMNOG-savings
- **Summary**

Summary

The AMNOG procedure

- Free pricing for new drugs was replaced by a negotiation procedure
- Transparent evidence-based assessments at the time of market entry
- Does not constitute a hurdle: launch and assessment run in parallel
  - ➢ free access to new medicine at time of launch
- Comprehensive information about new drugs publicly available
- Only few market exits
- Increasing amount of savings