



KBV

Kassenärztliche
Bundesvereinigung

Körperschaft des öffentlichen Rechts

**Międzynarodowe
Symposium**

**Evidence-Based
Health Care**

**Priorytety
w Ochronie Zdrowia**



Kraków, 2-3 X 2006

Drug reimbursement Recent developments in Germany

Dr. Bernhard Gibis, M.P.H.

Director

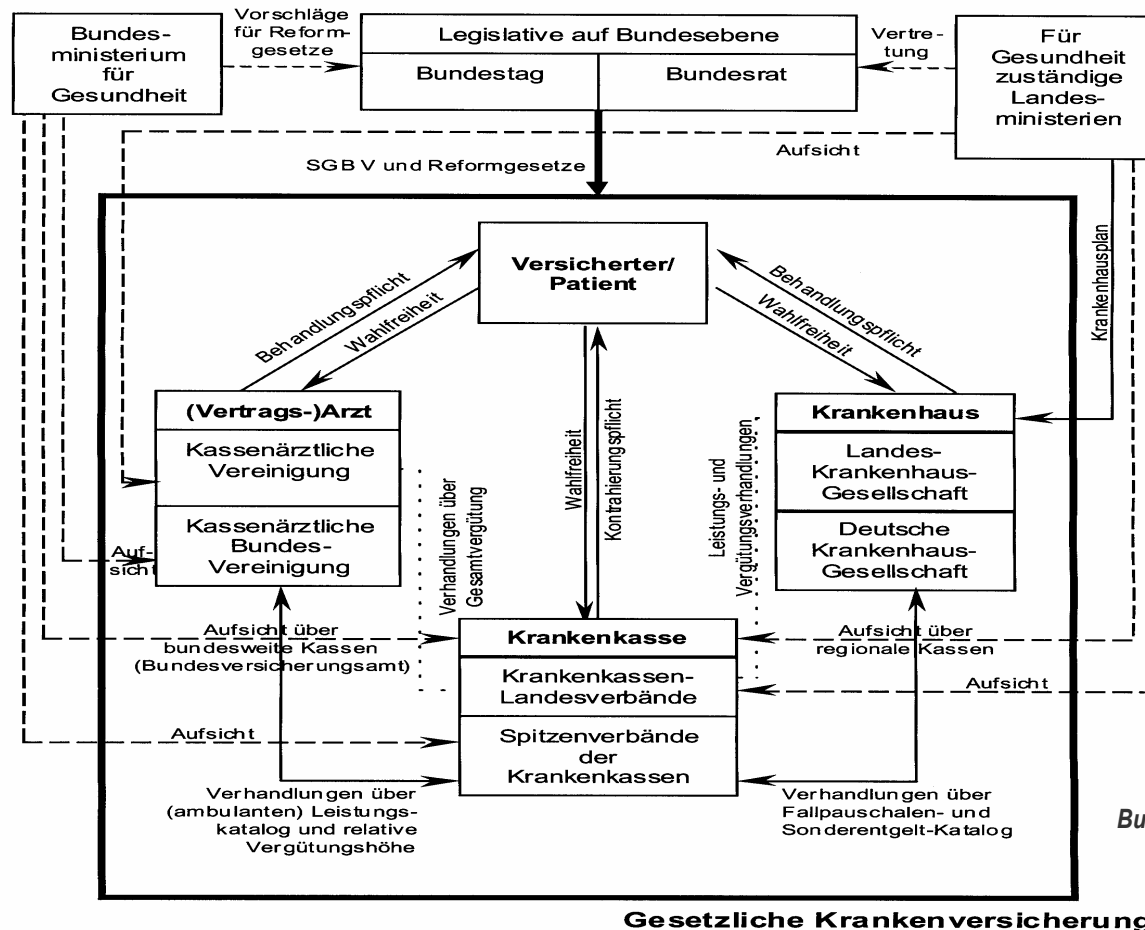
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- 1. *What it is all about – German health care***
- 2. *Role of pharmaceuticals***
- 3. *Role of regulation***
- 4. *New (?) trends***

1. Health care environment

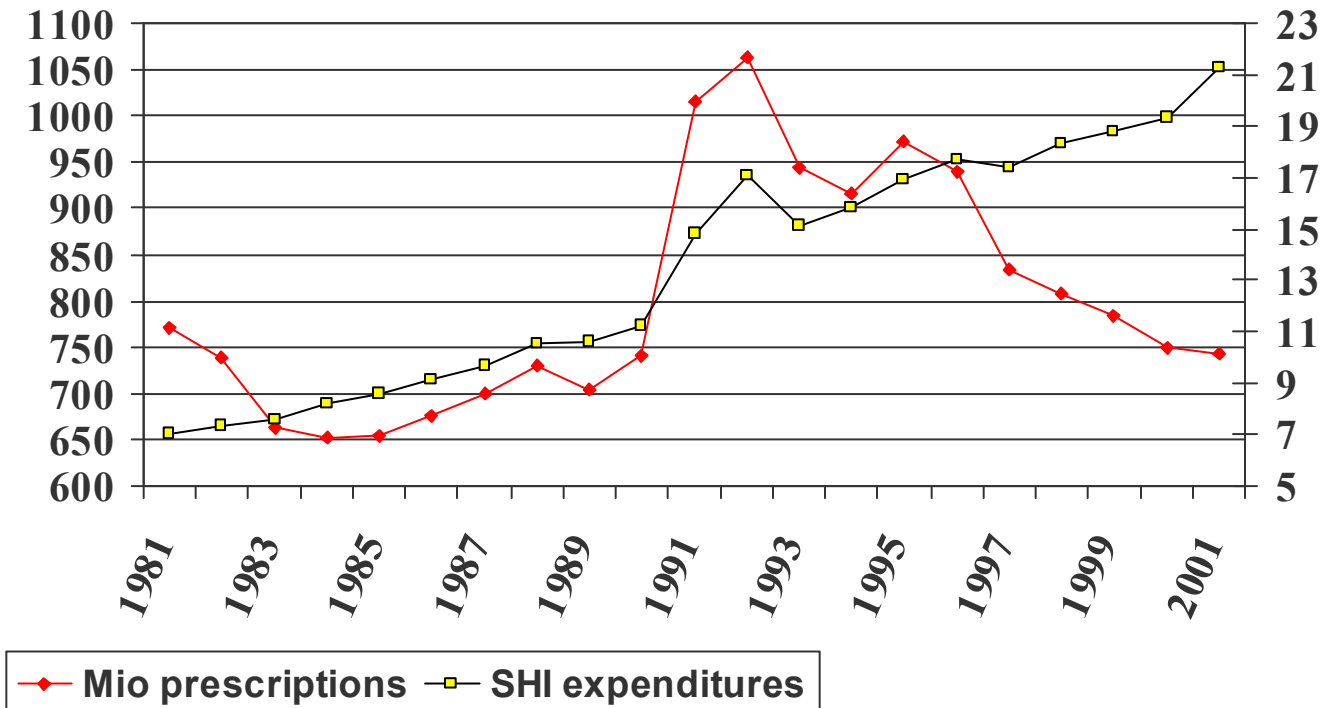
Simplified (!) structure of the German health care system



Busse, www.observatory.dk

2. Role of pharmaceuticals

Prescriptions and Turnover 1981-2001 (only SHI, without copayments)



2. Role of pharmaceuticals

- **Medical progress**
- **Increasing morbidity**
- **Demographic changes**
- **Patient needs**
- **Usage of guidelines**
- **Pricing rules of manufacturers**
- **Marketing of manufacturers (supplier induced demand)**
- **Hospital prescription habits**
- **Influence of pharmacists**
- **Promises of politicians**
- **Insufficient knowledge of physicians**

3. Role of regulation



3. Role of regulation

High Policy aims...

Secure quality

Maintain equity

Improve efficiency

Contain costs

Mossialos, Wailey & Mrazek 2005

3. Role of regulation

...but lost in translation?

1989 „Gesundheitsreformgesetz“ -> 23 letters

...

2003 „Gesundheitssystemmodernisierungsgesetz“

->38 letters!!

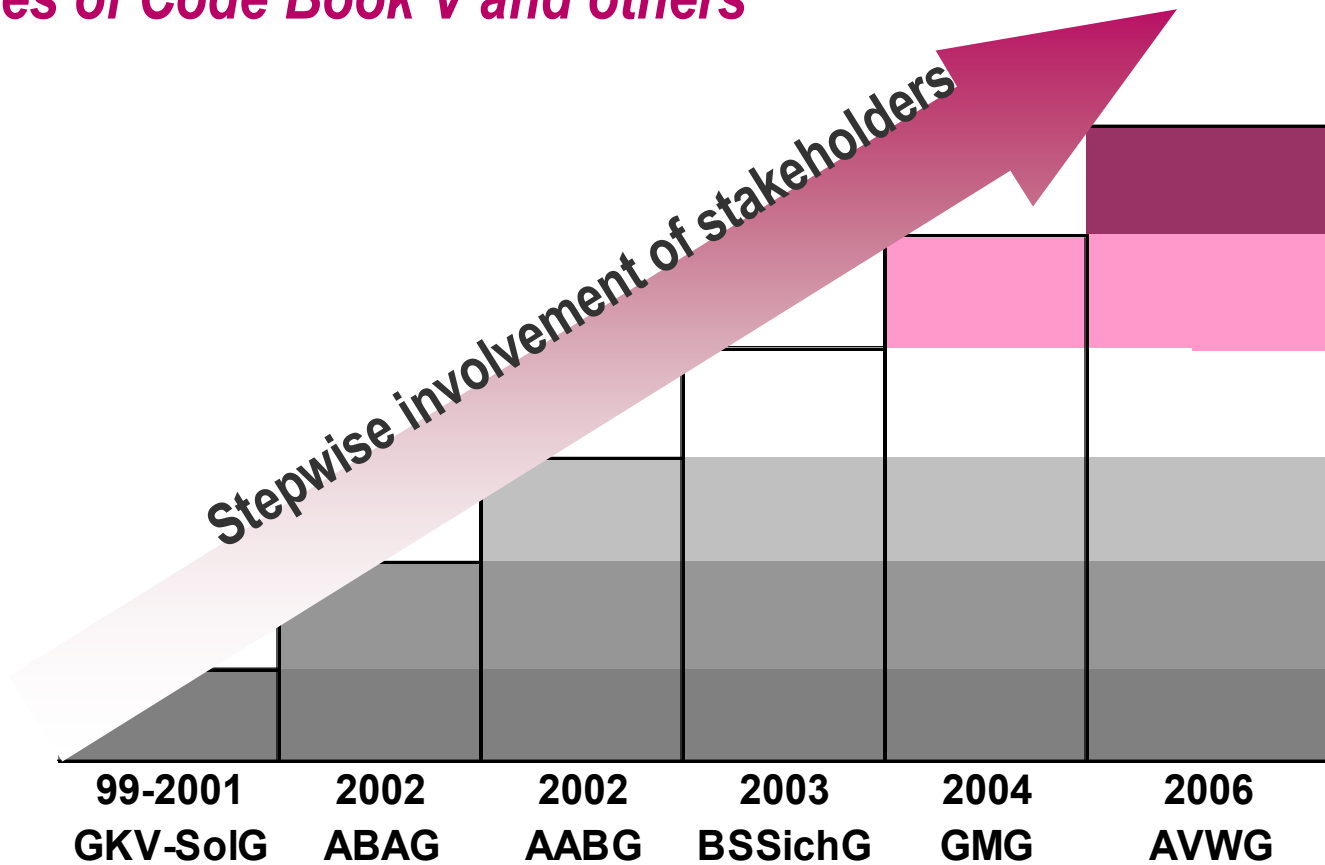
2006 „Arzneimittelversorgungswirtschaftlichkeitsgesetz“

-> 48 letters (say no more...)



3. Role of regulation

Changes of Code Book V and others



3. Role of regulation

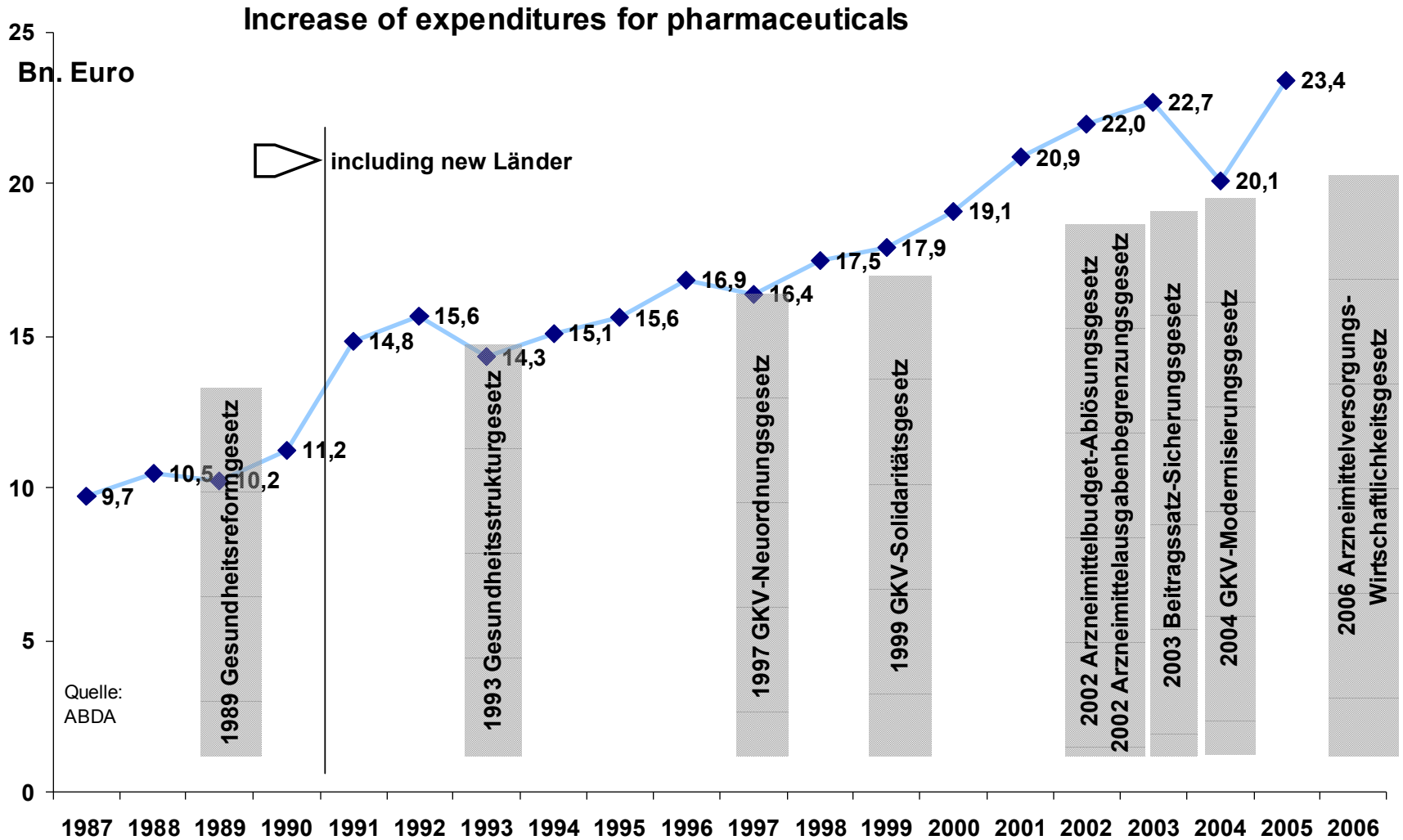
Regulatory measures to slow down drug expenditures in public health care

1989: reference pricing for off-patent drugs, co-payments

Law	99-2001 GKV-SolG	2002 ABAG	2002 AABG	2003 BSSichG	2004 GMG	2006 AWG
					insured patient	
				wholesale		
			manufacturers			
			pharmacists			
			sick funds			
Measures	Physician					
	prescribing Budgets, collective responsibility	regional contracts	pharmacy and manufacturer rebate, aut idem (substitution by pharmacist), prescription reports	whole sale and manufacturers rebate, moratorium	Exclusion of OTC, increased co- payments, Änderung Arznei- mittelpreisverordnung, inclusion of patented drugs into reference based pricing	local contracts, price moratorium, lowered margins for reference based pricing, denial of "natural" rebates, Bonus- /Malus-system, certification of prescription software



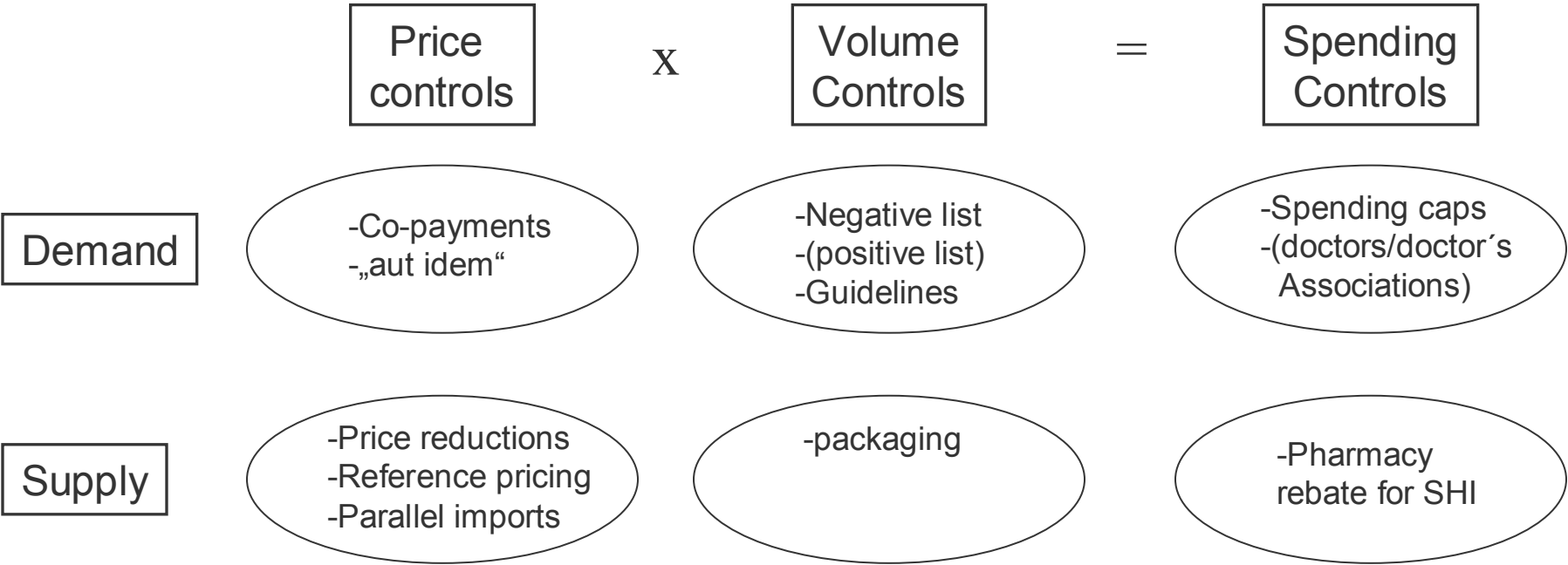
3. Role of regulation





3. Role of regulation

Measures to regulate expenditures for pharmaceuticals



Adopted from Schreyögg, Henke & Busse 2004

3. Role of regulation

So far not used:

- ***cost-effectiveness data*** ✓
- ***Selected listings (such as a positive list)***
- ***Price regulation for on-patent drugs*** ✓

New reform 2007: IQWiG should conduct pharmaco-economic studies in order to identify efficient drugs and to regulate prices of innovations

EbM means (according to (some) physicians and industry

The invasion of the bureaucrats



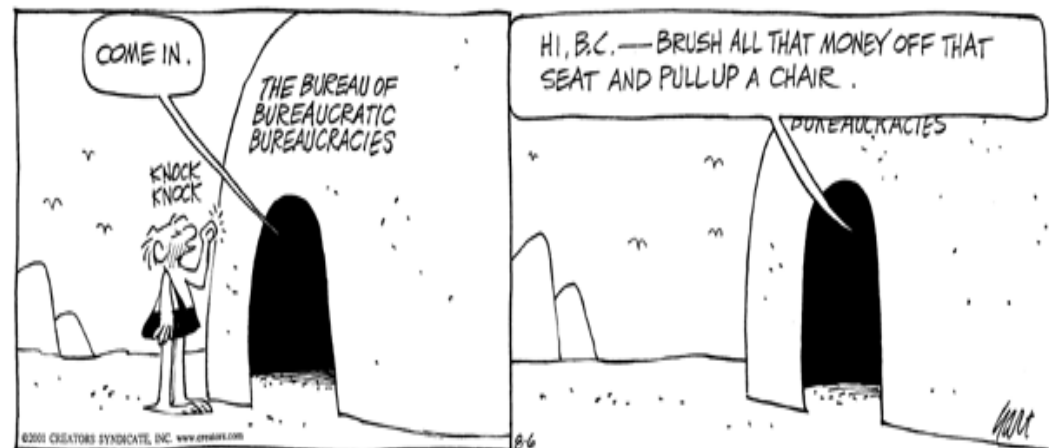
Government medicine

Destroys freedom of therapeutic choice

Medicine that does not consider the individual patient

Innovation blocking

Second class medicine



3. Role of regulation

The Institute's task (among others)

To assess the benefit („Nutzen“) of pharmaceuticals in order to give advice to Gemeinsamer Bundesausschuss

- a. Innovative (new class) pharmaceuticals with better efficacy
- b. Derivates of established pharmaceuticals with better efficacy
- c. Pharmaceuticals without better efficacy
- d. Plus aspects of cost-effectiveness

3. Role of regulation

Expected benefits:

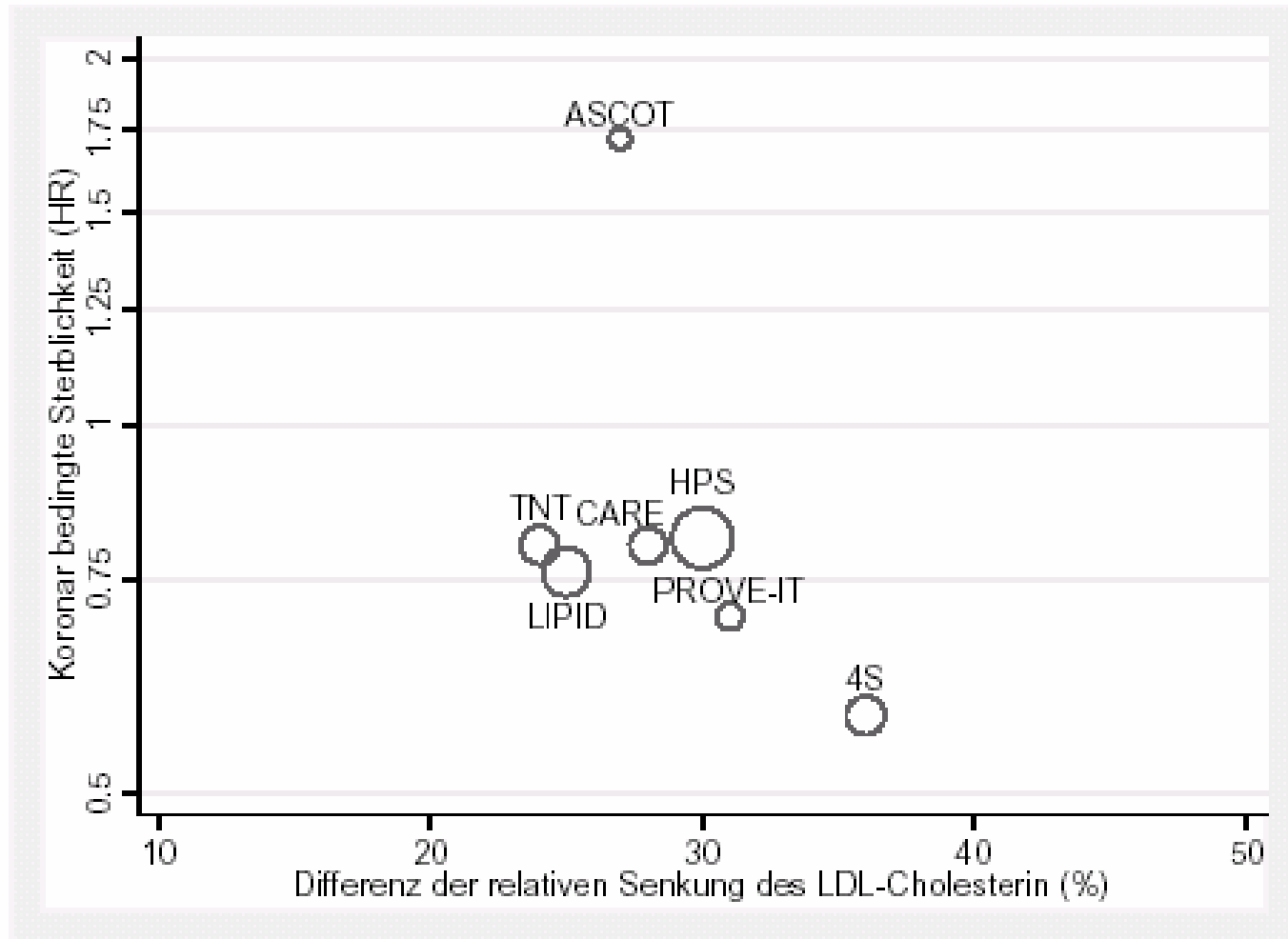


- Clear information for patients and doctors on pharmaceuticals
- Better resource allocation due to focus on effective innovations
- Incentive for drug industry to work on innovative drugs
- Outcome orientation

Landmark information reg. Insulins, cholesterol lowering drugs but:

- Processes are very slow
- Fierce response by industry and providers

Abbildung 10: Meta-Regression zum Endpunkt „Koronar bedingte Sterblichkeit“



p = 0,12 für Einfluss der Differenz der relativen Senkung des LDL-Cholesterins auf Hazard Ratio; Änderung des Hazard Ratio je 1%-Punkt Differenz der relativen Senkung des LDL-Cholesterins (mit 95% Konfidenzintervall in Klammern): 0,98 (0,95-1,01).

3. Role of regulation

„ ... IQWiG does not follow the rules of EbM. Are coronary morbidity and coronary mortality not relevant for patients?“

**National and international societies ... textbooks and medical examens say ... „the lower – the better“ Prof. Greten,
Deutsches Ärzteblatt, 11. 11. 2005**

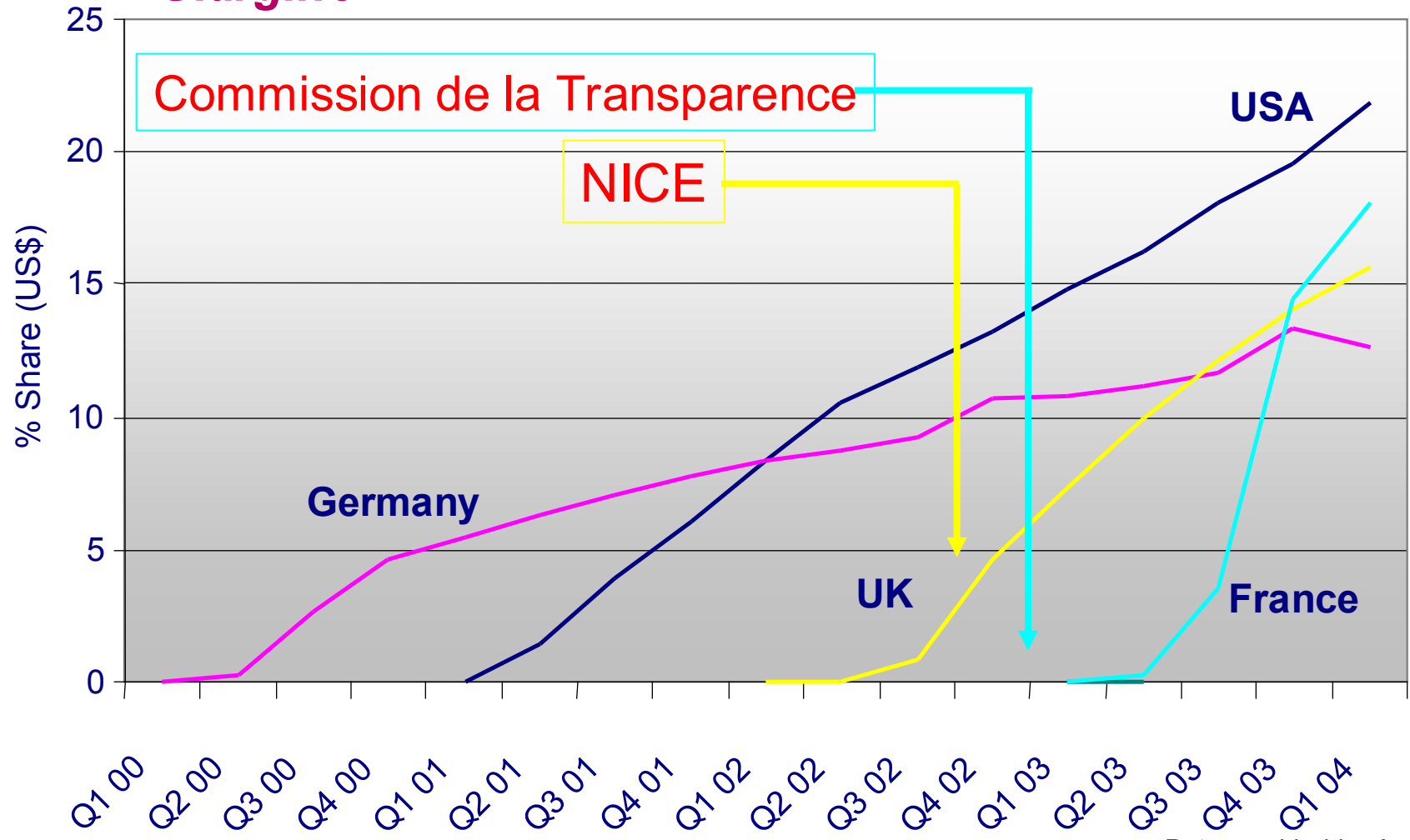


5.5 Conclusions

Most evidence concerning post-licensing evaluation of pharmaceuticals is derived from non-European countries like Australia and Canada. However, an increasing number of EU-countries also look back on several years' experience in comparative drug evaluation in connection with reimbursement or pricing decisions. There is consensus internationally that a new drug which is the first product offering an effective therapy for a particular indication should be classified as a therapeutic breakthrough. If a treatment alternative already exists, the majority of countries perform a systematic and evidence-based evaluation of a drug's clinical and economic characteristics in comparison to daily treatment routine. In the case of lacking or unreliable evidence results of a comparative drug assessment are considered as of preliminary nature. However, evaluation criteria, requirements and specific methodological issues still lack internationally consented standards.



Impact of decisions on market share, case of Glargine



Data provided by Aventis

On the horizon looms a positive list...

- ***Based on cost-effectiveness data***
- ***Reducing the number of available drugs***
- ***Giving advice to physicians***
- ***Clarifies the entitlements of patients***
- ***Limiting innovations?***
- ***Sound processes?***

Thank you for your attention!
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