Practice of benefit assessment of pain relieving medications

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Workshop 2: Evidence in pain therapy from a societal perspective

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Gemeinsamer Bundesausschuss

Agenda

- Challenges
- Regulatory framework in Germany
- Responsibilities of the G-BA
- No specific regulation for pain relieving drugs
- Other areas with relevance to pain
- Conclusions

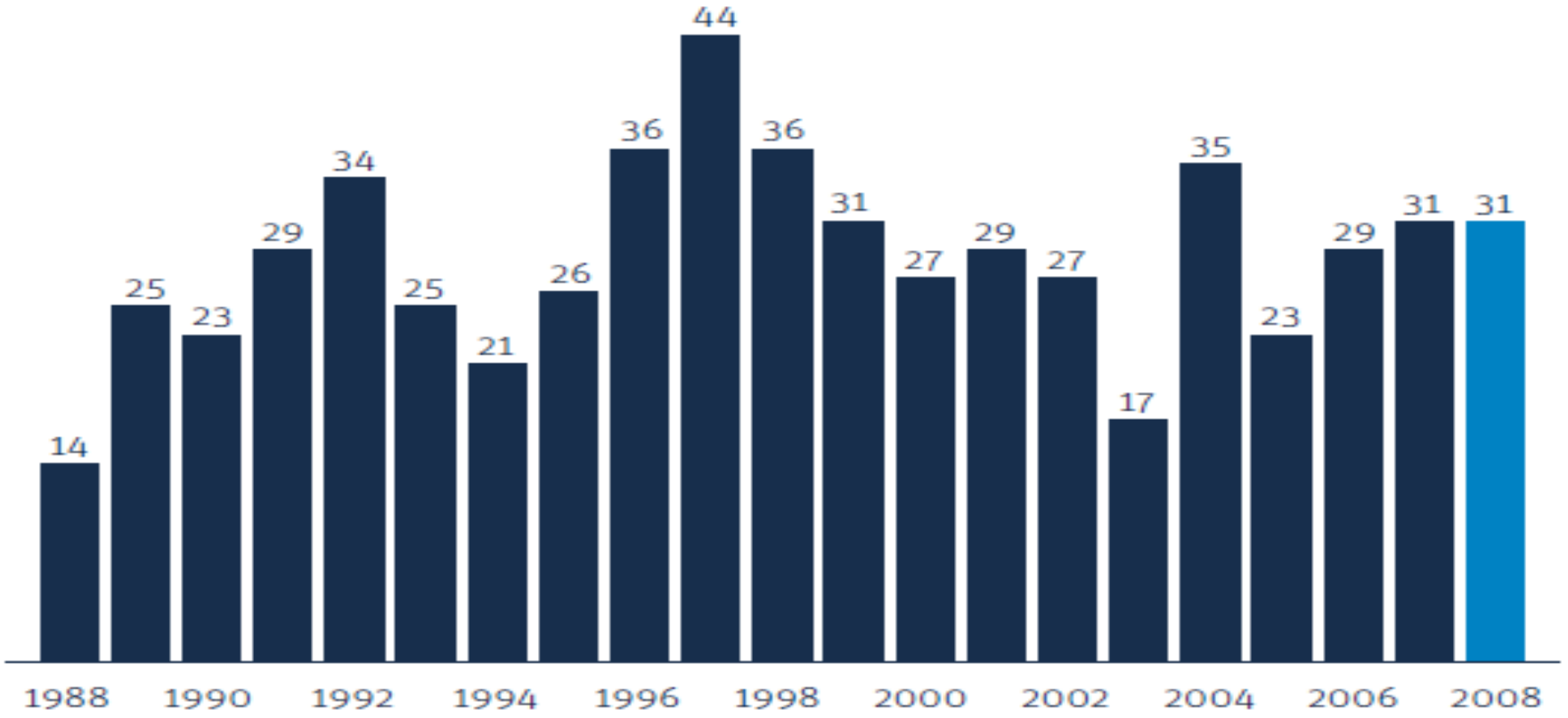
Challenges

- expenditure for drugs continue to rise above average in the German health care system
- cost-drivers are:
  - many new products often with only marginal added benefit
  - free price-setting in combination* with non-existing fourth hurdle
  - manipulation of prescription behaviour of physicians and demand by patients by industry

Innovative pharmaceutical industry:

New Molecular Entities in Germany

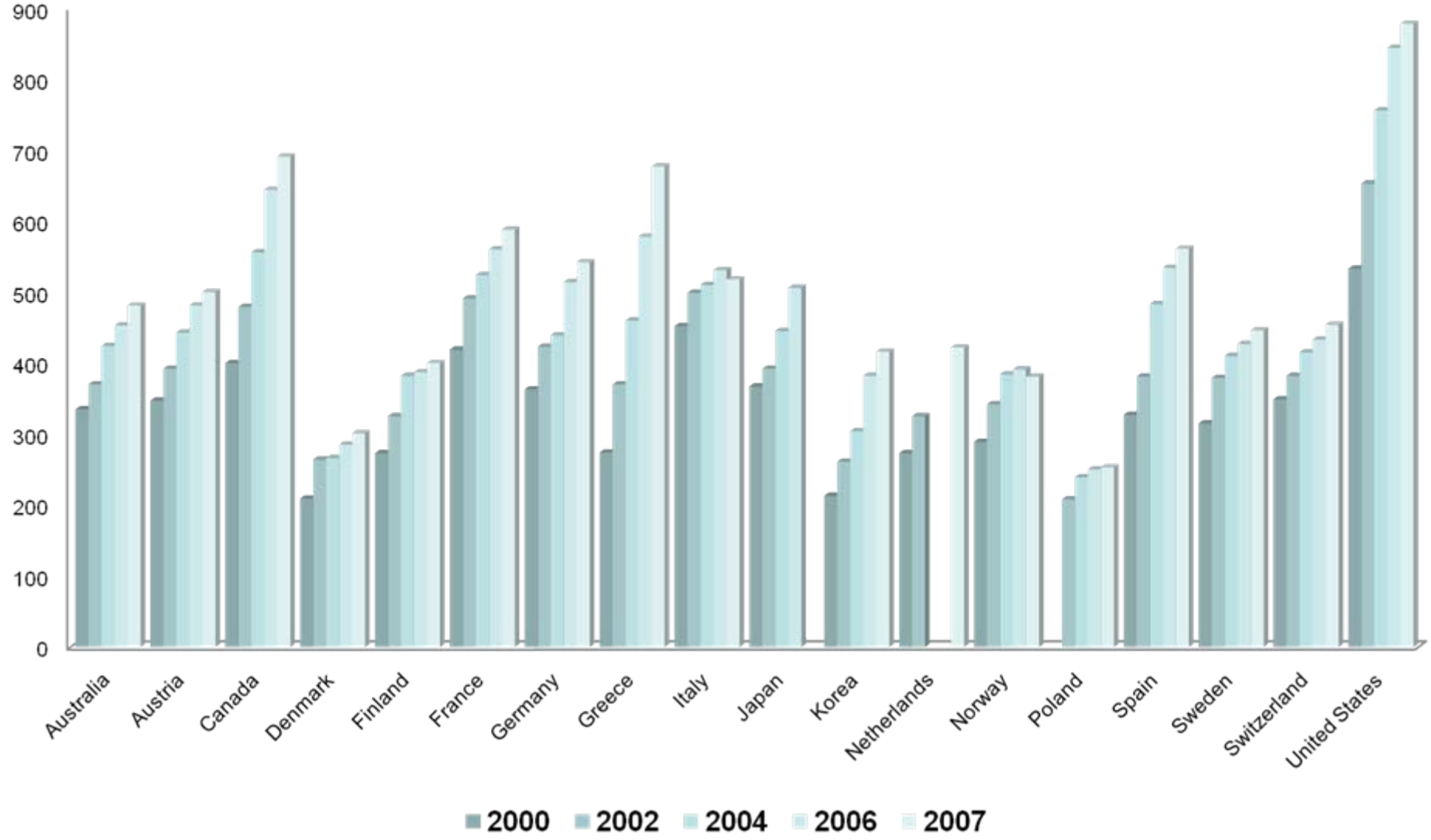
Number



Source: Pharmazeutische Zeitung, vfa

Expenditure for Pharmaceuticals

- per capita, US$ (Source: OECD) -



Regulatory framework for drugs in Germany

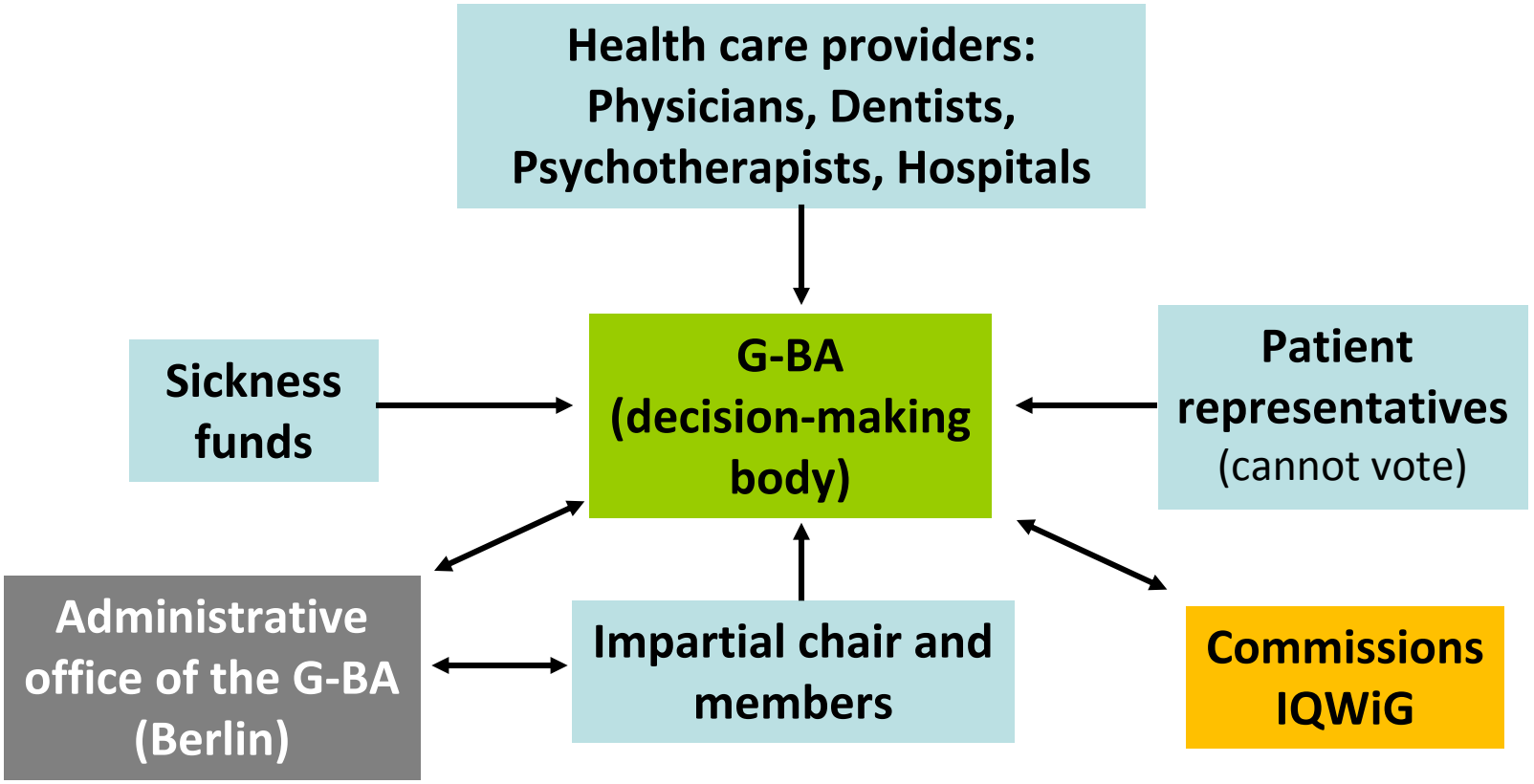
- Pharmaceuticals Law
- Pharmacy Law
- Drug Price Ordinance
- Social Code Book V (SGB V)

- Licensing, monitoring
- authorisation and operating pharmacies
- surcharges for wholesalers and pharmacies
- entitlements to benefits for patients, responsibilities of the **G-BA (drug directive)**

What is the G-BA?

- The G-BA (Federal Joint Committee) is
  - the main decision-making body in German health care (statutory health insurance only)
  - legitimised by law (Social Code Book V) to issue legally binding directives
  - established in 2004, reorganised 2008, but predecessor committees dating back to 1913
  - represents physicians, hospitals, sickness funds and patients
  - supervised by Minstry of Health
  - responsible for coverage decisions and quality assurance

Structure of the G-BA



Role of the IQWiG

- Institute for Quality and Efficiency in Health Care (www.iqwig.de)
- independent scientific institute, commissioned by the G-BA
- produces evidence-reports on
  - drugs
  - non-drug interventions
  - diagnostic and screening interventions
  - treatment guidelines (CPGs) and disease management programmes (DMPs)

Scope of the G-BA Drug Directive

- OTC drugs (prescribable but not prescription-only)
- life-style drugs
- reference prices
- evaluation of the benefit or the cost-benefit ratio
- off-label use
- second-opinion / prescription of special drugs
- prescription of medical devices
- therapeutic guidance

What is innovative?

- from a regulatory point of view: just new
  - any drug that enters the market for the first time
- proposal by Ferner et al. BMJ 2010;340:b5493
  - class of innovation:
    - treat a condition with no existing effective treatment
    - improve treatment of a condition that does not have a consistently satisfactory treatment
    - safer treatment
    - make treatment more convenient

Requirements for innovative drugs

- need marketing licence (EMA, BfArM)
- additional benefit as compared to existing drugs -> no further action
- no additional benefit but improved safety profile -> no further action
- no additional benefit / more expensive / unsafer / inexpedient -> exclusion
- benefit need to be demonstrated within RCT

Evaluation of cost-benefit ratio by IQWiG

- aim: setting appropriate maximum reimbursable price
- eligible: prescription drugs that have recently entered the health care system or important prescription drugs that are already available
  - and have demonstrated additional benefit compared to standard treatment
- only after commissioning by G-BA

No specific regulation for pain relieving drugs

- „Pain“ is by definition a condition eligible for coverage by German health care
  - ➢ not classified as lifestyle or quality of life-related
- only some combination drugs are excluded
  - ➢ e.g. analgesics in fixed combination with vitamins or caffeine
- references prices apply, among others, for
  - ➢ acetaminophen, diclofenac, tilidin, triptans

Other areas where G-BA issues directives with relevance to pain management

- (specialised) ambulatory palliative care / end-of-life care
  - ➢ one focus on professional pain management
- ambulatory treatment of rare diseases deserving specialised care in hospitals
  - ➢ includes pain management

Conclusions

- G-BA is responsible by law for provision of efficient health care for all patients with mandatory health insurance
- Concerning pain management, G-BA issues directives in the area of pharmaceuticals, end-of-life care

Thank you for your attention!

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