

# European Pharmaceutical Policy: Access for Patients or Improving Competitiveness

The European Commission's Vision

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Study day  
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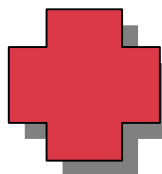
# Agenda

- Role(s) of the European Commission in the field of Pharmaceuticals
- Competitiveness or access for patients
- The Pharmaceutical Forum



# Roles of the European Commission in the field of Pharmaceuticals (1/2)

## (1) Health Perspective



- Intermediate between Member States, Industry, Patients and other stakeholders
- Ensure patient-access to the right medicines: Flu-vaccine, ARV access, Priority medicines, ATV
- Funding & facilitating: e.g. HTA-network, PPRI, ...

**Lead:  
DG SANCO**

## (2) Economic Perspective



- Intermediate between Member States, Industry, Patients and other stakeholders
- Ensure transparent national Pricing and Reimbursement decisions
- Support innovation, competitiveness and employment in the EU pharmaceutical sector
  - Support to Small en Medium-size Enterprises (mainly Biotech)

**Lead:  
DG ENTR,  
Unit F5**



# Roles of the European Commission in the field of Pharmaceuticals (2/2)

## (3) Product Perspective



- Ensure Quality, Safety and Efficacy of medicines
  - Marketing authorisations after scientific assessments by EMEA
  - Pharmacovigilance
  - Good Manufacturing Practices
- Ensure Protection (IP, counterfeit)
- Make new regulations (e.g. tissue engineering, paediatric medicine)

Lead:  
**DG ENTR,**  
Unit F2

## (4) Other

- European Regulations apply to Pharmaceutical sector as to other sectors, e.g. :
  - **DG Competition** checks planned Mergers and Acquisitions
  - **DG Research** supports and funds projects on lifesciences
  - **DG Trade** negotiations agreements with non-EU countries for EU pharmaceutical industry
  - ...

Lead:  
**All DG's**

European Commission



# Review of the Pharmaceutical Legislation

## Key elements

- Harmonised data protection periods for innovative medicines:
  - 10 years of protection, during last 2 generics can prepare (Bolar)
  - 1 extra year in case of extra innovation
- Increasing role of the European Medicines Agency (EMA)
  - More medicines centrally approved
  - Extra support for SME's
  - Foresee functioning of EMA with 25 Member States
- Earlier access for patients to new medicines
  - Conditional approval
  - Fast-track approval
  - EU-framework for compassionate use



# Transparency in National Pricing and Reimbursement Decisions

- Pricing and Reimbursement decisions on pharmaceuticals are **full national competences**. Member States can go the direction they want, but ...
- ... the European Legislation requests **fully transparent procedures** when taking these decisions (Directive EC/89/105). In particular in terms of...
  1. Timely decisions
  2. Public criteria for decisions
  3. Informing pharmaceutical companies
  4. Possibility for independent appeal

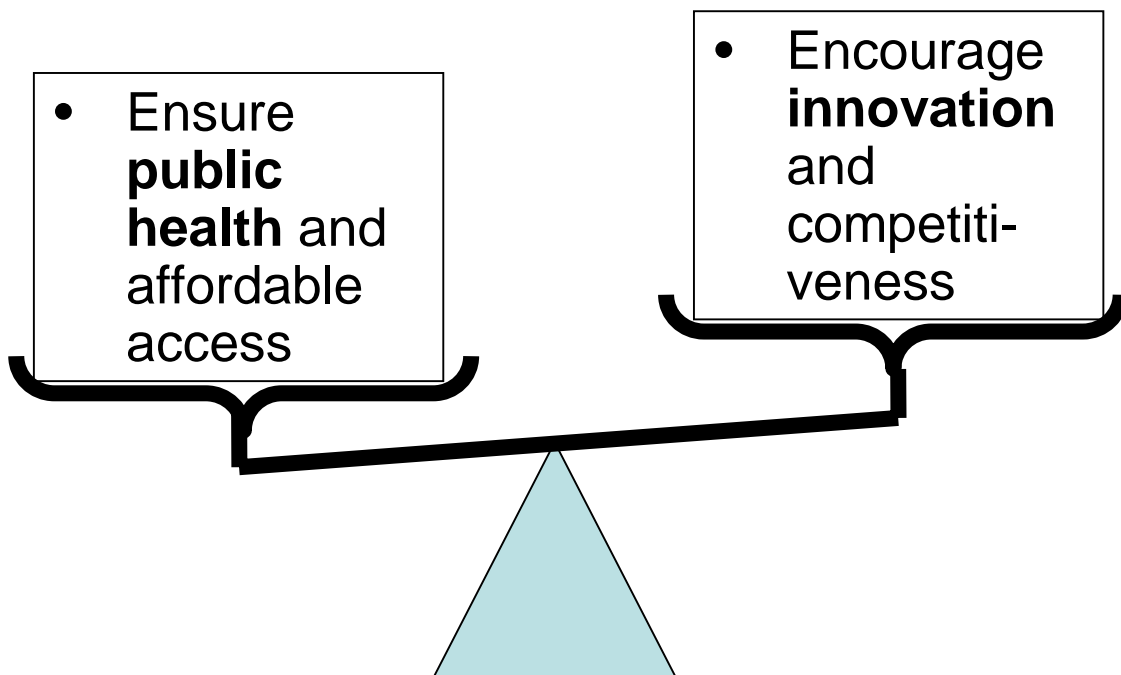


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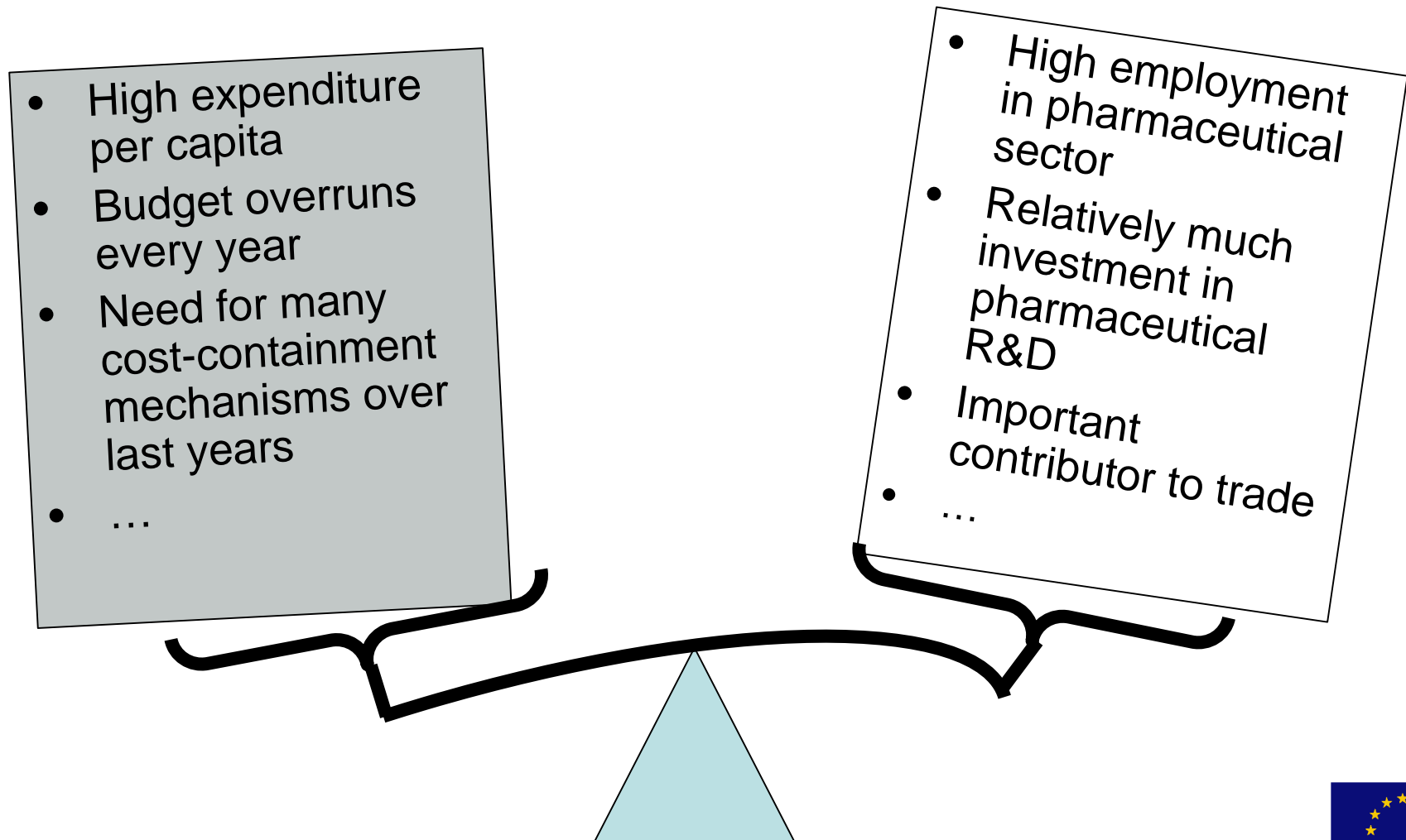
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# Governments in all EU Member States struggle to maintain a difficult balance

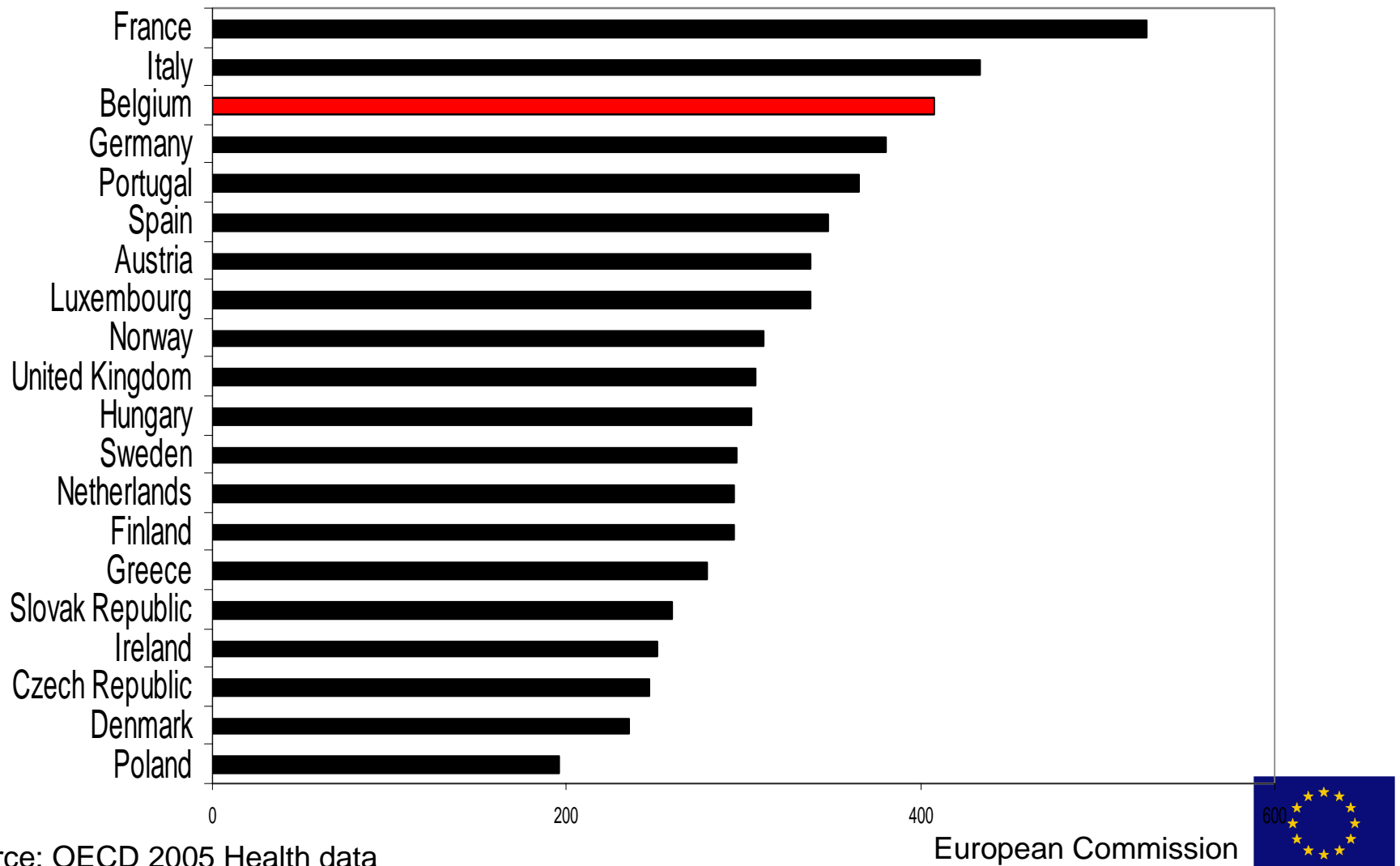


# A balance which is strongly loaded in Belgium



# Expenditure on pharmaceuticals in Belgium is amongst higher in Europe

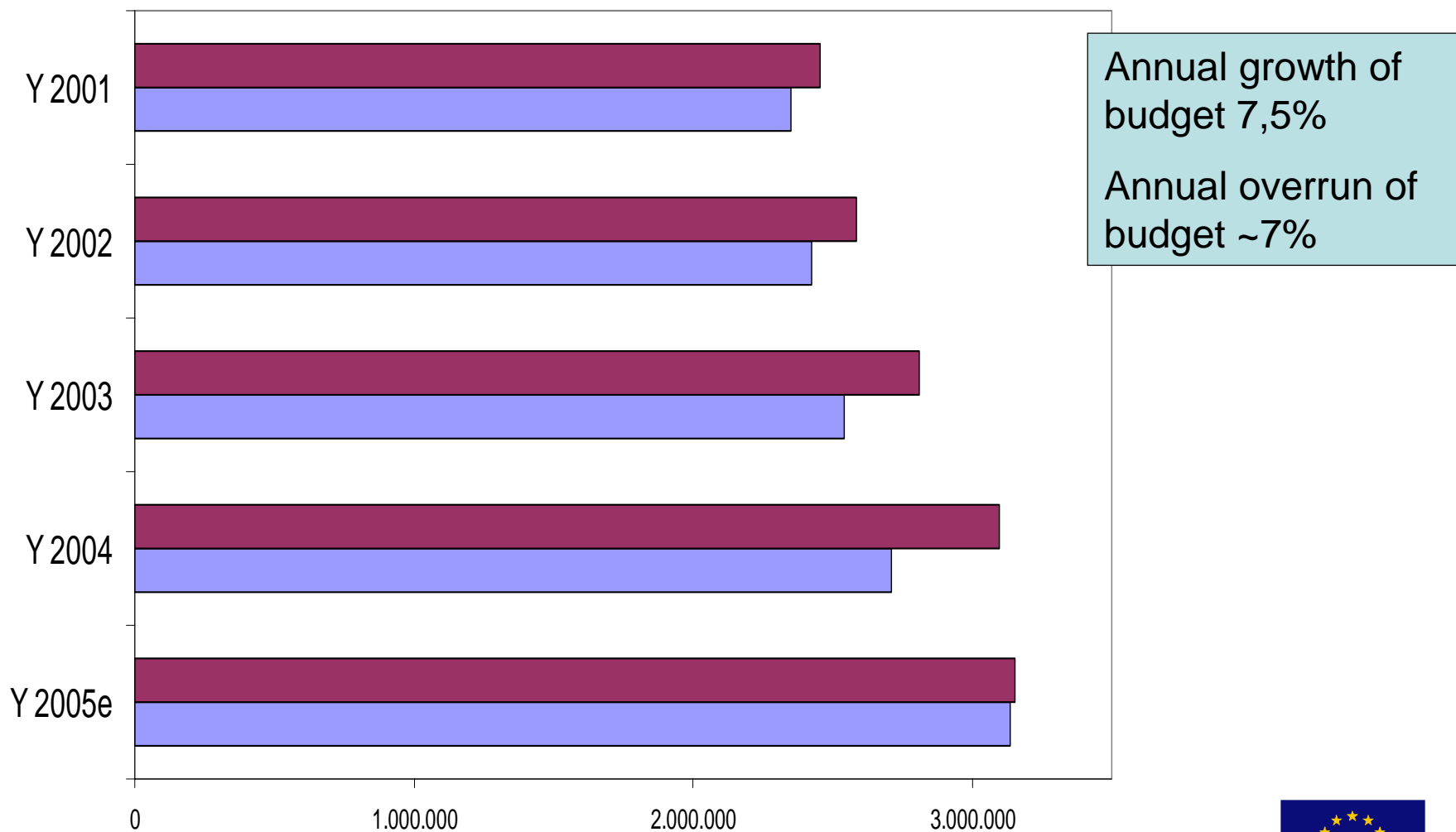
Annual Spending/Capita, Euro (2003)



# Budget evolution

Real spending  
Budget

RIZIV/INAMI, '000 Euro



# Need for many Cost Containment Measures

## Overview 2005

### Objective

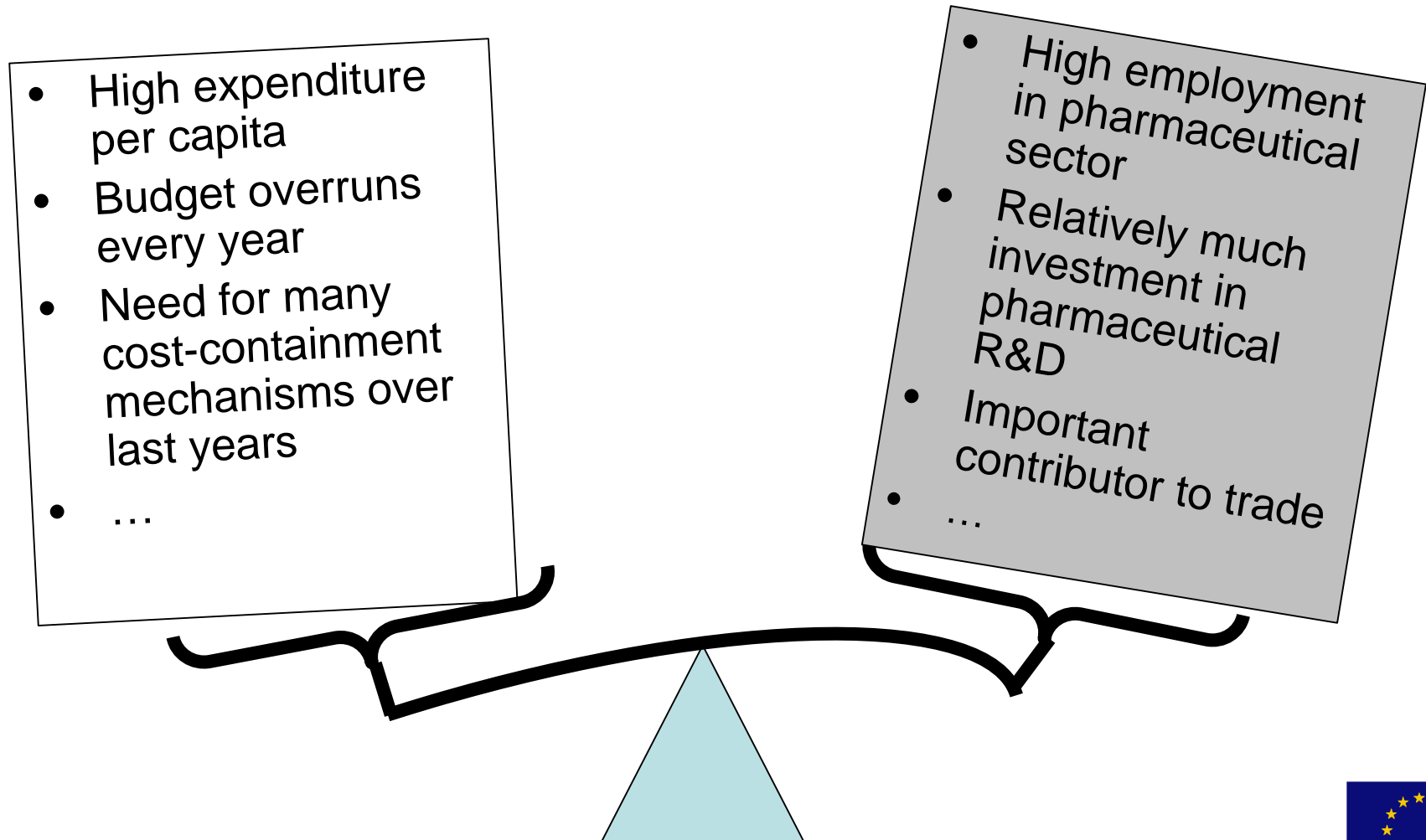
- Price reduction
- Promotion of low-price medicines
- Access control
- Industry contribution

### Measures

- Reference pricing
- Price-cut older drugs
- INN Prescribing
- Prescribing targets MD's
- Conditional reimbursement
- Co-pay ceilings
- Clawback
- Taxation

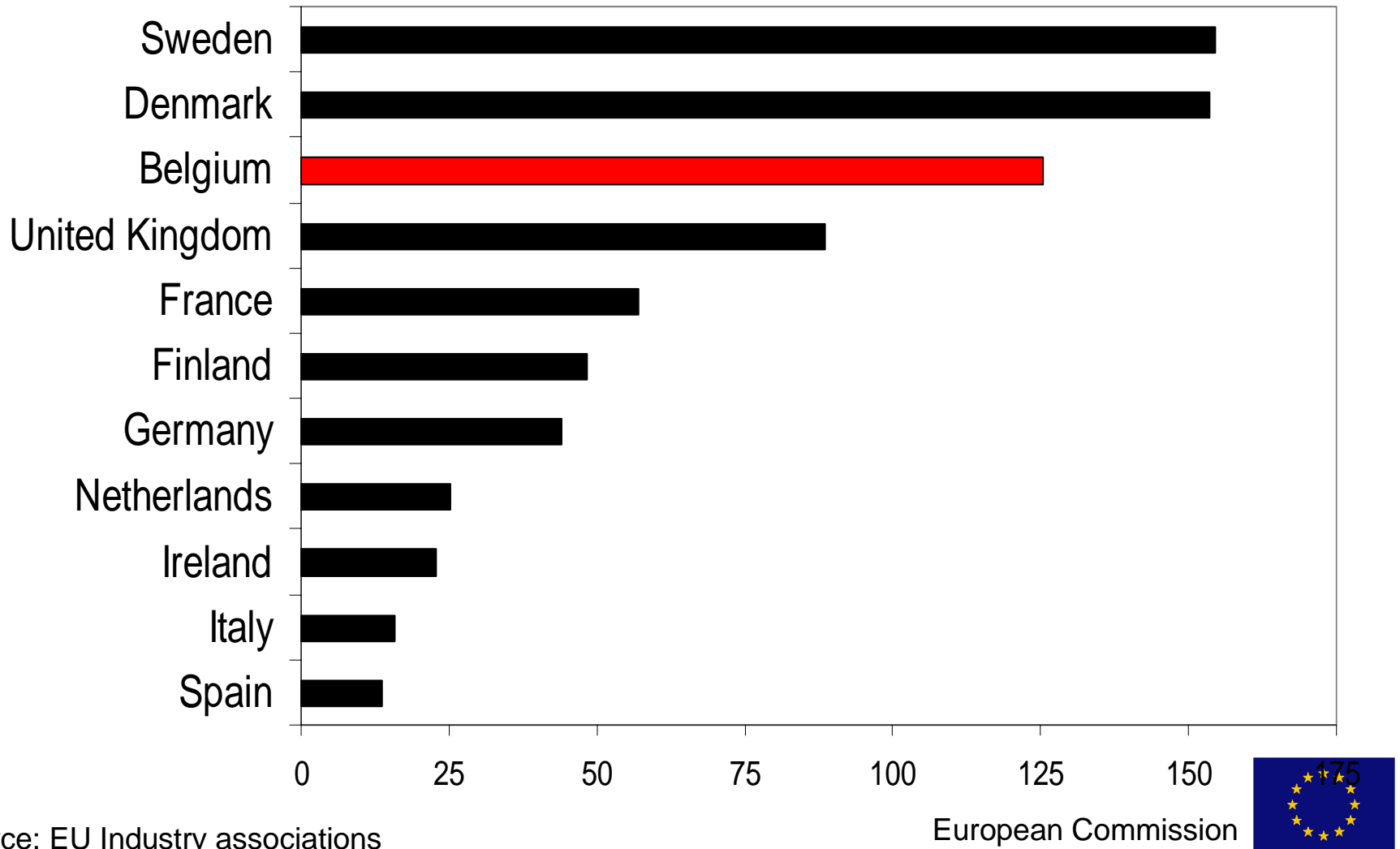


# A balance which is strongly loaded in Belgium



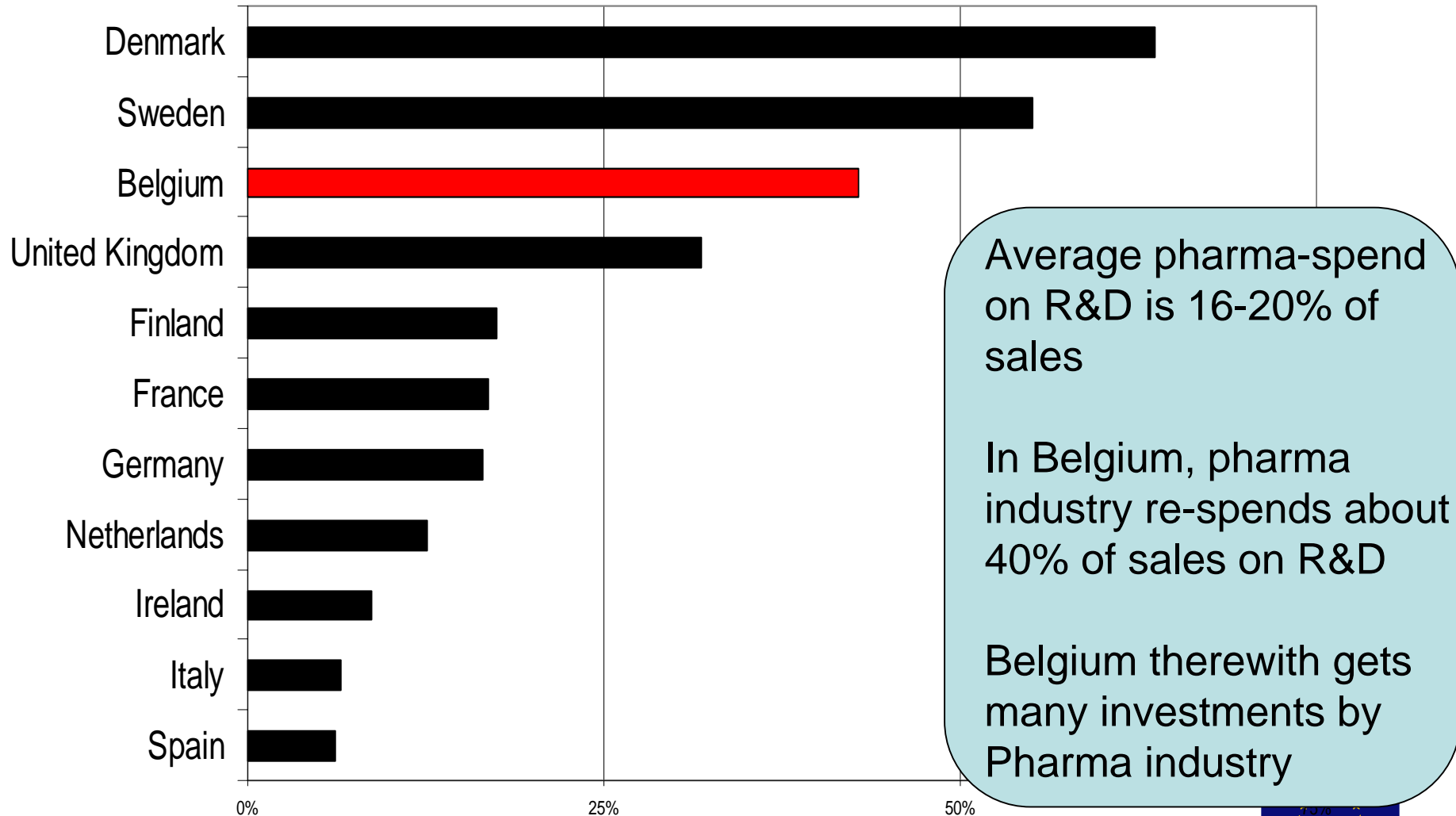
# Investment in pharmaceutical R&D in Belgium is amongst higher in Europe

Annual R&D Spending / Capita, Euro (2002 estimates)



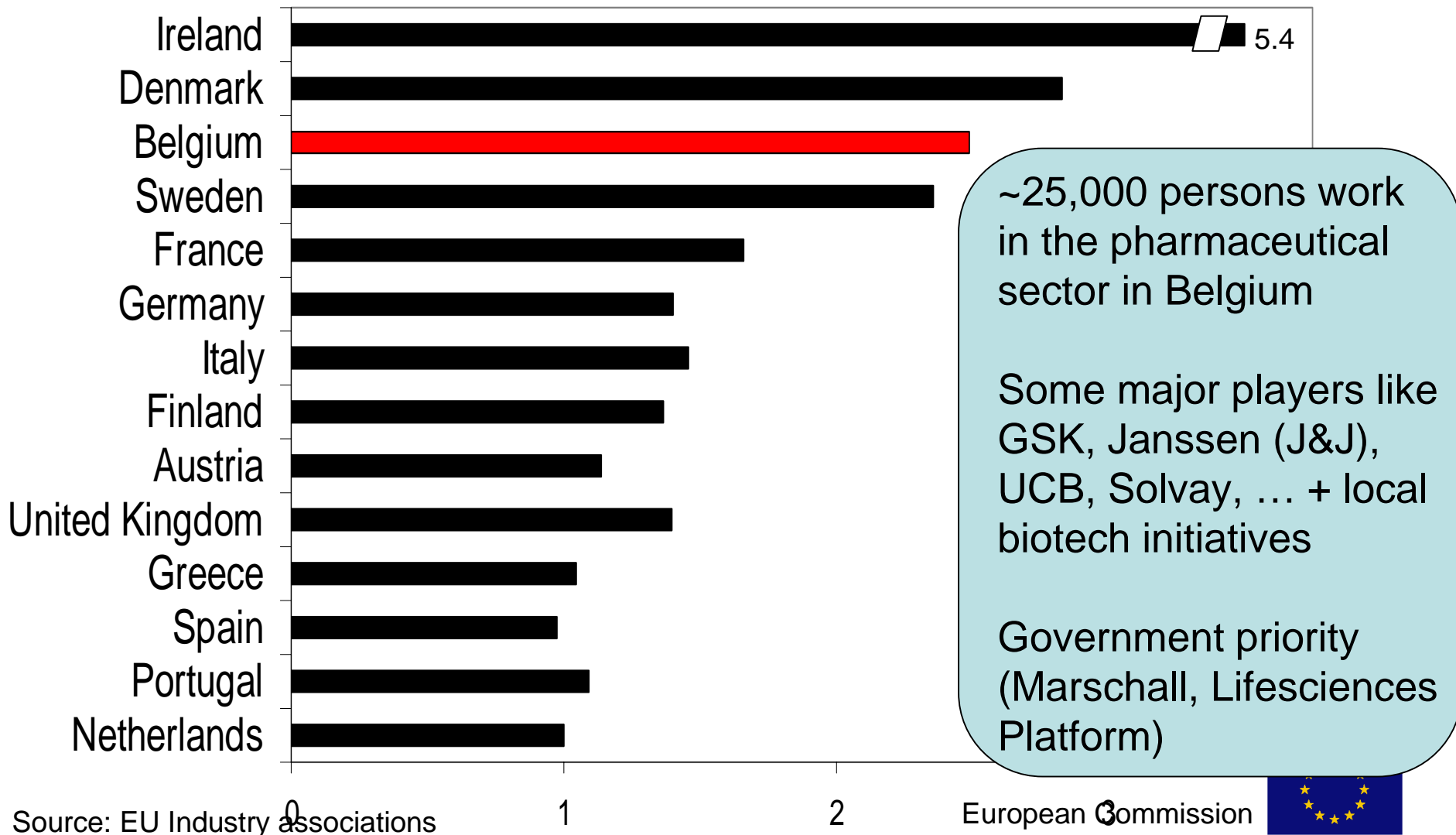
# Investment versus Sales

Annual R&D spending / Ex-factory Sales, % (2002 estimates)



# Pharma sector is employing intensively in Belgium

Employees in pharma / Inhabitants (2002 estimates)



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# G-10 High Level Group

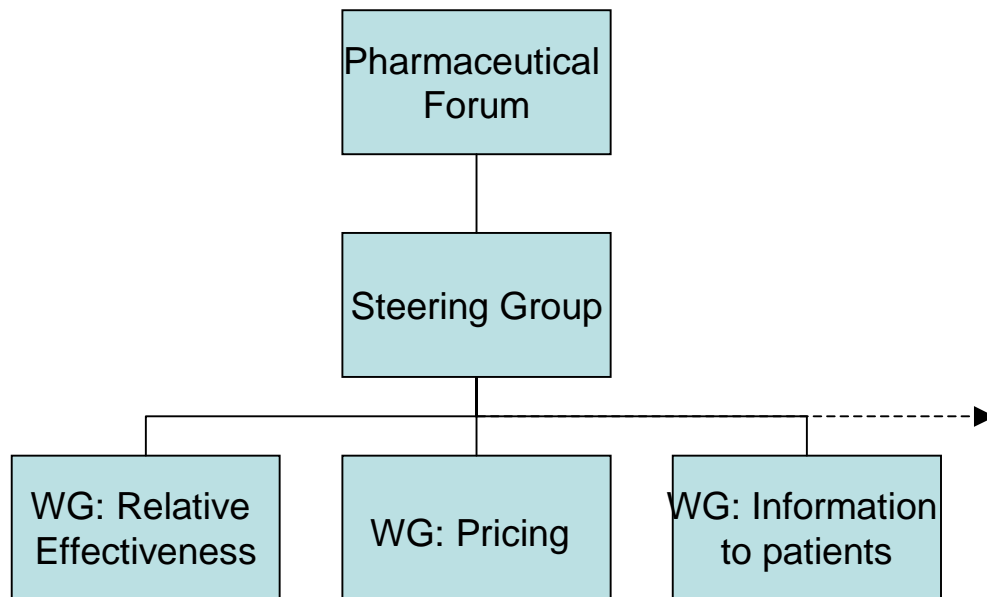


## Recommendations

- Benchmark Competitiveness and Performance Indicators
- Regulation and access to markets
  - Timing of pricing and reimbursement
  - Generics, OTC,
  - Relative effectiveness
  - ...
- Improving the EU science base
- Patients
  - Information
  - Safety
- Enlargement



# Set-up of the Forum



## Principles

- Broad participation
- Highest level political participation + technical preparation
- Collaboration, facilitated by EC
- Open set-up, all issues and proposals can be considered



# Relative Effectiveness

## New, complex, though promising area

- Allows to target limited public funds towards most valuable medicines
- Requires in-depth scientific and clinical experience of each Member State
- Available information is usually fragmented
- Absence of standard procedures makes creates a lot of rework

## Working Group on Relative Effectiveness

- Examine how to share experiences and build common approaches
- Double focus possible:
  - Streamline process
  - Clarify value of innovation
- Take account of existing initiatives:
  - MEDEV, Baltics, HTA-network, Industry, Transparency Committee
- Includes clinical efficiency and cost-effectiveness



# Pricing

## Multiple expectations and regulations

- Need to balance 2 expectations on pricing
  - MS duty to keep healthcare affordable
  - Industry's need for a return on investment
- National competence
- Decision-process needs to be in line with Dir 89/105/EEC (timing, criteria, publications)

## Working Group on Pricing

- Share and examine experiences with different P+R mechanisms and cost-containment strategies on
  - Impact on **cost**
  - **Access** to market
  - **Reward** for innovation
- Consider impact of cross-national mechanisms (parallel trade, int'l reference pricing)
- Aim for a long-term perspective for both Member States and Industry



# Information to Patients

## Need to improve information to patients but how?

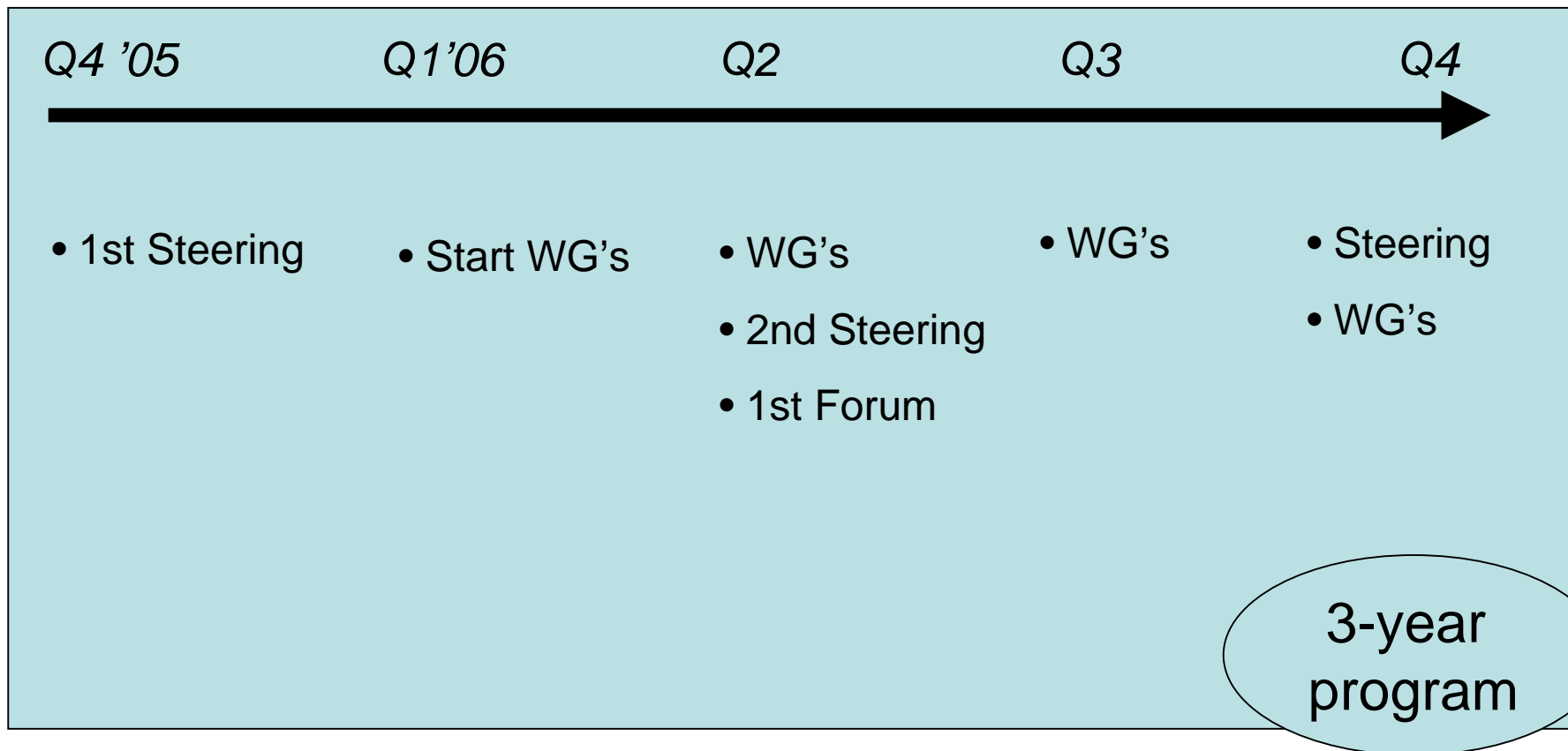
- Legislation on information drafted before the Internet
- No clear distinction between information & advertising
- Factors to consider
  - Increasing pressure on national healthcare budgets
  - Potential role of industry
  - Growing demands from patients for more & better info

## Working Group on Patient Information

- Examine options to
  - Provide information to patients in their own language, considering different factors
  - Put medicine information into a broader context
  - Build a central EU information tool
- Build on existing expertise and take account of existing initiatives:
  - EuroPharm Database (EMEA)
  - EU Health Portal (SANCO/INFOS)



# Timing



# Further Information

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