

## Determining value for new medicines in Europe

Panos Kanavos, PhD  
 London School of Economics, UK  
 AcademyHealth, Boston, 26 June 2005

## Agenda

- Policy objectives
- Health and pharmaceutical care financing in Europe
- Drug pricing and reimbursement schemes in six key European countries
  - Cost sharing
  - Pricing and price levels
  - Cost effectiveness
  - Other regulatory measures
  - Criteria for reimbursement
  - Industrial policy

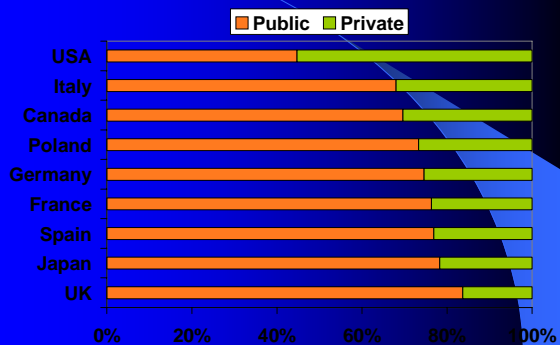
## Policy objectives

- Universality
- Equity
- Macroeconomic efficiency
- Quality
- Industrial policy

## Health care delivery in G5: Stylised facts

	Germany	UK	France	Italy	Sweden	Spain
Health spend % GDP (2003)	10.9	7.7	9.7	8.5	8.1	7.6
Health spend per capita (US\$ PPP)	2817	2160	2736	2166	2360	1646
Health spend public (%)	78.5	83.4	76.0	75.6	87.0	71.4
Drug spend as % GDP (2003)	2.2	1.2	2.5	1.9	1.4	1.9
Drug spend as % health spend	14.5	16	20.8	21.9	13.1	21.5
Per capita spend on drugs (US\$ PPP)	408	252	570	484	329	354

## Role of government in funding health care



## Cost-sharing

### Generous coverage resulting in modest co-payments

Country	Type of co-payment
UK	Flat £6.50 per item; significant exemptions
Germany	10% of prescription cost up to €10 per item
France	35% and 65% co-insurance for non-essential drugs; significant exemptions; supplementary insurance covering co-pays
Italy	Modest fixed fees varying by region; RP difference
Spain	35% (and 10% for elderly); exemptions apply
Sweden	Annual (SEK900) modest deductible plus co-insurance up to a maximum limit pa; exemptions

## Pharmaceutical pricing policies, EU G6, 2005

Country	Key measure
Germany	Free pricing in principle, Institute of Healthcare quality being set up Reference pricing for off-patent drugs Reference pricing for selected in-patent drugs
UK	Free pricing subject to "profit" control and 7% price cut Price control for generics (a "reference-based" pricing) Reimbursement subject to NICE positive guidance/CE pricing
France	Price negotiation which includes mandatory cost-effectiveness Price "notification" for ASMR I-II products, which can be challenged Reference pricing
Italy	Price negotiation (in practice a paper-based system) Cost effectiveness pricing International price comparisons Reference pricing for off-patent segment
Sweden	Free pricing for not reimbursed medicines; conditional free pricing prior to CEA; Cost effectiveness mandatory for price premium
Spain	Price control and reference pricing in off-patent segment

## Reimbursement criteria

- Positive list (formulary)
- Clinical effectiveness
- Cost effectiveness
- Value for money (budget impact)
- Benefit criteria (defining patient groups)

## Price differences due to differences in price regulation across Europe

Prices per pill, DDD-adjusted in selected EU countries, 2002 in € ex-M						
Drug	UK	Germany	Sweden	Spain	Italy	Greece
Lipitor	1.01	1.37	1.04	0.96	0.63	0.55
Zocor	1.25	1.06	1.02	1.19	0.74	0.62
Prilosec	1.60	1.77	1.83	0.43	1.50	0.84
Zyprexa	5.48	5.78	5.37	3.57	3.60	3.30
Paxil	0.93	1.16	0.85	0.80	0.77	0.69

## The uptake of (clinical) cost effectiveness

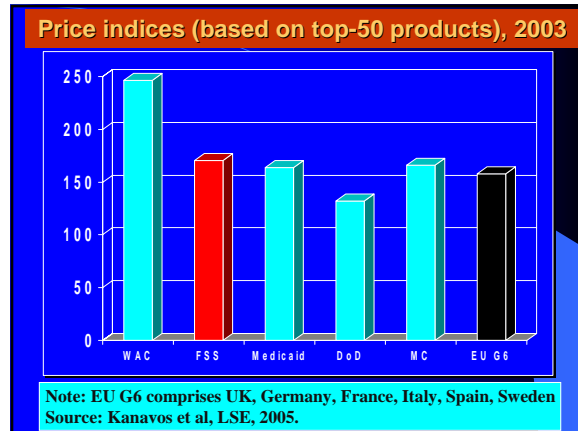
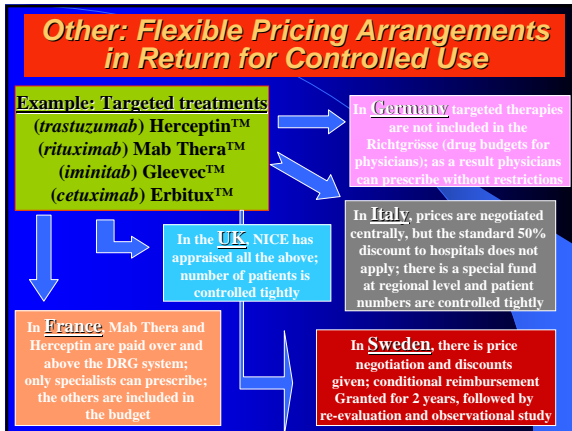
Country	Use of economic evidence in decision making
UK	NICE; operating on Demand-side; issues guidance which is binding; focus on clinical cost effectiveness and budget impact analysis
Germany	IQHC; operating on supply-side; issues guidance on effectiveness (only); drugs not proved superior are downgraded or included in RPS
France	Statutory requirement in reimbursement negotiations; submission of CEA mandatory, although may not play key role in setting price
Italy	Statutory requirement in reimbursement negotiations; submission of CEA mandatory, although may not play key role in setting price
Spain	No role in decision-making, but evaluation takes place at regional level
Sweden	Mandatory requirement for awarding price premium

## Other regulatory measures

Country	Price cuts	Reference Pricing	Substitution	Payback	Rebate	Generic Rx	Budgets
UK							
Germany							
France							
Italy							
Spain							
Sweden							

## Industrial policy

Country	Strength of industrial policy
UK	PPRS; explicit incentives to invest in R&D coupled with price/profit incentives
Germany	Price levels and science base acting as (indirect) incentive to inward R&D investment
France	"Good citizenship" approach; industrial policy explicitly considered at reimbursement negotiations
Italy	No explicit industrial policy
Spain	Some state funding for R&D
Sweden	Favourable approach to pricing/reimbursement and good science base, coupled with some government incentives to invest in R&D



- ### Concluding remarks
- **Cost sharing:** continues to be modest with significant exemptions
  - **Coverage:** continues to be comprehensive
  - **Pricing:** several methods apply, but reimbursed prices can (and are) on many occasions higher than in the US on a like-for-like basis
  - **Cost effectiveness:** Need to demonstrate value of new products
  - **Reimbursement:** variety of criteria apply, including medical value, but also definition of patient groups that benefit most

- ### Payor mindset: The European perspective
- Perceived Medical and Clinical Need:
    - "Is it needed?"
  - Medical Appropriateness:
    - "Is it useful?"
  - Effectiveness:
    - "Does it work?"
  - Quality of Evidence:
    - "Is it proven?"
  - Political Expediency:
    - "Can we get away without funding it?"
  - Potential for abuse or extended use:
    - "Can we keep a lid on it?"
  - Budgetary impact/cost effectiveness:
    - "Can we afford it and is it worth it?"