The European experience in drug policy, efficiency and cost containment

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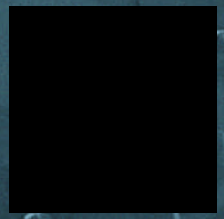
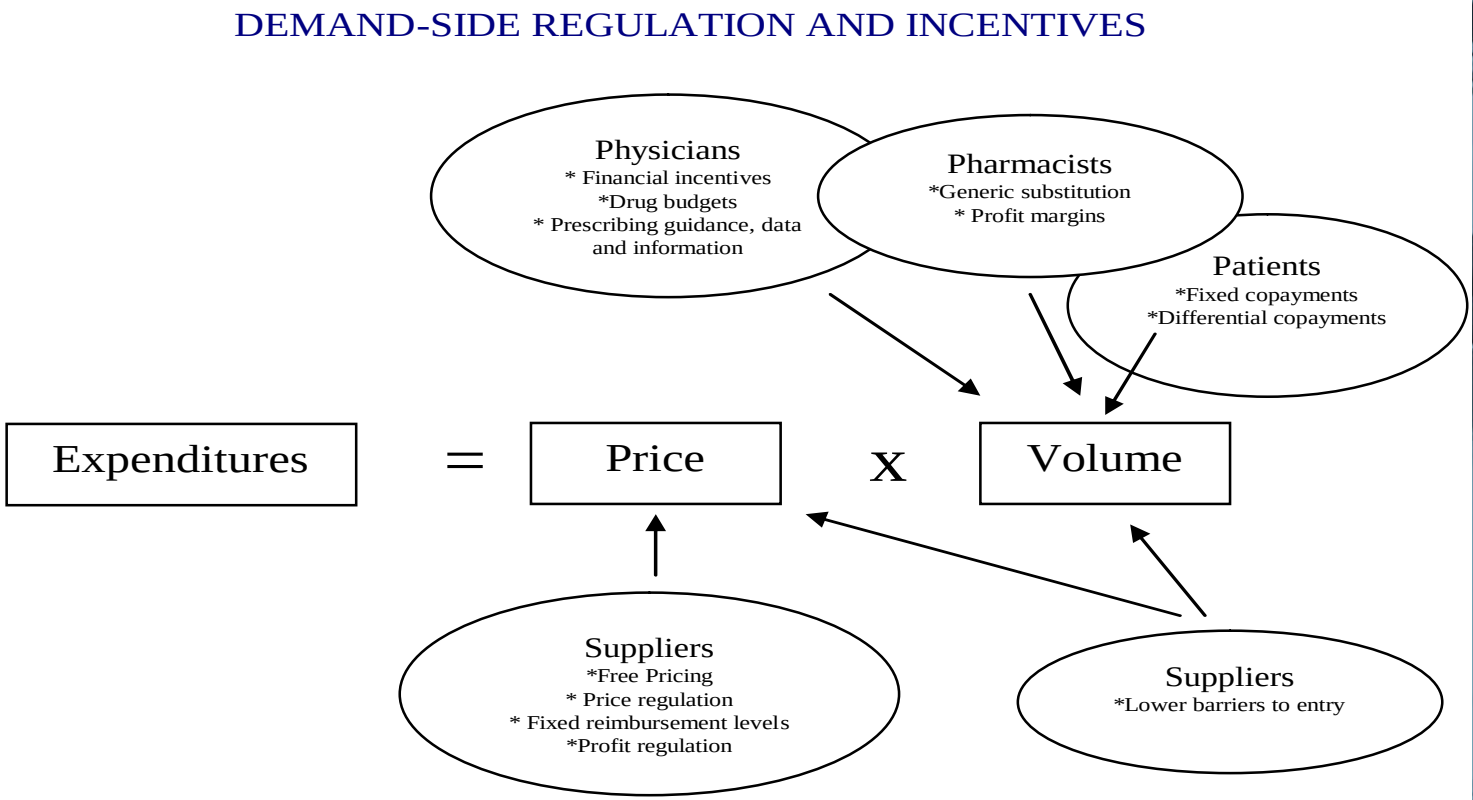


Regulatory Framework for European Pharmaceutical Markets



Approaches to drug regulation: EU

Measure	In-patent drugs	Off-patent drugs
Free Pricing	Germany, France(?), Malta, UK	UK
Direct price controls	Austria, Finland, France, Cyprus, Greece, Ireland, Italy, Spain Netherlands, Portugal, Baltics, Sweden, Poland, Czech, Hungary, Slovakia, Slovenia	Austria, Finland, Greece, Ireland, Netherlands, Sweden
International price comparisons	Austria, Belgium, Denmark, Finland, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, Baltics, Poland, Czech, Hungary, Slovakia, Slovenia	Austria, Belgium, Denmark, Finland, Greece, Ireland, Netherlands, Portugal, Spain, Sweden
Profit control	UK	
Reference pricing	Netherlands, Hungary, Germany	Belgium, Denmark, France, Germany, Italy, Portugal, Spain, UK

Price Determinants

A regulator's perspective

- 1. Scientific criteria & assessment of therapeutic benefit
  - What is innovation?
- 2. Economic criteria
  - Price control (RPI-X, Cost-plus, average pricing, cross-country referencing)
  - Budgets, Paybacks, Clawback
  - Assessment of (clinical) cost effectiveness
- 3. Industrial policy (good citizenship approach)
  - R&D
  - Employment
  - Exports

What type of regulation?

- Theoretically, Monopoly Power is controlled through Price Regulation, traditionally through
  - *Rate of Return (RoR) Regulation*
  - *Price Setting*

Rate of Return (RoR) Regulation

- ‘Reasonable’ Return on Capital Investment
- Within this range, there is free pricing
- UK PPRS

- Overinvestment in Capital Assets
- Inefficient Operation (Increased Costs Increased Revenue Margin)
- ‘Economically Correct Rate of Return’ to Enhance Innovation?

What about:
1. Cost control?
2. Access to innovation?

Price Setting

- Historical Pricing + Justifiable Cost Increases
- Different variations
- Basic cost
- Cost-plus
- RPI-X

- Inevitable, Arbitrary Categorisation
- Exhaustive Rules Loopholes or Tedious Updating Process
- Enforcement Dependent on Resource Potential of Agency

Country experience: Spain, Portugal, Italy, France, Greece, Czech, Hungary, Austria, Poland, Slovenia, Croatia, Slovakia, Baltics

Criteria for pharmaceutical reimbursement (EU, Canada)

Criteria	UK	GER	FRA	SPA	NET	POL	ITA	CAN
Clinical	✓	✓	✓	✓	✓	✓	✓	✓
Budgetary	✓	✓	✓	✓	✓	✓	✓	✓
CEA	✓	✓	✓		✓		✓	✓
Industrial policy	✓	✓	✓	✓				✓
Defining who benefits most	✓	✓	✓	✓	✓	✓	✓	✓
Volume	✓	✓	✓	✓	✓	✓	✓	✓
Foreign prices	✓	✓	✓	✓	✓	✓	✓	✓
OTC exclusion	✓	✓	✓	✓	✓		✓	✓
Tender	✓	✓	✓	✓	✓	✓	✓	✓

- Evidence-based reimbursement
- Negotiation on the basis of multiple criteria
- Policies differ depending on national priorities
- Reference pricing is often used esp. in patent-expired products

Policies on the proxy-demand: Physicians

Criteria	UK	GER	FRA	ITA	SPA	DEN	POL	NET
Monitoring Rx	✓	✓	✓	✓	✓	✓		✓
Audit Rx	✓	✓	✓	✓		✓		✓
CE Rx	✓		✓	✓	✓	✓	✓	✓
EBM Rx	✓	✓	✓	✓	✓	✓	Y	✓
Budgets	✓	✓	✓					✓
Financial incentives	✓	✓	✓					

- Gradual focus of drug policy on physician Rx
- This is achieved through a multiplicity of policies which are in many cases followed and observed
- Policy enforcement is more important than policy adoption
- Role of IT and organisations monitoring Rx is key
- Policies frequently involve incentives or disincentives

Pricing and reimbursement of pharmaceuticals in Europe: trends and conclusions

1. Regulatory Practices Intensify

Initially, emphasis was on supply-side measures, i.e. price (price control, cost-plus, price cut, price averaging, reference pricing)

Demand-side measures have attracted a lot of attention over the past 10 years: focus on Rx habits of physicians, dispensing patterns of pharmacists, consumer power, and incentive structures

- **Evidence-based medicine**
- **Budget-impact analysis**
- **Value for money**
- **Decentralisation**

Overall
a very complex environment with the need of continuous adaptation to new circumstances given fluctuations in policy

Source: Scrip, 2005.

2. Defining Eligibility for Public Reimbursement

Assessing technologies and restricting number of beneficiaries

NICE (UK)

Acetylcholinesterase inhibitors (AChEI) received positive technology appraisal in 2001...

"Donepezil, Rivastigmine and Galantamine should be made available in the NHS as one component of the management of those people with mild and moderate Alzheimer's disease…"

BUT…

received a provisional negative re-appraisal in '05.

Risk-sharing programmes and central funding

Public agencies in Europe

Targeted treatments in most (European countries)

Tougher environment and fixed budgets

3. Health Economics "Fourth Hurdle" Determines Market Access

Current standard

- England & Wales (NICE)
- The Netherlands
- Finland
- Denmark
- Sweden
- Norway
- Switzerland
- Portugal
- Baltic states
- Italy

Future implementation

- Germany?
- France
- Hungary
- Czech Republic
- Greece
- Spain
- Poland

Evidence-based purchasing and clinical cost-effectiveness: significant current and future uptake, but differences in implementation

4. Flexible Pricing Arrangements in Return for Controlled Use

Example: Targeted treatments

(*trastuzumab*) Herceptin™

(*rituximab*) Mab Thera™

(*iminitab*) Gleevec™

(*cetuximab*) Erbitux™

In **Germany** targeted therapies are not included in the Richtgrösse (drug budgets for physicians); as a result physicians can prescribe without restrictions

In the **UK**, NICE has appraised all the above; number of patients is controlled tightly

In **France**, Mab Thera and Herceptin are paid over and above the DRG system; only specialists can prescribe; the others are included in the budget

In **Sweden**, there is price negotiation and discounts given; conditional reimbursement Granted for 2 years, followed by re-evaluation and observational study

5. Europe: Continued Fragmentation and Diversity in P&R Systems

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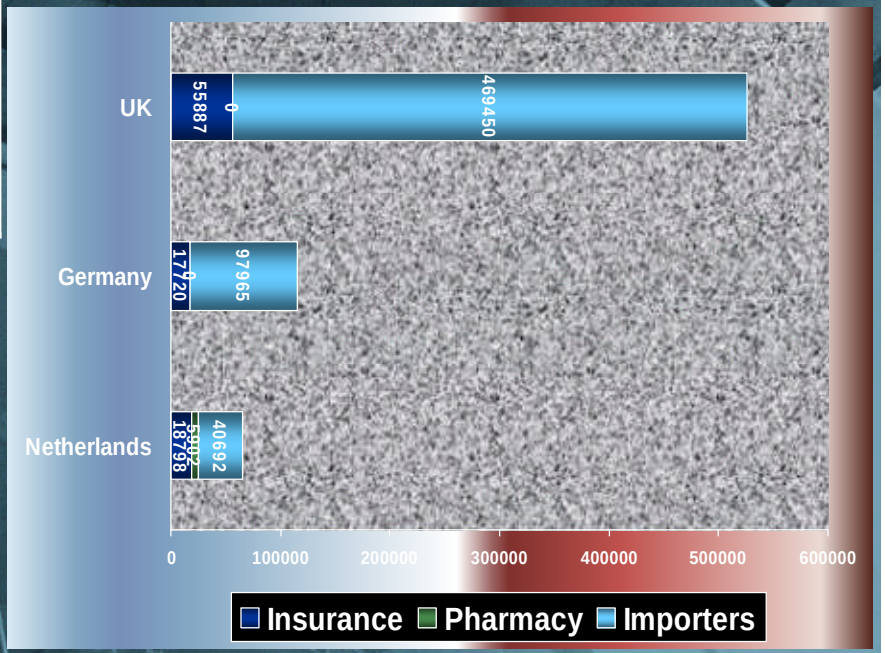
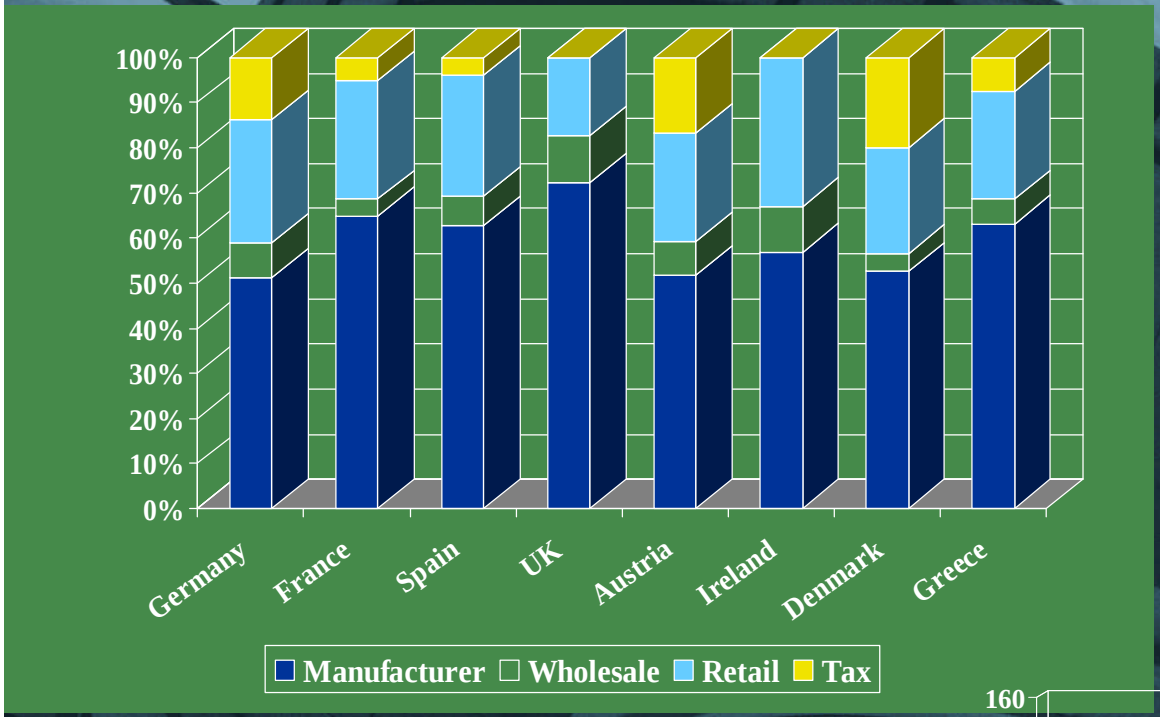
There are 25 different systems of P&R with different requirements and different assessment criteria; most frequently, multiple policies co-exist in each country

One of the results of fragmentation & differential policies is parallel trade, benefiting the distribution chain and harming the R&D based industry



Source: London School of Economics, 2004.

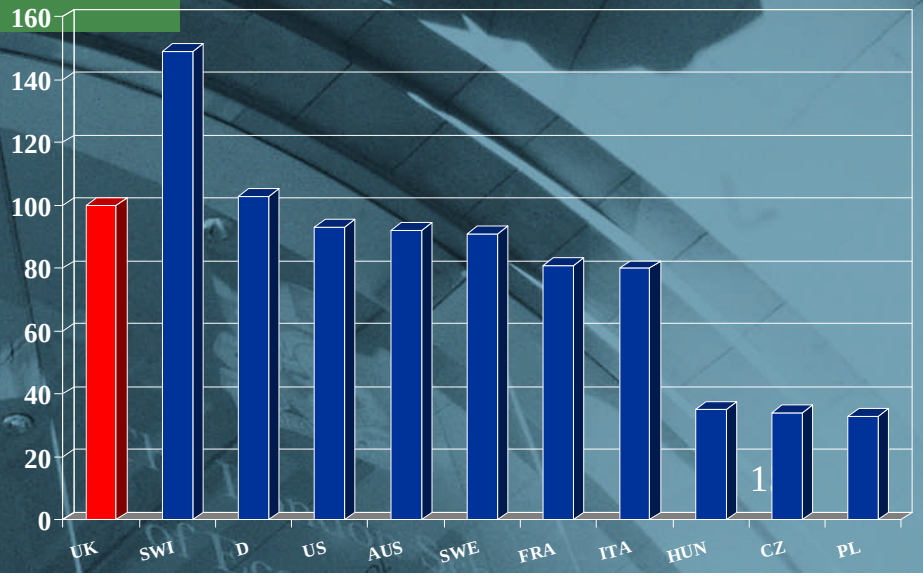
6. Europe: Certain stakeholders Continue to Benefit Disproportionately From the Pharmaceutical Value Chain



Distribution margins and taxes range from 30% to 50% of retail drug prices

Fragmented generic markets mean there are significant differences in generic drug prices across Europe

Manufacturers' discounts to wholesalers or pharmacists can reach 80% off reimbursed prices (UK, France)



Source: LSE, 2006.

Conclusions

- Continued emphasis on supply-side either directly (through price control) or indirectly (budget control)
- Increased emphasis on (proxy) demand-side
- Attempts to introduce rationality (either on supply-side or the demand-side) through health economic assessments
- Significant inefficiencies in parts of the value chain
- Regulation at times ad hoc and not appropriately targeted
- In a nutshell, balancing cost, efficiency and improved access continues to pose a significant conundrum