



Pharmaceutical Pricing Regulation and Central Health System Structures

Panos Kanavos

London School of Economics

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Pricing of Medicines: The Context

- Supply-side
 - Regulatory environment (MA and IPRP)
 - **Pricing policy**
 - **Reimbursement policy**
 - Industrial policy
- Proxy demand-side
 - Physicians
 - Pharmacists
- Demand-side
 - Patients: cost-sharing, OTCs, patient information, public health

Price is the outcome of the negotiated process between a monopolist (pharma industry) and a monopsonist (purchaser) [bilateral monopoly].

Pricing

A regulator's perspective

- **Scientific criteria & assessment of therapeutic benefit**
 - what is innovation?
- **Economic criteria**
 - budgets
 - assessment of cost effectiveness
- **Industrial policy (good citizenship approach)**
 - R&D
 - Employment
 - Exports

Pricing criteria for originator products in selected OECD countries

Feature	UK	GER	FRA	ITA	SPA	DEN	POL	NET
Medical value			?			?		?
Comparator prices			?					?
Cross country comparisons			?	?	?		?	?
Sales volumes			?					
Conditions of use	?	?	?	?	?	?	?	?
Price freedom	?	?	?			?		

- Pricing process usually kept separate from reimbursement process
- Multiple criteria often apply to set prices
- Administrative simplicity of price setting may be outweighed by pricing policy in other parts of the market
- Evidence-based pricing over the medium-term

Approaches to drug pricing regulation and country examples

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

Making sense of pricing methods for in-patent pharmaceuticals

- Theoretically, Monopoly Power Control through Price Regulation, traditionally through
 - *1. Rate of Return (RoR) Regulation*
 - *2. Price Setting*
 - *3. Value-based pricing*
 - *4. Controlling use*

1. Issues in Rate of Return (RoR) Regulation

- 'Reasonable' Return on Capital Investment
- Within this range, there is free pricing
- Strict demand-side
- Application: UK PPRS (with relative pricing freedom)
- Overinvestment in Capital Assets
- Inefficient Operation (Increased Costs Increased Revenue Margin)
- 'Economically Correct Rate of Return' to Enhance Innovation?

2. Issues in Price Setting regulation

- Historical Pricing+Justifiable Cost Increases
- Different variations
- Basic cost
- Cost-plus
- International comparisons
- 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

Price setting: Cost-Plus Pricing

- $P = (AVC + FC\%)*(1 + MK\%)$
- Price is set by government following application by relevant company
- Method includes production costs, and allowances for local content of R&D and promotion
- Forces companies to be "good citizens" in terms of research/development, employment and/or exports
- Notorious for attempting to inflate costs
- Transfer pricing?

Reference Price Systems

Variations

- **1. External referencing**
 - 1a. Average Pricing
 - 1b. International Price Comparisons
 - 1c. Average Pricing with Wealth Adjustments

- **2. Clustering (Internal reference pricing)**
 - Different types of Clustering
 - Foreign prices in terms of PPPs

1a. Average Pricing

- Take average of prices in a predetermined number of reference countries
- Price per pack/pill/DDD
- System needs close monitoring to ensure changes are incorporated
- exchange rate variations?

1b. International Price Comparisons

- Take into account in price negotiations
- Real cost data difficult to get
- Little knowledge of company internal pricing by regulators
- What countries to reference? (similar income? Where product has been launched?)

1c. Average Pricing with Wealth Adjustments

- Determine basket of comparator countries
- Usually a mix of high- and low-priced countries
- Take average price of basket
- Apply a notional wealth adjustment
- E.g. $P = (\text{Average Price}) * 85\%$

3. “Value-based” pricing in 2007

Current practice

- Denmark
- Switzerland
- Sweden
- Finland
- The Netherlands
- England & Wales [NICE]
- Portugal
- Norway
- Baltic states (Estonia, Latvia, Lithuania)
- Italy
- Australia
- Canada
- New Zealand
- Korea
- Turkey
- Brazil
- Mexico

Under preparation or rising in influence

- France
- Greece
- Poland
- Spain
- Hungary
- Slovenia
- Czech Republic
- Slovakia

3. Issues in value-based pricing

- To determine (extent of) price premium
- Explicit versus implicit
- Ex ante versus ex post
- What perspective?
- What costs?
- What data/outcomes?

4. Controlled use combined with Flexible Pricing Arrangements

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 Italy, prices are negotiated centrally, but the standard 50% discount to hospitals does not apply; there is a special fund at regional level and patient numbers are controlled tightly

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

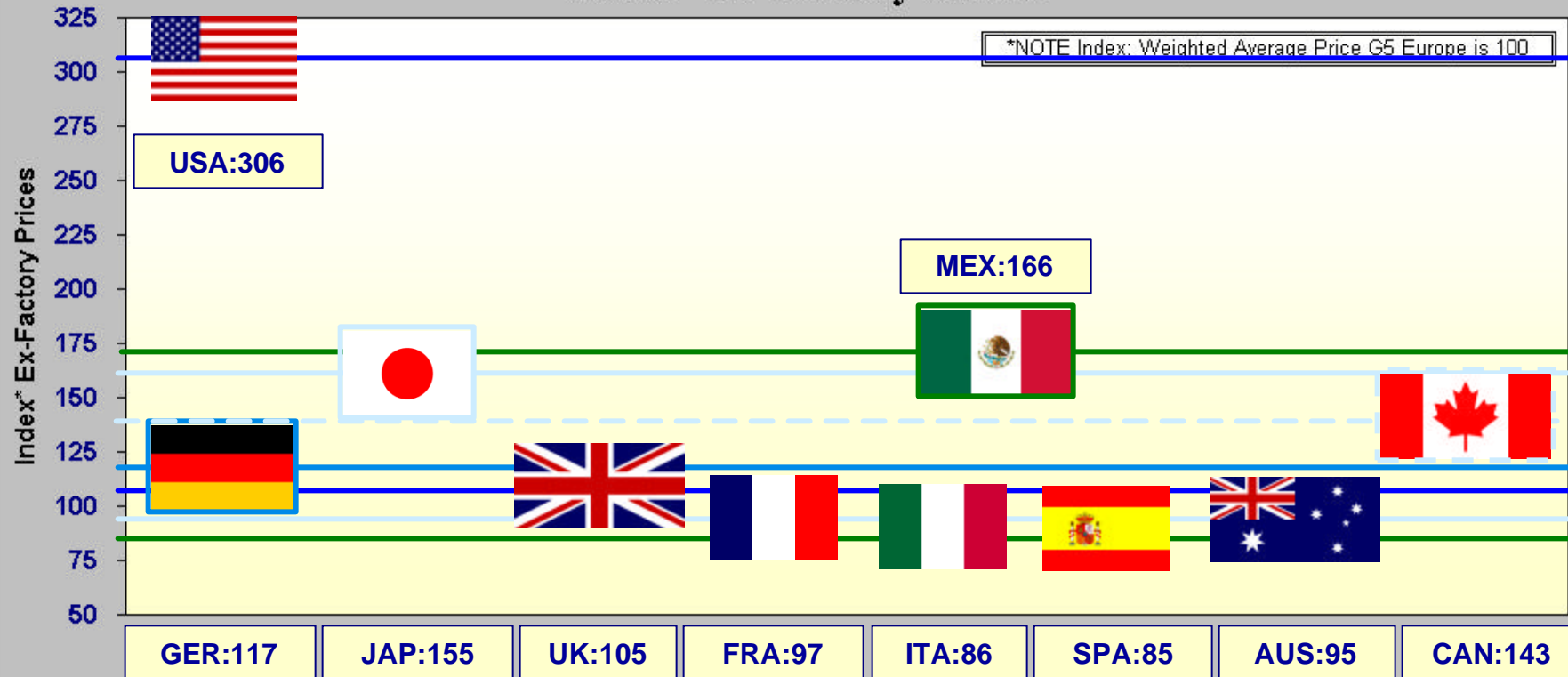
In France, Mab Thera and Herceptin are paid over and above the DRG system; only specialists can prescribe; the others are included in the budget

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

Price Levels in 2007 for top 50 original brands

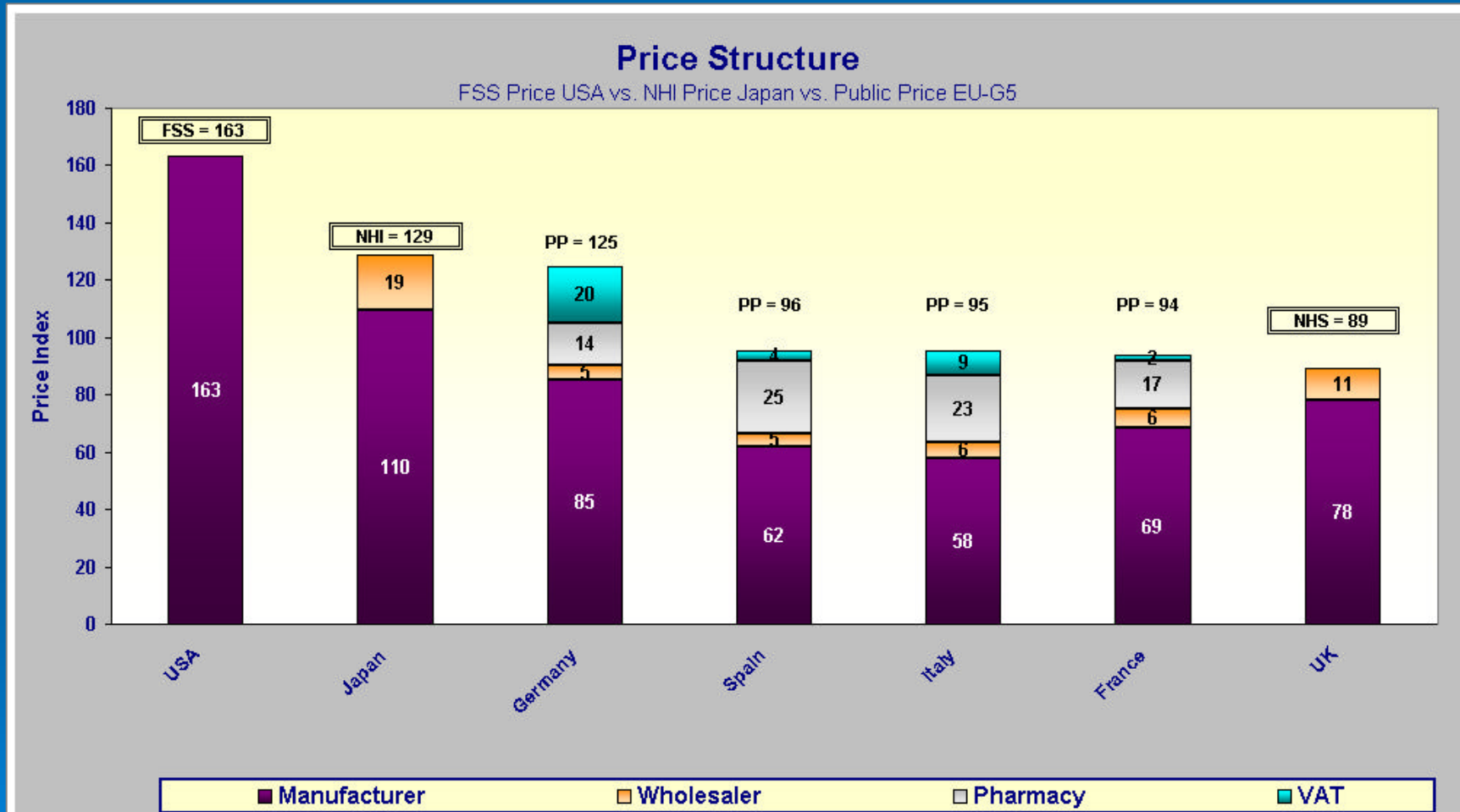
Great Price Differences across G10

Top 50 Sales G10 Index* Ex-Factory Prices



Impact of Price Levels and Distribution Margins

Payer perspective: Prices paid by governments

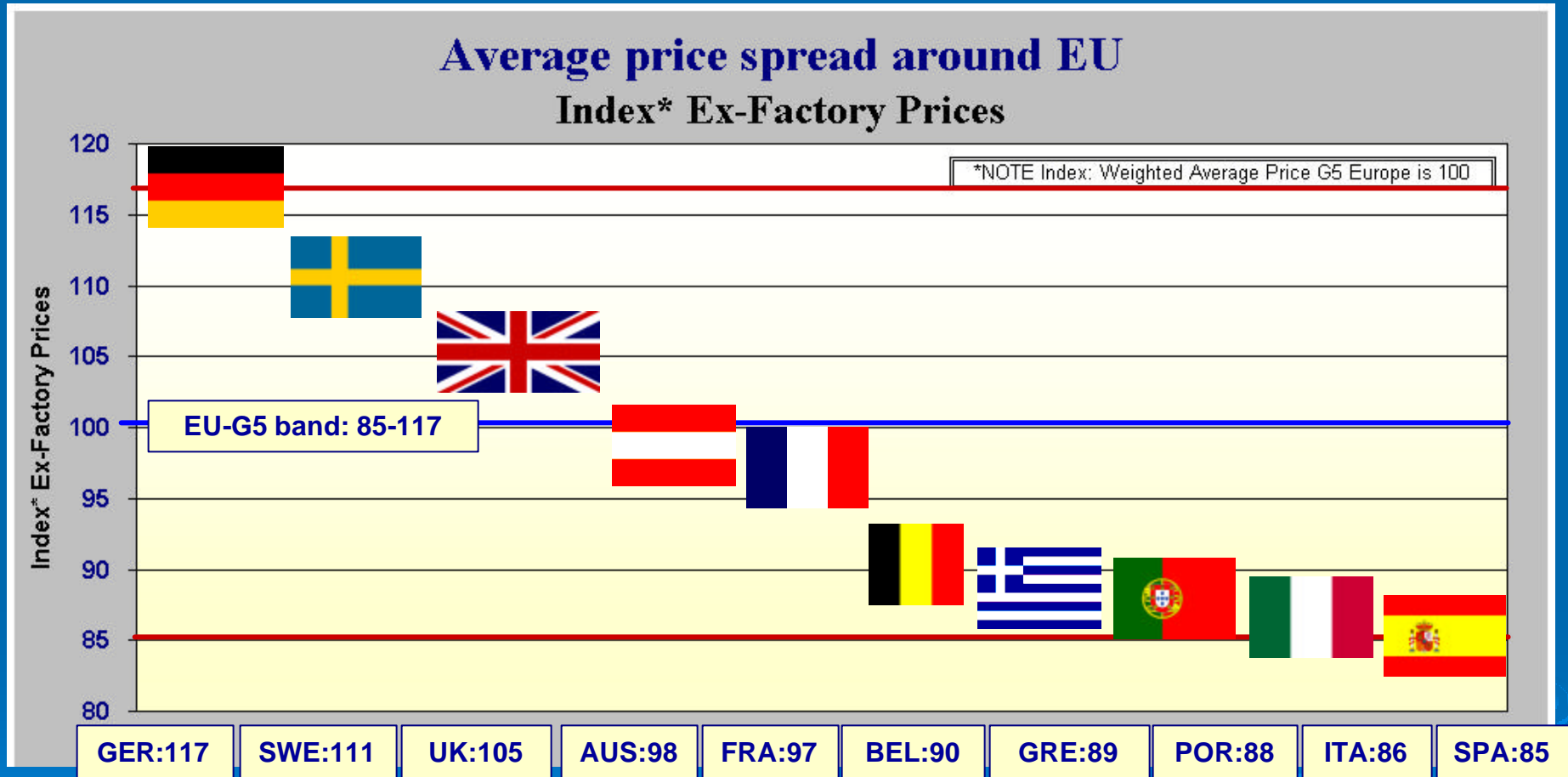


Price gap between US and G5 narrows when comparing FSS prices with PP

*NOTE: FSS is the only published government price in the US and is guiding price setting of overall procurement of pharmaceuticals of state and federal government. No information on margins is available

Price Levels in 2007 for top 50 original brands

Great Ex-factory Price Differences across the EU



- Germany, Sweden and UK above G5 average
- Southern Europe and Belgium at the low end
- France and Austria closer to G5 average

Criteria for drug reimbursement



Criteria for pharmaceutical reimbursement

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
- Increased coverage, epidemiological patterns and current lifestyles in Russia may place strain on available resources and as a result reimbursement policy needs to be streamlined (perhaps using benchmarks such as EBM principles or/and economic criteria)

Pricing of off-patent pharmaceuticals

- Pricing often linked to branded originators
- At times there is managed competition with tiered price reductions once entry occurs
- Price freedom model
- Reimbursement regulation through reference pricing (clustering)

Generic policy a cornerstone of
drug policy in many countries

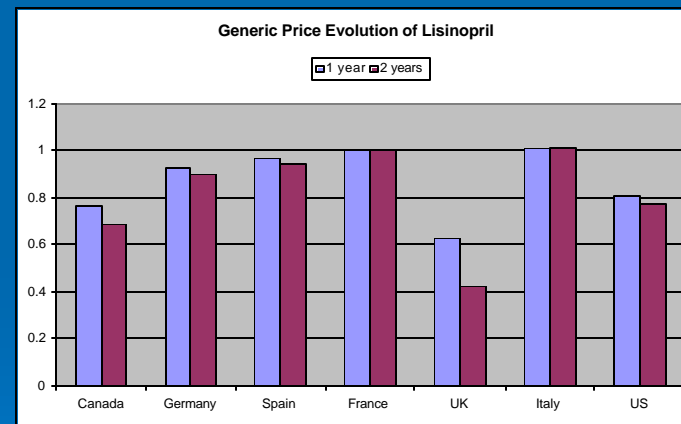
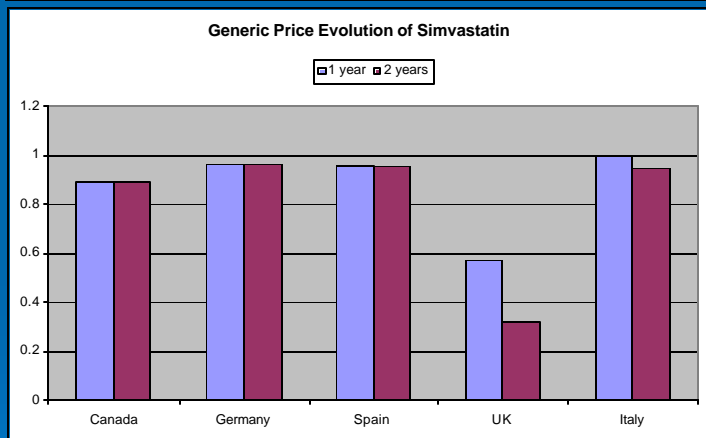
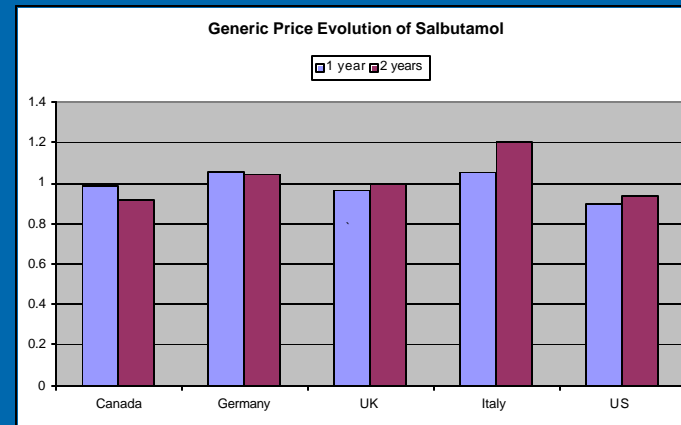
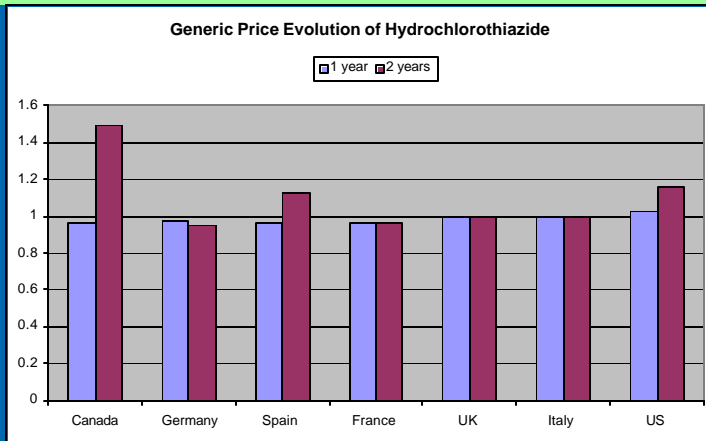
The promotion of generics in selected EU countries

Strongly	Yes	No	Country	Substitution		
				Limited form	If doctor agrees	Emergencies
		✓	Belgium		✓	
✓			Denmark		✓	
	✓		France	✓		
✓			Germany	✓		
	✓		Italy	✓		
✓			Netherlands	✓		
	✓		Spain	✓		
	✓		Ireland		✓	
		✓	Greece			✓
	✓		Portugal		✓	
	✓		Luxembourg			✓
✓			UK		✓	

Impact of Government Policies on Generic Prices and Competition

Generic price impact 1 & 2 years post generic entry

Generic price decreases one and two years post generic entry, volume adjusted



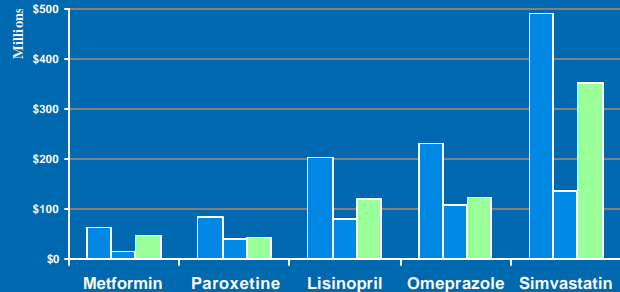
- Generic price declines post patent expiry have been exaggerated; prices may decline but not as fast as originally thought, esp. when regulated.
- On certain occasions prices of generics rise in the second year post patent expiry
- US and UK show, on average, greater price declines than Germany, France, Italy, Spain or Canada

Impact of Government Policies Effect of Discounts

Discounts often exceed 84% of reimbursed prices

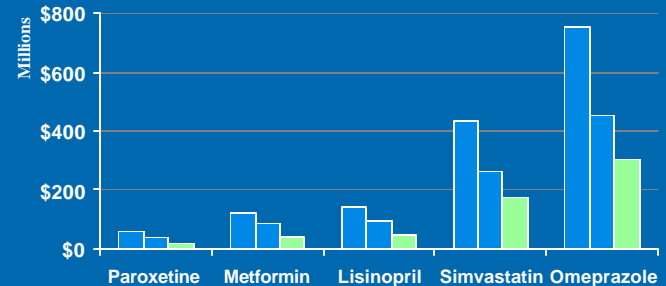
High discounts in EU G5 countries

United Kingdom



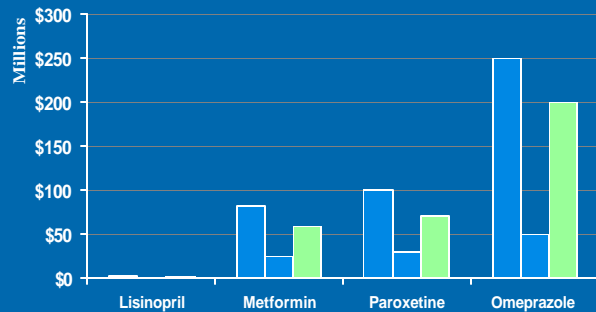
Allowable discounts to pharmacy exceed the reimbursement price by at least 200% in 65% of cases

Germany



Discounts can be sizeable and may exceed 35%, although their exact extent is unknown due to the different modes operating (price, volume, rebates, sales)

France



Discounts are significant and may exceed 75% of the reimbursed price, exceeding the officially allowable 10.75% discount to generics

- Cost to payer
- Cost after discount
- Potential payer saving

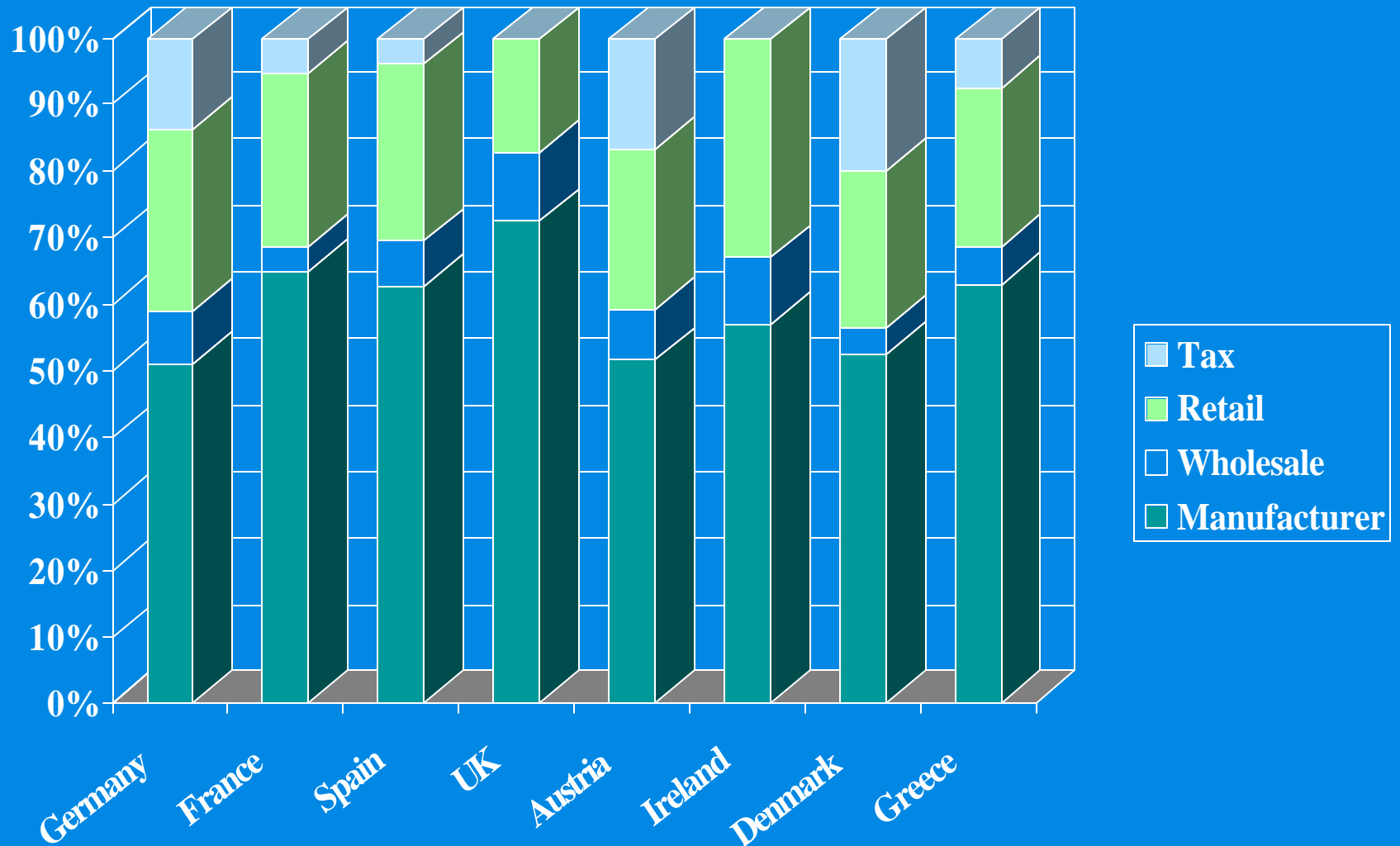
Distribution



Wholesale and retail margins as a % of retail price (RP) in selected EU Member States

Member state	Wholesale margin (% of RP)	Retail margin (% of RP)
Austria	14.9%	35.5%
Belgium	13.1%	31.0%
Cyprus	18.4%	25.0%
Denmark	7.4%	30.1%
Finland	4.3%	33.3%
France	9.7%	20.6%
Germany	9.8%	24%
Greece	7.8%	25.9%
Ireland	13.0%	33.3%
Italy	9.1%	26.7%
Malta	10.9%	16.7%
Portugal	10.7%	20.0%
Spain	9.6%	27.9%
UK	12.5%	10.4%

Distribution margins and taxes range from 30% to 45% of retail drug prices



Impact of Price Levels and Distribution Margins

Ex-Factory Prices vs Public Prices

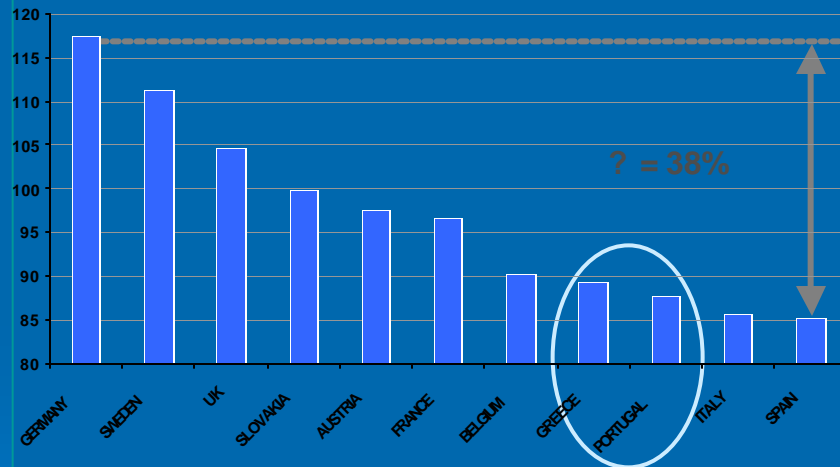
Similar EFP does not automatically lead to similar PP in EU15+

Ex-Factory Price (EFP)

Wholesale price

= Price that pharmaceutical companies charge directly to the local wholesalers (excl. VAT)

Ex-Factory price Index, G5 = 100



Greece / Portugal ? = 1%

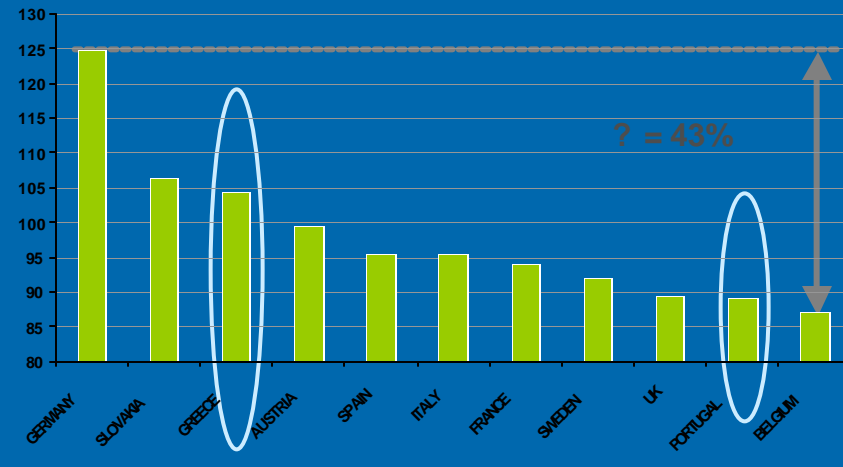
Note:

Public Price (PP)

Retail price

= Pharmacy selling price (incl. VAT)

Public price Index, G5 = 100



Greece / Portugal ? = 17%

Note:

*

*NOTE Index: Weighted Average Price G5 Europe is 100

Conclusions I

- Few countries allow free pricing of in-patent medicines or allow it with conditions
- Several pricing methodologies to suit different regulatory settings
- Pricing often kept separate from reimbursement
- There is a tendency towards (international) price comparisons and reference pricing
- Cost effectiveness is increasingly used to assess “value” of new products
- Generics very often subjected to reimbursement regulation

Conclusions ?

- **Pricing**: continued emphasis on price setting and gradual movement towards a negotiation model, compared with a command-and-control approach
- **Reimbursement**: multiple criteria for inclusion into the positive list, emphasizing medical benefit, cost effectiveness and budget impact; some industrial policy considerations
- **Role of health insurance**: key in not only paying the bill, but also setting policy on drug reimbursement and its parameters
- **Reimbursement policy**: needs to be characterised by transparency and visibility, although this is not always achieved