

ESF-IfW Conference on the Global Health Economy

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**Comparative Efficiency of Pricing Strategies
for drugs and their impact on technological
innovation.**

Reference Pricing: From theory to Practice.

**Some reflections from the Spanish
Pharmaceutical experience**

THE PHARMACEUTICAL SECTOR

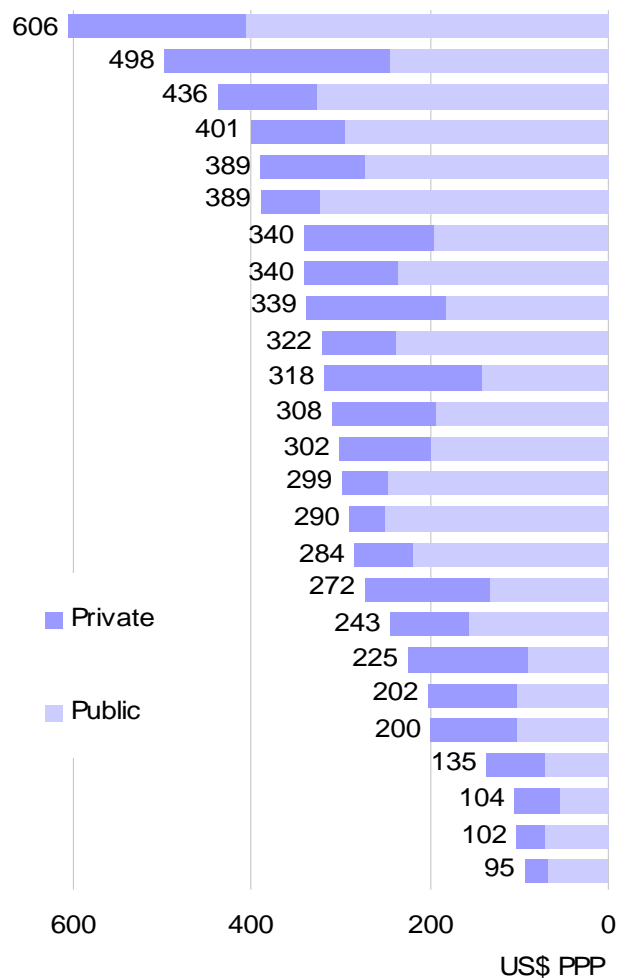
Total Pharmac sales /cápita, US\$ PPC

	2004
Australia	252
Czech Republic	376
Denmark	341
Finland	316
France	422
Germany	282
Greece	646
Iceland	552
Italy	382
Japan	382
Luxembourg	383
Holland	261
New Zealand	103
Norway	367
Portugal	271
Slovaquia	209
Spain	305
Sweden	347
Switzerland	400
Turkey	107
United Kingdom	282

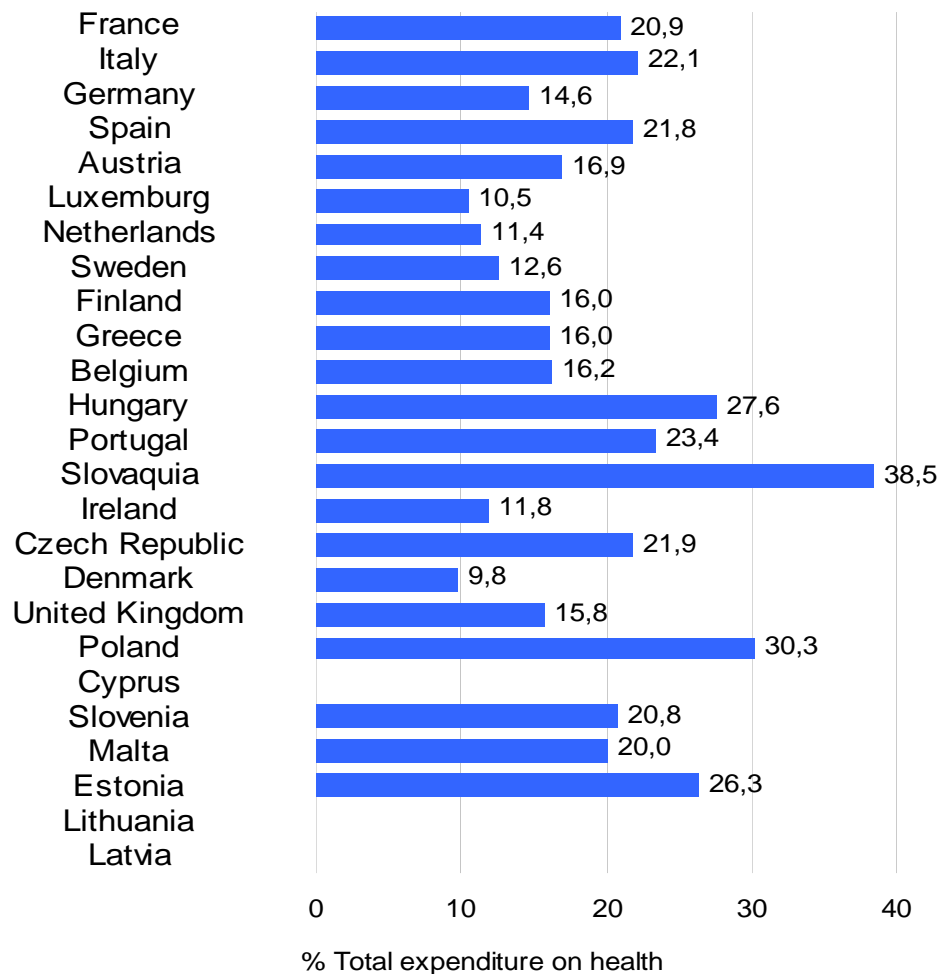
Many differences in the pharmaceutical expenditure

Pharmaceutical Expenditure in EU- 25

Expenditure on pharmaceuticals, per capita,
2003



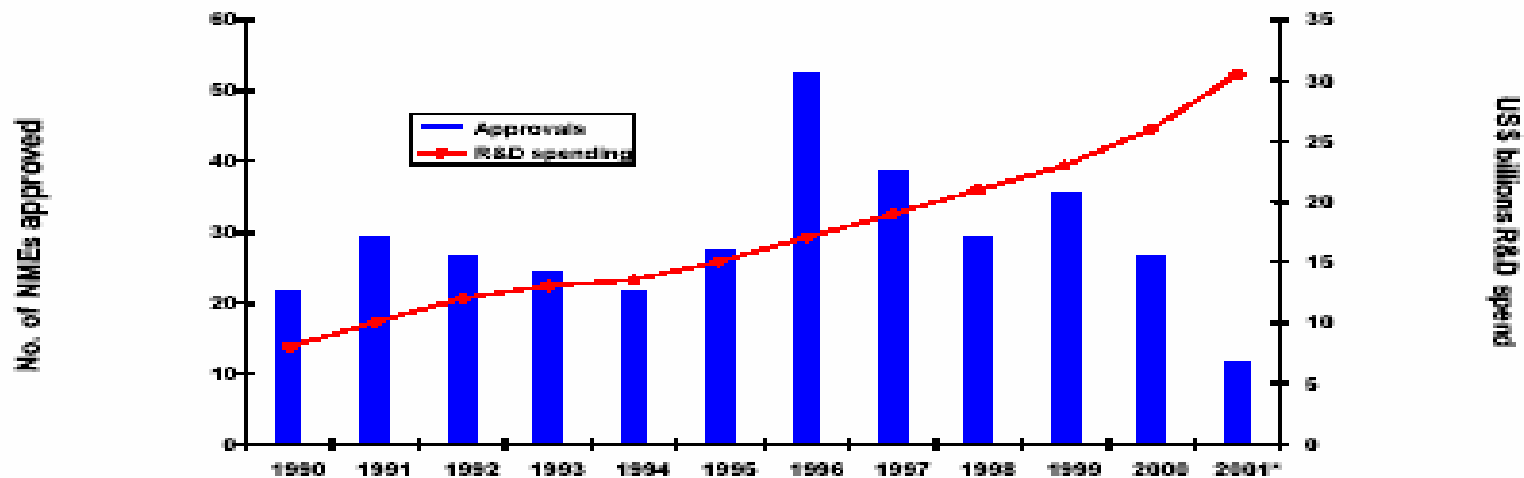
Pharmaceutical spending as a percentage of
total health expenditure, 2003



Source: The data are mainly from OECD Health Data 2005 and Health for All Database (HFA-DB). WHO/Europe . 2005. Data of some countries are different from 2003.

The innovation puzzle

R&D spending has increased but new molecular entity approvals have not

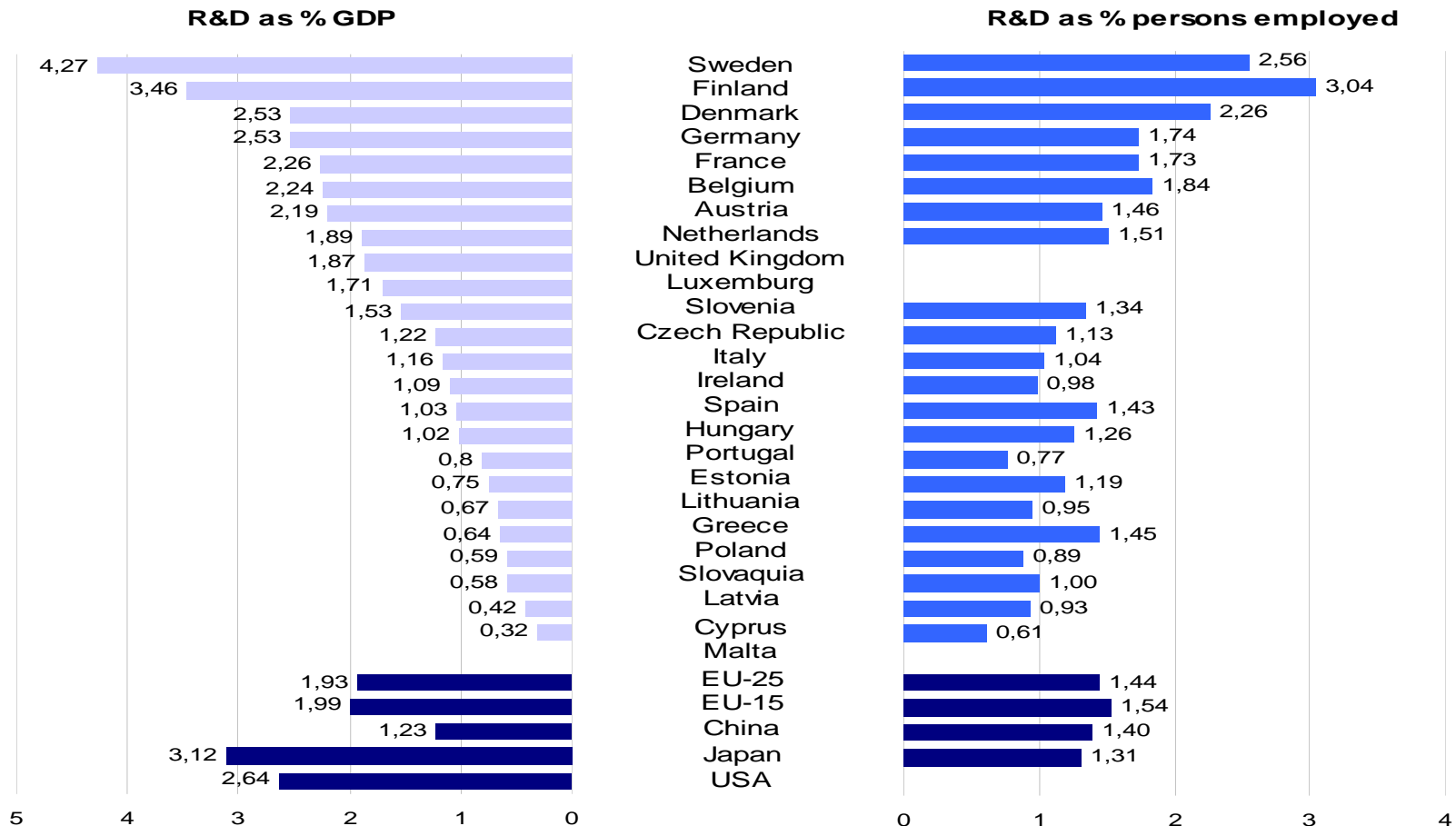


*NME (new molecular entity) total is through August 22, 2001. R&D spend for 2000 and 2001 are estimates. Source: Washington Analysis, LLC and PhRMA

Source: Panavos K (2007) from Priority Medicines for Europe and the World. WHO. November 2004

Expenditure on R&D: Far from the Lisbon Strategy(3%)

R&D in Europe (EU-25), China, Japan and USA. (2002)*.



*N: R&D % GDP Greece, Netherlands, Sweden data 2001

Source: Data from *European Commission. Science and Technology in Europe. 2005 Edition*

THE PHARMACEUTICAL SECTOR in the WORLD HEALTH CARE CONTEXT

DIFFERENCES IN AVERAGE ANNUAL EXPENDITURES PER CAPITA ON PHARMACEUTICAL PRODUCTS AMONG THE WORLD'S PRINCIPAL REGIONS

• North America	123,90
• European Community	102,90
• Other Western Europe	85,70
• Japan	276,60
• South and East Asia	5,00
• China	4,80
• Latin America	20,30
• Sub-Saharan Africa	3,30

- United Nations staff estimates for 1990 (in 1980 US dollars at prevailing exchange rates), quoted by F.M. Scherer (2000)

PRICE DIFFERENCES IN A SINGLE EUROPEAN UNION MARKET

Table 9-2. Weighted average price of pharmaceuticals in the main European Union countries in 2001 (Spain 100)^a

	Retail price + VAT %
Germany	203
Netherlands	176
UK	186
Belgium	169
Italy	116
Spain	100
France	93

Source: La industria farmacéutica en cifras, Farmaindustria, 2001.

^a A valuation that is properly adjusted to reality ought to consider the weightings of these prices in greater detail (given the diversity in amounts of consumption affected) and their different composition between prices of old and new products (given the effect this can have on their dynamics). Other studies provide a variety of data, quantifying with various weightings and at PPP values, but to date we have not encountered any statistic that offers a synthetic price index that is higher than the European Union average. Obviously, if this were not the case, the well-known problem of parallel trade would not exist.

DIFFERENT INTERESTS

Pharmaceutical Sector in Europe make for extremely controversial cost containment policies that affect the rate of investment in new health technologies

GOVERNMENTS

Contribution to health/

Drugs accessibility/ Control expenditure/

Innovation, trade, Industrial & employment policies

PHARMA INDUSTRY

Patents/ Profits

EUROPEAN UNION

Free movement of goods

Competitiveness

The concern for cost containment: Different pricing strategies

Table 6.1 Summary of approaches in the regulation of pharmaceutical prices in EU member states, 2003

	<i>Market segment</i>	<i>Free pricing</i>	<i>Direct price controls</i>	<i>Use of international price comparisons</i>	<i>Profit controls</i>	<i>Reference pricing</i>
Austria	In-patent		✓	✓		
	Off-patent		✓	✓		
Belgium	In-patent		✓	✓		
	Off-patent			✓		✓
Denmark	In-patent			✓		
	Off-patent			✓		✓
Finland	In-patent		✓	✓		
	Off-patent		✓	✓		
France	In-patent		✓	✓		
	Off-patent					✓
Germany	In-patent	✓				
	Off-patent					✓
Greece	In-patent		✓	✓		
	Off-patent		✓	✓		
Ireland	In-patent		✓	✓		
	Off-patent		✓	✓		
Italy	In-patent		✓	✓		
	Off-patent					✓
Luxembourg	In-patent		✓	✓		
	Off-patent		✓	✓		
Netherlands	In-patent		✓	✓		✓
	Off-patent		✓	✓		✓
Portugal	In-patent		✓	✓		
	Off-patent			✓		✓
Spain	In-patent		✓	✓		
	Off-patent			✓		✓
Sweden	In-patent		✓	✓		
	Off-patent		✓	✓		
UK	In-patent	✓			✓	
	Off-patent		✓			

Source: Updated from Mrazek (2002a).

Different reimbursement strategies

Table 7.1 Reimbursement and related features affecting the pharmaceutical market in selected countries

	<i>France</i>	<i>Germany</i>	<i>Italy</i>	<i>Netherlands</i>	<i>Spain</i>	<i>Sweden</i>	<i>Switzerland</i>	<i>UK</i>	<i>Australia</i>
Conditional/limited reimbursement exists	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
National guidelines on pharmacoeconomics	Planned	No	No	Yes	No	No	No	Yes	No
Pharmacoeconomics used in pricing decisions	Possible	No	Some products	Some products	No	Yes	Sometimes	Not directly	Yes
Drugs budget funded by	National	National	Regional	National	Regional	Local	Local	National	National
Co-payment culture exists	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Capped profits/sales rebates	Yes	No	Yes	No	Yes	No	No	Yes	No
Company free to set launch price	No	Yes	No	No	No	No	Yes	Yes	No

Source: UK Pharmaceutical Industry Competitiveness Task Force (2002).

Source: Regulating pharmaceutical in Europe, *European Observatory on*

MAIN COMPARATIVE STRATEGIES FOR PRICING DRUGS IN SOME EU COUNTRIES

PHARMACEUTICAL PRICE CONTROL STRATEGIES IN SOME EUROPEAN UNION COUNTRIES

	REFER. PRICING	INTERNAT REFEREN.	PROFIT CONTROL	POSITIVE LIST	NEGATIVE LIST	PRICE FREEZE AND CUTS
BELGIUM			*	*		*
FRANCE				*	*	*
GERMANY	*				*	*
ITALY		*		*	*	*
NETHERLANDS	*			*	*	*
SPAIN	*	*	*	*		*
UK			*		*	*

MAIN COMPARATIVE STRATEGIES FOR PRICING DRUGS IN SOME EU COUNTRIES

⁴From more to less regulated, the first group includes Italy, France and Japan where launch prices are regulated and afterward are revised downwards over the drug's life cycle. The price of new varieties is related to the price of established varieties. In addition, consumer and physicians demand are expected to be inelastic due to insurance coverage, and generics substitution by pharmacists was not allowed in France and Italy at the time of the study. Moreover, pharmacies are paid a margin on the product price which may encourage the sale of more expensive products. The second group includes UK and Germany where corporations are free to set prices at launch but prices cannot increase (freely) later on. In addition, in both countries there is some type of upper bound to prices, implemented either through a reference price (Germany) or a maximum overall rate of return (UK). Generics substitution by pharmacists is the main source of price-demand elasticity, since they keep the margin between the reimbursement price and the manufacturers price. This is possible in UK, and to a lesser extent in Germany. The third group includes US and Canada where prices are free, consumers' and physicians' demands appear to be less inelastic and generic substitution on the side of the pharmacist is encouraged as a means to promote competition.

BASICS FOR REFERENCE PRICING.

- A PROCUREMENT POLICY: A SYSTEM WHERE A MONOPSONIST BUYING AGENT DECIDES ON A REIMBURSEMENT PRICE AND THEN THE USER/PATIENT OR INSURER PAYS THE DIFFERENCE IF THE MEDICINE OF CHOICE IS MORE EXPENSIVE
- HOWEVER, *RP* DIFFERS IN THE DETAILS AND SCOPE
 - GERMANY, THE NETHERLANDS, SWEDEN, DENMARK, NEW ZEALAND, POLAND, SLOVENIA, SPAIN, USA, BRITISH COLUMBIA (CANADA), ITALY AND AUSTRALIA, BUT WITH SIGNIFICANT DIFFERENCES.

REFERENCE PRICING

– THE BASICS OF RP

- WE CALL PR THE REFERENCE PRICE, PC THE PRICE FACED BY THE CONSUMER, PL THE PRICE CHARGED BY LABORATORIES AND K THE EXISTING COPAYMENT PERCENTAGE
- Case 1: If $Pl_1 < Pr$, Pc is set at kPl .
- Case 2: If $Pl_2 > Pr$, Pc is set at $Pl - Pr + kPr$.
- The implicit unit subsidy in each case is $T_1 = (1 - k)$ and $T_2 = (Pl_2 - Pc) / Pl_2 = (Pr - kPl_2) / Pl_2$

REFERENCE PRICING

– THE BASICS OF RP

- Since $Pl_1 < Pl_2$ and $Pl_2 > Pr$, T_1 will compare with T_2 according to k and Pr . This is, the per product net subsidy is larger when lower is the difference between Pr and Pl_2 , and lower is the co-payment k .
- Although a k parameter depending on $(Pl-Pr)$ might be postulated too.

REFERENCE PRICING

- CHARACTERISTICS

- **THE THIRD-PARTY PAYER (PUBLIC OR PRIVATE INSURER) DIRECTLY SETS A CEILING (EXERCISING A SORT OF A RELATIVE *MONOPSONY POWER*) TO THE AMOUNT TO REIMBURSE TO THE MANUFACTURER FOR A PRESCRIBED PHARMACEUTICAL PRODUCT.**
- **RP IS EQUIVALENT TO SETTING A *COPAYMENT* WHICH:**
- **IMPLIES A *VARIABLE* AMOUNT DEPENDING ON THE PRICE OF THE SELECTED DRUG; AND**
- **MAY BE *AVOIDABLE* IF IT IS CHOSEN A PRODUCT NOT PRICED ABOVE THE REFERENCE PRICE.**

REFERENCE PRICING

– (...) CHARACTERISTICS

IDENTICAL REIMBURSEMENT CEILINGS ARE DEFINED BY GROUPS OF PHARMACEUTICAL PRODUCTS. ‘CLUSTERS’ OF PHARMACEUTICALS ARE DEFINED IN TERMS OF THEIR *INTERCHANGEABILITY*.

- **INTERCHANGEABILITY MAY BE INTERPRETED, FROM A MORE TO A LESS RESTRICTIVE SENSE, ACCORDING TO CHEMICAL, PHARMACOLOGICAL OR THERAPEUTIC EQUIVALENCE.**
- **CLUSTERS MAY OR MAY NOT INCLUDE PATENTED PRODUCTS.**

REFERENCE PRICING

– (...) CHARACTERISTICS

- **THE REIMBURSEMENT CEILINGS ARE ESTABLISHED BY THE INSURER USING (ie. THE OBSERVED DOMESTIC PRICES OF THE PRODUCTS INCLUDED *IN THE SAME CLUSTER* OR GROUP).**
- **THESE REIMBURSEMENT CEILINGS ARE ADJUSTED PERIODICALLY BY A PREVIOUSLY, ANNOUNCED OR NOT, ADJUSTMENT FACTOR. THE CONCEPT OF INTERCHANGEABILITY AND THE CRITERIA TO SELECT THE REFERENCE PRICE ARE REVIEWED AND POSSIBLY CHANGED TOO.**
- ***RP IMPLIES A REIMBURSEMENT LIMIT RATHER THAN A FINAL MARKET PRICE.***

Main learnings on the effects of RP on Health Teechnology investments

- RP is not anymore a device for Pharmaceutical Reimbursement in markets with free prices, but an extra tool of many countries for cost containment policies. RP is 'context dependent'
- This loss of focus is affecting the whole spectrum of health care: side effects on other spending items, on incentives to invest in R&D, uncertainty on bioequivalence criteria and on consumers demand.

Main learnings (cont.)

- Expected positive welfare effects in making demand more elastic and reducing market power, by promoting price competition under product differentiation,.... to be tested against potential delays in favouring a competitive market for generics and creating the 'generic paradox' (brand product prices go up due to differentiation and consumers brand loyalty)
- For all these effects implementation details are extremely important; particularly whether RP affects only off-patent drugs (Germany, Denmark, Norway, Spain, Sweden) and just for chemical equivalence groups (not extended to pharmacological and therapeutical –more heterogeneous equivalence criteria-, as in Germany, Netherlands and New Zealand)

Main learnings (cont.)

- Impact on dynamic efficiency due to medium term effects on investment in R&D, depending on the scope of the implementation and global incidence on sales (‘quantity’ and not just price controls).
- The overall assessment of the RP policy may depend on the initially observed price differences between clustered products, the size of the existing generics market and how quickly and misleadingly RP moves prices to marginal costs given the initial sunk costs of the investments made by the pharmaceutical company.

THE EFFECTS OF COST CONTAINMENT POLICIES IN THE PHARMACEUTICAL MARKET

- ANALYSIS OF THE EFFECTS:
 - **CHANGES THAT AFFECT THE AVERAGE RATE OF EXPENDITURE GROWTH (FOR INSTANCE, BEFORE AND AFTER THE INTRODUCTION OF RP);**
 - **A ONCE-FOR-ALL SHIFT REDUCTION WHICH DOES NOT HELP TO CHANGE THE EFFECTIVE RATE OF INCREASE (THE SLOPE);**
 - **PERVERSE CHANGES WHEN A STEP DECREASE IS REPLACED BY AN EVEN HIGHER THAN BEFORE INCREASE IN EXPENDITURE TREND,**
 - **SUCCESSFUL REFORMS WHEN BOTH SHIFT AND SLOPE DECREASES APPEAR AFTER THE CHANGES.**

IN ASSESSING THOSE EFFECTS

- THE ROLE OF DRUGS MUST BE SEEN IN THE CONTEXT OF THE HEALTH CARE SYSTEM AS A WHOLE
- AND WE NEED TO KEEP IN MIND THAT INCENTIVES FOR DEVELOPING NEW DRUGS ARE ESSENTIAL TO THE LONG TERM PRODUCTIVITY AND EFFICIENCY OF THE ENTIRE HEALTH CARE SYSTEM.

NEW CONTEXT FOR DRUGS POLICIES

- NEW POWER RELATIONSHIPS IN THE PHARMACEUTICAL SECTOR
- *MANAGED CARE* (HMO TYPE, UNDER PER CAPITA FINANCING
- AND ‘CHARGE-BACK STRATEGIES WITH MANUFACTURERS)

- *PHARMACEUTICAL BENEFIT MANAGEMENT ORGANIZATIONS*
- (TO MANAGE THE PAYMENT PAPERWORK ON OUT-PATIENT
- PRESCRIPTION DRUG INSURANCE CLAIMS, USUALLY
- UNDER RISK TRANSFER)

NEW BALANCES OF FINANCIAL RISK HOLDING AND MANAGEMENT

How financial resources are allocated at the micro level

Table 1: FRAMEWORKS FOR HEALTH CARE AND EVOLUTIONARY STAGES

Departure point:

Planning/ Finance/ Insurance coverage/ Purchasing care/ Production
Health Department, integrating all the providers as budget units (cost centers)

Evolution:

A)
Planning/ Insurance **Purchasing** **Production**
Health Depart. **Central Health Care Service Unit** **Manag. Units**

B)
Planning/ Insurance **Purchasing** **Production**
Health Depart. **Regional Health Care Service Unit** **Manag. Units**

COMPARATIVE STRATEGIES FOR PRICING DRUGS IN CONTEXT

*How financial resources are
allocated at the micro level*

C)

<u>Planning</u>	<u>Insurance</u>	<u>Purchasing</u>	<u>Production</u>
Health Depart.	Health Care Service	Health Areas	Manag. Units

D)

<u>Planning</u>	<u>Insurance</u>	<u>Purchasing/ Production</u>
Health Depart. Networks of Manag. Units	Health Care Service	Health Areas, Primary care physicians,

E)

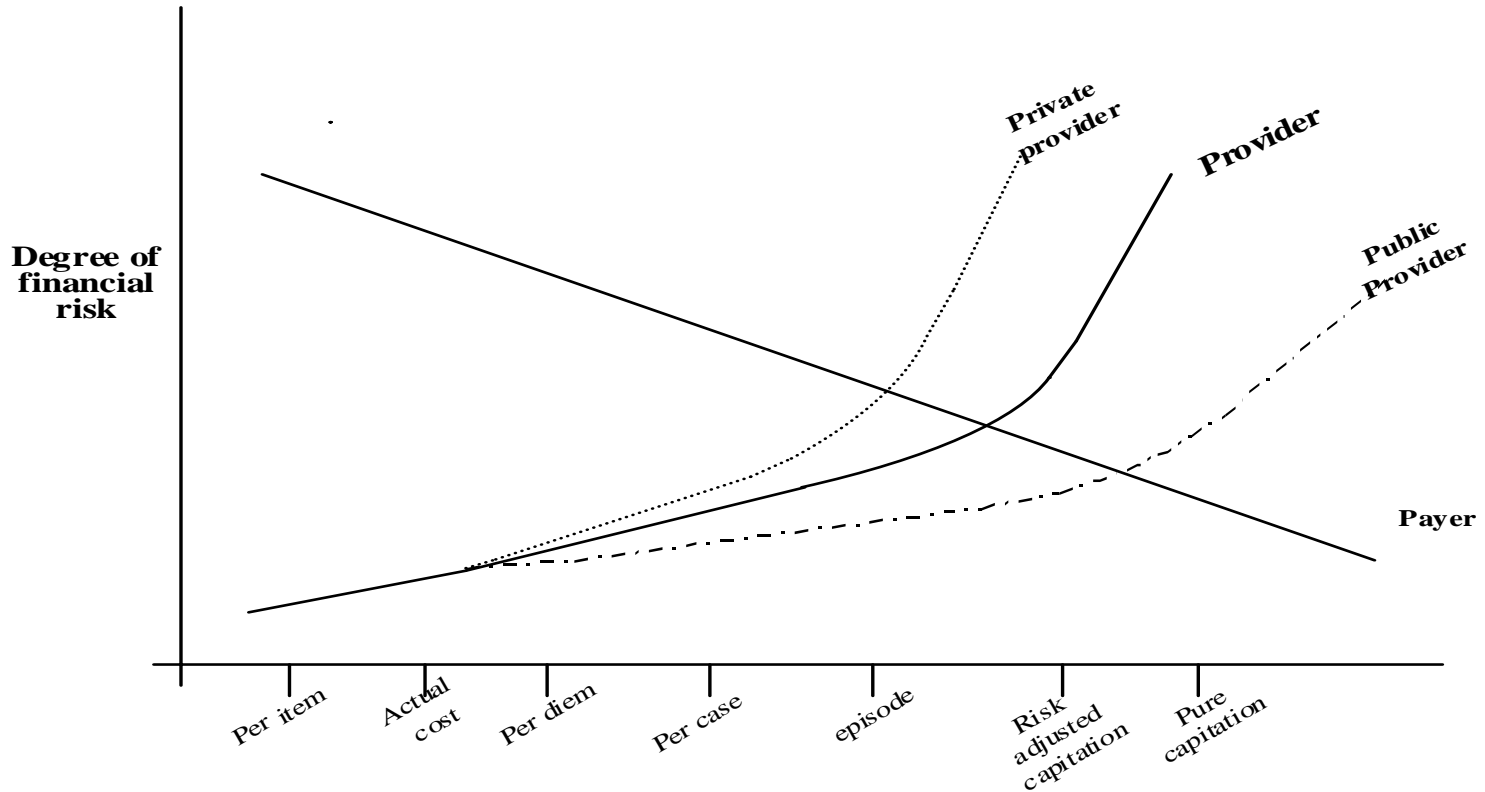
<u>Planning/ Insurance</u>	<u>Insurance Management/Purchasing</u>	<u>Production</u>
Health Depart/ Health Care Service	Networks of providers/ Non public Insurers	Health Care Manag. Units



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Source: Averhill (2004): transferring financial risk
from payers to providers



OTHER CONTROVERSIAL ISSUES ON PHARMACEUTICAL REGULATION:

**ON LICENSING (L), PRICING (P), REIMBURSEMENT (R)
AND PRESCRIPTION POLICIES (M),**

- a) **A CENTRALISED vs. A DECENTRALISED STRATEGY: THE ROLE OF THE CENTRAL STATE**
- b) **THE REGIONAL DISCRETION IN PHARMACEUTICAL POLICIES (BEING THE FINAL PAYERS OF THE DRUGS BILL)**

- AND IN SOME COUNTRIES:
- ...WITHIN A SOCIAL SECURITY CONTEXT WITH SOME ROLE FOR THE NATIONAL INDUSTRIAL (INNOVATIVE?) PHARMACEUTICAL SECTOR...
- ...WITH A PROTECTED DISPENSATION NETWORK OF PHARMACISTS, AS INDEPENDENT PROFESSIONALS CHARGING % MARGINS...

- **TOO MANY VECTORS FOR COST CONTAINMENT PUT IN PLACE:**
- BREAKING THE MONOPSONY: WHO IS HERE HAPPY?
- BREAKING THE DISPENSATION MONOPOLY: HOW TO DEAL WITH THE TRANSITION?
- REFERENCE PRICING (AVOIDABLE COPAYMENT OR UNDER THE FORM OF FACE 'TARIFFS' OR YOU ARE DELISTED)
- HIGH PRICES, FROZEN INCREASES, THERAPEUTICAL MINOR INNOVATIONS, DEVOLUTION OF EXCESS OF REVENUES...



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SOME MESSO-MACRO GLOBAL BUDGETING TECHNIQUES:

–THE PHARMACEUTICAL BENEFIT MANAGEMENT COMPANIES EXPERIENCE IN MANAGED CARE: ‘VISADOS’ (SECOND OPINION), ‘FORMULARIES’, TREATMENT PROFILES IN MANAGING ILLNESSES EPISODES..

–UNDER CAPITATION IN REGIONAL FINANCCE, REGIONAL HEALTH AUTHORITIES TEND TO FOLLOW HEALTH MAINTENANCE ORGANISATIONS). PRICES ARE SIMILAR BUT NOT PER UNIT COSTS OF DRUGS



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•**SOME OTHER MICRO AREAS**

•**Competition: ARE PVP MAX PRICES?**

•**Incentives: THE ROLE OF THE DISPENSER IN
DRUG SUBSTITUTION**

•**Clinical budget holding: CHANGING PRESCRIBING
PRACTICES UNDER NEW RISK-TRANSFER
SCHEMES TO PROVIDERS**

REFERENCE PRICING

– SOME CONTROVERSIAL ISSUES

- *THE CONCEPT OF INTERCHANGEABILITY*
- **LEVELS: CHEMICAL, PHARMACOLOGICAL AND THERAPEUTIC EQUIVALENCE**
- **QUESTIONS ON THE HETEROGENEITY IN THE SAME GROUP OF MEDICINES**
- **DOES THE DEGREE OF POTENTIAL HETEROGENEITY DIFFER BETWEEN LEVELS OF INTERCHANGEABILITY?**
- **WHAT ARE THE EXPECTED EFFECTS OF HETEROGENEITY IN THE SAME GROUP OF MEDICINES?**

REFERENCE PRICING

– (...) SOME CONTROVERSIAL ISSUES

- **THE DEGREE OF POTENTIAL HETEROGENEITY DIFFERS BETWEEN LEVELS OF INTERCHANGEABILITY.**
 - **FOR LEVELS 2 AND 3, FURTHER HETEROGENEITY PROBLEMS MAY ARISE**
 - **SORTS OF PROBLEMS ARISING FROM HETEROGENEITY BETWEEN CLUSTERING DRUGS (“THE COSTLY CONSEQUENCES OF ASSUMING ALL PATIENTS ARE THE SAME”) PARTICULARLY IMPORTANT IN LEVEL 2 AND 3 GROUPS.**

REFERENCE PRICING

- IMPACT

- IT APPEARS THAT *RP* PRODUCED *SHORT TERM* REDUCTIONS IN INSURER'S *EXPENDITURE*. *RP* DOES NOT RESULT IN IMPORTANT *LONG TERM* SAVINGS.
- THE *PRICE* OF PRODUCTS COVERED BY *RP* TEND TO DECREASE. INITIAL PRICE REDUCTIONS ARE REPORTED IN ALL COUNTRIES WHICH INTRODUCED THIS MECHANISM.
- PRICE AND MARKET SHARE OF *NON COVERED PRODUCTS* INCREASED NOTABLY. GENERALLY, PHARMACEUTICAL FIRMS INCREASED THE PRICES OF PRODUCTS NOT DIRECTLY AFFECTED BY *RP*.

REFERENCE PRICING

- (...) IMPACT
- **WHEN THE *GENERIC* SUBSTITUTION RATE WAS HIGHER BEFORE IMPLEMENTING REFERENCE PRICING, THE EFFECT OF *RP* ON GENERIC MARKET SHARE HAS BEEN MINIMAL, ALTHOUGH IN SOME COUNTRIES AS IN GERMANY, A MODERATE INCREASE IN THE SHARE OF GENERICS IS OBSERVED**
- **AT ANY RATE, THERE EXISTS *DIFFERENT TYPES OF REFERENCE PRICE SYSTEMS*:**
 - **DIFFERENCES IN THEIR PRODUCT COVERAGE: LEVEL OF EQUIVALENCE (CHEMICAL, PHARMACOLOGICAL AND THERAPEUTIC) AND INCLUSION OR EXCLUSION OF PATENTED DRUGS.**

REFERENCE PRICING

- ADVANTAGES AND DISADVANTAGES
- **MANUFACTURERS REMAIN FREE TO SET ANY PRICE THEY WISH. PHARMACEUTICAL COMPANIES MAY INCREASE THEIR MARKET SHARE IN A FULLY TRANSPARENT CONTEXT.**
- **RP DOES NOT SET LEGAL LIMITATIONS ON THE FREEDOM OF THE DOCTOR TO PRESCRIBE DRUGS, SINCE ALL DRUGS ARE AVAILABLE (IN CONTRAST WITH POSITIVE AND NEGATIVE LISTS).**
- **POTENTIAL REDUCTIONS IN PHARMACEUTICAL EXPENDITURE (THE COST CONTAINMENT EFFECT) MAY BE ACHIEVED WITHOUT ANY SACRIFICE IN EFFECTIVENESS (RP HENCEFORTH WILL IMPROVE COST-EFFECTIVENESS)**

REFERENCE PRICING

- (...) ADVANTAGES AND DISADVANTAGES
- **REFERENCE PRICING MAY FAIL TO CONTAIN PHARMACEUTICAL SPENDING.**
- **(A) *RP* CAN ONLY BE APPLIED TO A NARROW PROPORTION OF THE PHARMACEUTICAL MARKET, AND USUALLY NOT TO THE DRIVING FACTOR OF THE DRUGS BILL GROWTH.**
- **(B) FIRMS MAY MINIMIZE THE EFFECT OF *RP* ON TOTAL PHARMACEUTICAL REVENUES: ATTEMPTING TO RECOVER LOSSES BY INCREASING PRICES OF THOSE NON COVERED BY *RP*. *RP* STIMULATES THE INDUSTRY TO MAKE A MAJOR EFFORT IN ORDER TO PROMOTE DRUGS THAT ARE NOT UNDER THE SCHEME.**

REFERENCE PRICING: ADVANTAGES AND DISADVANTAGES

- **(C) SAVINGS IN PHARMACEUTICAL EXPENDITURE UNDER *RP* ARE BASICALLY ACHIEVED AT THE EXPENSE OF INCREASED EXPENDITURES IN THE UTILIZATION OF OTHER HEALTH CARE SERVICES, AS HIGHER HOSPITAL ADMISSION RATES OR HIGHER RATES OF REFERRAL TO OTHER PHYSICIANS (HIGHER COSTS ELSEWHERE IN THE HEALTH SYSTEM).**
- **RP IS ALSO QUESTIONED BECAUSE OF ITS INSENSITIVITY TO DIFFERENCES IN THE CLINICAL PROFILE OF DRUGS THE HETEROGENEITY PROBLEM IS PRESENT IN EQUIVALENCE LEVEL 2 AND 3.**
- **FINALLY, *RP* IS ALSO CONTENTIOUS BECAUSE OF THE POSSIBLE NEGATIVE EFFECTS ON EFFICIENCY AND ON R&D.: WHAT DOES IT ADD TO A WELL DEVELOPPED COMPETITIVE MARKET FOR GENERICS?**

REFERENCE PRICING in THE SPANISH CONTEXT

- **ADDENDA ON INSTITUTIONAL DETAILS IN SPANISH**

- **Global: In 2004 total health expenditure amounts 8.1% of the Spanish GDP, 1.594 US \$ pc. (80% public, 20% private)**
- **% public health expenditure on drugs: 23%;**
- **public/total expenditure on drugs: 80%**
- **co-payment rate for public expenditure on drugs: 7%**
- **public expenditure on drugs per capita: 9 % below average EU**



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Some data on pharmaceutical expenditure in Spain

- **total expenditure on drugs per capita: 9 % below average EU**
- **price of drugs (weighted average): 12 % below EU**
- **increase in the average cost of prescription 1990-2000: 100%**
- **increase in the average price 1994-2001: 50%**



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- **1986: Ex-factory price: 100; wholesale margin: 13.6; Pharmacy margin: 46.2; VAT: 9.6; Retail price (including VAT): 169.4**
- **2000: Ex-factory price: 100; wholesale margin: 10.6; Pharmacy margin: 42.8; VAT: 6.1; Retail price (including VAT): 159.6**
- **Public financed Drug expenditure, at constant prices: 8% (29% is price; 27% is population growth; 44% is prescription per person annual growth)**
- **RP ‘savings’ over the 1998-2001 period just a 4% of total estimated savings**

Explanatory factor of the consumption growth	Annual acumulative growth rate	% of the cost's total growth
DEMOGRAPHIC FACTORS	3,59	38,1
-Increase of the population protected by SNS	1,89	20,2
- Ageing of the protected population*	1,67	17,9
Increase in consumption intensity (amount)	1,45	15,5
INCREASE IN PRESCRIPCION SALES PRICE	3,91	41,7
-General inflation (IPC)	3,63	38,8
-- Specific inflation and quality changes	0,27	2,9
PUBLIC FINANCING INCREASE (effective co-payment reduction)	0,13	1,4
MIXED EFFECTS (residual factor)	-	3,3
TOTAL INCREASE	9,35	100

Source: Own estimation from Farmindustria data (2003).

* Estimation made on a basis where a pensioner, on average, consumes 6 times more medicaments than the rest of the population.

Pharmaceutical consumption and expenditure in Spanish Social Security prescriptions per insured person per year (1995-2001) in pesetas/year

Pharmaceutical consumption	1995	1997	1999	2001
Pharmaceutical consumption ^a	21,552	25,036	30,035	33,724
Consumption of products	19,406	22,588	27,156	30,647
Pharmaceutical expenditure by the Social Security ^a	19,645	22,978	27,825	31,379
Beneficiary's contribution ^a	1,908	2,059	2,210	2,358
Number of prescriptions ^a	14.1	15.1	15.2	15.7

^a Includes consumption of products, formulas, effects and accessories, through prescriptions dispensed through pharmacies.

Source: *La industria farmacéutica en cifras*, Farmaindustria, 2002.



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- **SPANISH RP settings:**
- According to 1999's Royal Decree, reference prices were established from a weighted average by the sales of the public prices sales of the minimum amount of smaller price presentations, necessary to reach a market share in 20% units.



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- If the difference between the calculated price and the highest one in the group was less than a 15%, the reference price resulted in reducing the highest price in a 10% (with a 10% saving guaranteed)
- If the difference between the calculation and the highest one was more than a 50%, the reference price was recalculated.
- The generic speciality with a lowest price in an homogeneous group was established as the price's minimum.



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RP setting:

- When the medical prescription overcome the amount of the reference price, the pharmacist will not be obliged to a substitution when no generic pharmaceutical specialty that fulfils the interchangeability requirements demanded exist.



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- **RP settings:**
- **When no substitution is due to the inexistence of a generic, the pharmacist will have to deliver the prescribed speciality with the reference price, price on which the beneficiary will have to make the contribution that corresponds to him. In that case, the laboratory will have to pay the difference between the sale price of authorized laboratory and the one that corresponds with the reference price.**



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- **RP settings:**
 - A former modification (2003) made for not accounting anymore for the market quota, choosing to consider just the arithmetic average rate of the three costs/ treatment/day minor for each form of administration.
- The new proposal (2007) means a new modification that adds the requirement that the three selected presentations to fix the price of reference will have to belong to three different enterprise groups.



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- **the reformulation of the reference prices' system has suppressed the exceptions to the substitution by the pharmacist of the specialty prescribed by the doctor with a greater price than the reference one.**
- ...as a result, if the patient decides to follow the prescription of his doctor, he will have to assume the totality of the brand price and not the difference between his sale price to the public and the price of reference, as in the past, unless a cheapest group's generic one does not exist: as said, this is equivalent to an exclusion de facto of the public financing of the brand specialties with prices above the price of reference.**



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- **So far, it does not seem that the new RP system is helping to the creation of a true market of generics (the market is stuck in a 4%) and no new incoming companies are appearing in this section of business but the large pharmaceutical Companies, offering its “brand” generics with prices near the reference one, according to the regulated calculation.**

(in principle to protect this market, no product with a price under 2 € is computed for the price calculation).

CONCLUDING REMARKS

- **RP- EFFECTS, CONTEXT DEPENDENT...**
- **IT IS NOT SO MUCH THE IDEA IN ITSELF BUT HOW THIS IS IMPLEMENTED: PUBLIC PROCUREMENT WITH SOME POLITICAL DISCRETION, INCENTIVES TO THE AGENTS, CONTROVERTED MEDICAL BIOEQUIVALENCES**
- **RP- MAY MEAN EQUITY AND EFFICIENCY AT THE SAME TIME**
- **SOME CAVEATS ON THE EFFECTS ON CREATING A FULLY COMPETITIVE MARKET FOR GENERICS AND ON R&D**