

## PPRI Conference 2011\*

Balancing pharmaceutical policies between equity and cost-containment  
– a critical discussion and lessons learned

# Internal Reference Pricing

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## Conflict of Interest Statement

- No conflict of interest
- Professor in the Andalusian School of Public Health (EASP), a Spanish regional academic institution. The EASP has received funds from pharmaceutical companies to do academic independent studies
- I have taken part in training/academic activities funded or sponsored by pharmaceutical companies
- The results presented here are based on an independent academic research. A previous work on this topic was made by EASP under an European Commission co-funded project

## Agenda

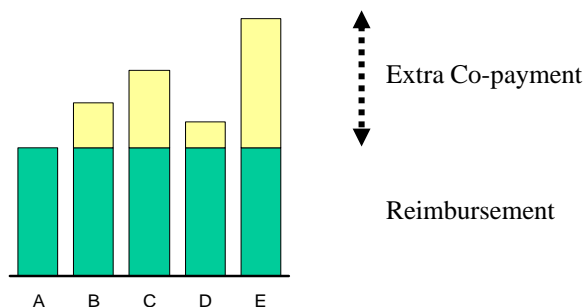
- Definition and objectives of RP
- Modalities
- Generics RP v. Therapeutic RP
- Conclusions

## Some preliminary remarks

- A updating a of previous literature search have been carried out to prepare this presentation
- The literature on reference pricing offers, as a main results for this presentation:
  - Three literature reviews (Health Policy -2000- Cochrane Collaboration Review -2006- and Pharmacoeconomics 2011 )
  - Two articles – *Health Policy* 2007 – with evaluation on reference pricing in two countries and one article with theoretical approach – *Journal of Health Economics* 2007.
- Often confused with External Price Referencing

## Definition

- **Reference Pricing (RP) is a financing mechanism** that establishes a **maximum level of reimbursement** for a group of drugs assumed to be therapeutically equivalent. The share of the price above the reference price is borne by the consumer.
- In spite of is not a price control instrument, it has a **lot of influence in the price** (specially, in countries where the price of medicines is not directly regulate -Germany, Denmark-)



## EXAMPLE

Clase	Código	Nombre	P.V.P.	Precio Ref.
P. Activo	4278	OMEPRÁZOL		
Especialidad	8242016	OMEPRÁZOL ABDRIUG(40 MG 14 CAPSULAS)	5,42	5,49
Especialidad	8242351	OMEPRÁZOL ABDRIUG(40 MG 28 CAPSULAS)	10,97	10,98
Especialidad	6566077	OMEPRÁZOL ABDRIUG(40 MG 28 CAPSULAS)	10,69	10,98
Especialidad	6306406	OMEPRÁZOL ABDRIUG(40 MG 500 CAPSULAS)	227,02	
Especialidad	8807659	OMEPRÁZOL ACYFABRIK(20 MG 14 CAPSULAS)	4,2	
Especialidad	8805839	OMEPRÁZOL ACYFABRIK(20 MG 28 CAPSULAS)	8,43	
Especialidad	6253847	OMEPRÁZOL AFSÁ(20 MG 500 CAPSULAS)	102,31	
Especialidad	6590829	OMEPRÁZOL AGEN(40 MG 14 CAPSULAS)	5,48	5,49
Especialidad	6590836	OMEPRÁZOL AGEN(40 MG 28 CAPSULAS)	10,27	10,98
Especialidad	6025482	OMEPRÁZOL AGEN(40 MG 500 CAPSULAS)	131,5	
Especialidad	8801381	OMEPRÁZOL ALTER(20 MG 14 CAPSULAS)	3	3,12
Especialidad	8801466	OMEPRÁZOL ALTER(20 MG 28 CAPSULAS)	4,5	5,49
Especialidad	9999193	OMEPRÁZOL ANGENERIC(20 MG 14 CAPSULAS)	3	3,12
Especialidad	9999209	OMEPRÁZOL ANGENERIC(20 MG 28 CAPSULAS)	4,5	5,49
Especialidad	9100834	OMEPRÁZOL APHAR(20 MG 14 CAPSULAS)	3	3,12
Especialidad	9144814	OMEPRÁZOL APHAR(20 MG 28 CAPSULAS)	5,48	5,49
Especialidad	7470489	OMEPRÁZOL ARAFARMA(10 MG 14 CAPSULAS)	2,11	3,12
Especialidad	7470557	OMEPRÁZOL ARAFARMA(10 MG 28 CAPSULAS)	3,12	3,12
Especialidad	7464204	OMEPRÁZOL ARAFARMA(20 MG 14 CAPSULAS)	4,2	
Especialidad	6534137	OMEPRÁZOL ARAFARMA(20 MG 14 CAPSULAS)	3,11	3,12
Especialidad	6534144	OMEPRÁZOL ARAFARMA(20 MG 28 CAPSULAS (BLISTER))	4,48	5,49
Especialidad	6562833	OMEPRÁZOL ARAFARMA(20 MG 28 CAPSULAS (BOTE))	4,48	5,49

Maximum than Spanish Health Authorities are willingness to pay for Omeprazol 40 MG 28 Tablets.

Different RP for different products

Source: BOT Plus database

## Objetives

- **Reference Pricing aims to**
  - **reduce pharmaceutical prices and expenditure** for third party payers while ensuring a standard quality of the product.
  - reinforce **price competition** in pharmaceutical markets through increasing **price-sensitivity** of consumers.

## Modalities

Reference drug pricing can be applied to different levels of drug groups

**Generic  
Reference  
Pricing –GRP-**

Level 1. Grouping of drugs that have identical bioactive ingredients and therefore are considered therapeutically interchangeable i.e. generic groups. This has been used in many countries. Examples are Canada (Ontario), Denmark, Italy, Norway, Sweden and the USA (Medicaid).

**Therapeutic  
Reference  
Pricing –TRP-**

Level 2. Drugs are pooled in analogue groups, i.e. chemically slightly different but related drugs with comparable or identical indications (e.g. the analogue group of angiotensin-converting enzyme (ACE) inhibitors, the analogue group of histamine-2 receptor antagonists (H2RAs)). This is, for example, used in British Columbia.

Level 3. Grouping of all drugs used to treat a particular condition (e.g. all drugs for hypertension.). This is, for example, used in the Netherlands and Germany.

Source: Aaserud M, Dahlgren AT, Kösters JP, Oxman AD, Ramsay C, Sturm H. Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.: CD005979. DOI:10.1002/14651858.CD005979.

## Modalities (II)

Table 2  
A simple classification of existing reference pricing schemes according to product coverage

Interchangeability level	Off-patent drugs	Patented and off-patent drugs
Chemical equivalence	Sweden Denmark Norway	
Chemical and pharmacological equivalence	British Columbia	
Chemical, pharmacological and therapeutic equivalence	Germany	Australia New Zealand  The Netherlands

Source: López-Casasnovas G, Puig-Junoy J. Review of the literature on reference pricing. Health Policy 54 (2000) 87-123

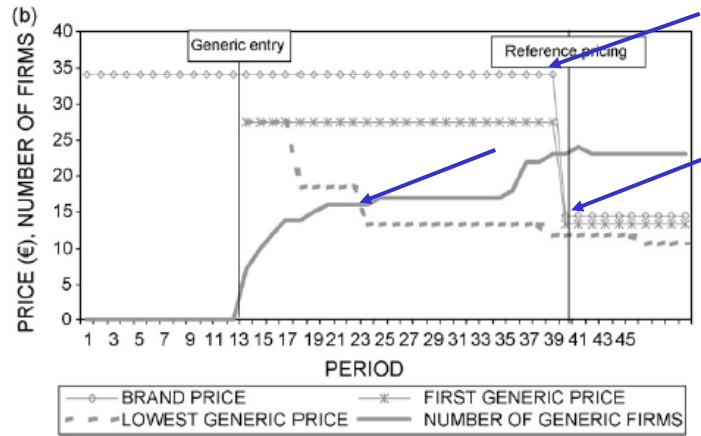
## Reference Pricing in Europe

COUNTRY	DATE	GROUP	STANDARD/CLASSIFICATION	REIMBURSEMENT LEVEL
BE	June 2001	Drugs that have the same active ingredient(s)	ATC5	% determined for each individual (new reference specialty)
DK	1980	Drugs that have the same active ingredient(s)	ATC4	Fixed at the lower 30 % of the Price Range within the Group.
DK	1993	Drugs in the RPP system on the basis of active ingredient(s), form(s) and strength	ATC5	The lowest drug price in the group.
EE	2003	Drugs that have the same active ingredient(s) and form(s)	ATC5	The second lowest price in the group.
EL	Over 20 years	Drugs that have the same active ingredient(s) and form(s)	ATC5	A Reference Price per therapeutic category and a Reference Price per medicinal product are established.
es	1000	Drugs that have the same active ingredient(s)	ATC6	The average of the 3 lowest prices, calculated by cost of manufacturing.
HU	1993	Drugs that have the same active ingredient(s) and form(s) - 1993 Medicines chemically slightly different but related - 2003-	ATC5	In a RPP group (ATC5), the lowest price per unit (DPPU).
IT	2003	Drugs that have the same active ingredient(s) and form(s), are interchangeable and have the same therapeutic indications (when generics are available). Medicines that are slightly different chemically, but related (without generic competition)	ATC 4	The lowest drug price in the group (which, by law, must be at least 20% cheaper than the original). Calculation of the average cost per DDD (dependent on net E' (calculated in net DDD) and the % of utilization and expenditure in the actual.
LT	1995	Drugs that have the same active ingredient(s) and form(s)	ATC 5	Reimbursement level is determined according to the disease.
LV		Drugs that have the same active ingredient(s) and form(s). Drugs that have the same active ingredient(s). Medicines that are slightly different chemically, but still related.	ATC 3, 5	The lowest drug price in the group.
NL	1991 (cluster reimbursement level from 1996)	Drugs with a (more or less) similar indication, route of administration, targeted age group and for which no similarity remain: differences in outcomes apply.		Before 1996: The weighted average price of the group based on prices. After 1996: Cost-effective products - the price of the first product becomes the reimbursement limit of the cluster in which both products will be priced.
PL	1999	Drugs that have the same active ingredient(s) and form(s). Medicines slightly different chemically, but still related.	ATC4	The lowest drug price in the group.
PT	March 2003	Drugs with the same active ingredient, pharmaceutical form and dosage (cluster).		Reference price corresponds to the highest generic price for each cluster on the market.
RO	1997	Drugs that have the same active ingredient(s) and form(s)		The lowest drug price in the group.
SE	1993 to 30.06.2002	Drugs that have the same active ingredient(s) and form(s). Drugs that have the same active ingredient(s), if the form was considered clinically relevant.		The lowest drug price in the group.
SK	1996	Drugs that have the same active ingredient(s) and form(s).	ATC5	The lowest drug price in the group.
SI	November 2003	Drugs that have the same active ingredient(s) and form(s) and the same strength (dose of active substance) and the bioequivalent (BEC) representation of generic definition (since Directive 2001/83)	ATC5	The lowest drug price in the group.

Source: Espín, J. y Rovira, J. (2007): «Analysis of differences and commonalities in pricing and reimbursement systems in Europe». A study funded by DG Enterprise and Industry of the European Commission, EASP Final Report, June 2007

Price of brands and generics, and number of generic firms from January 2001 to October 2004

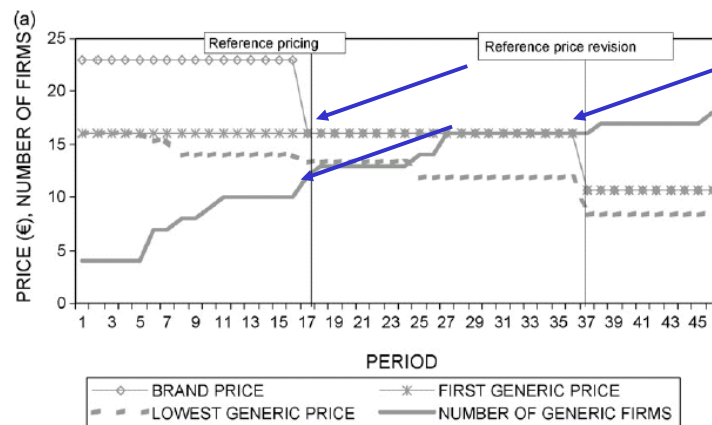
**SIMVASTATIM 20 MG 28 Tables**



Source: The impact of generic reference pricing interventions in the statin market. Health Policy 84 (2007), 14-29

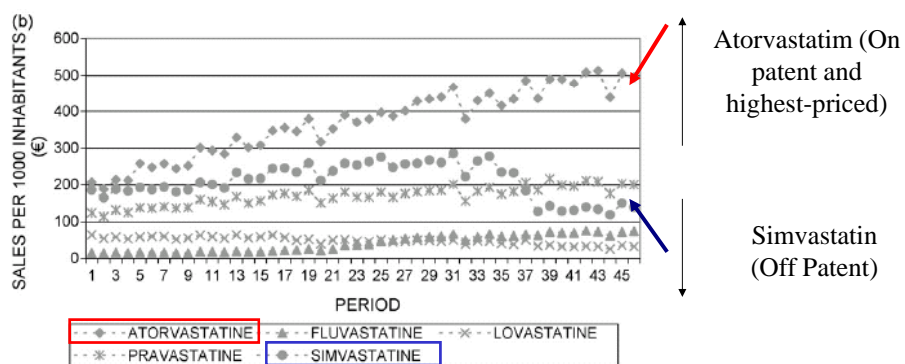
Price of brands and generics, and number of generic firms from January 2001 to October 2004

**LOVASTATIN 20 MG 28 Tables**



Source: The impact of generic reference pricing interventions in the statin market. Health Policy 84 (2007), 14-29

Sometimes there is a shift to expensive medicines out of controlled clusters.



the physician incentive to increase the proportion of off-patent prescribed statins has not been enough to counteract industry pressure in favour of on-patent statin prescriptions.

### Generics RP (GRP) v. Therapeutic RP (TRP)

GRP: Patients can be switched between product without any medical consequences

Could we do the same with TRP?

## Statins in TRP

Therefore the most critical question is how to select reference products when efficacy differences among products exist, [redacted]

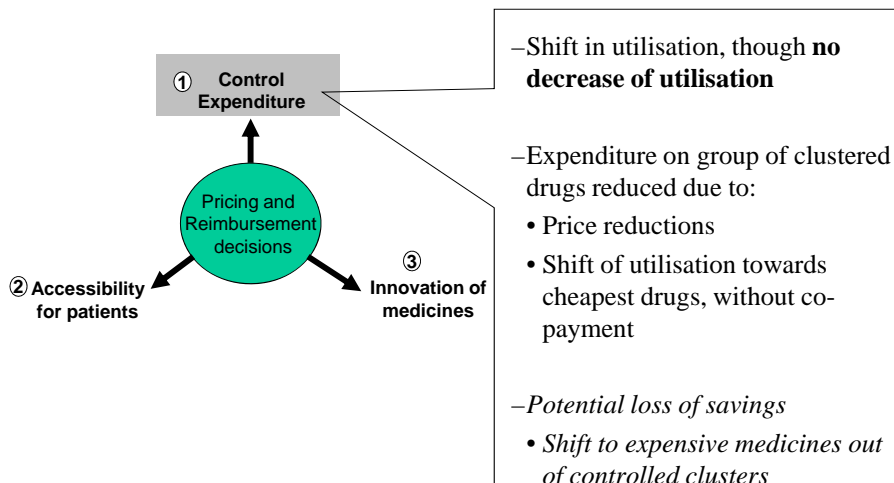
### Could we change statins without consequences?

ration. However, which statin is prescribed clearly matters in terms of cost [9] (in the absence of solid evidence of differences in clinical benefits/outcomes).

[redacted] Statins were rarely included in the reference pricing schemes due to their high variability and low interchangeability [20] [redacted]

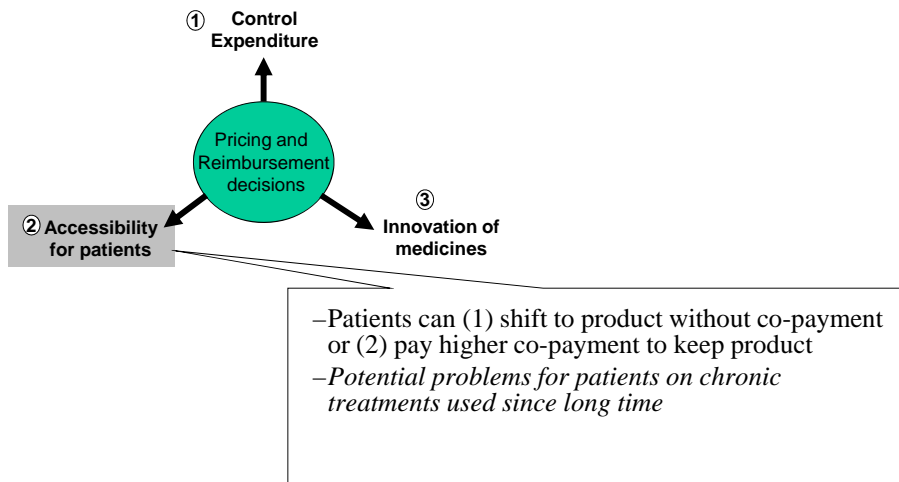
[redacted] In New Zealand patients were switched from simvastatin to low dose fluvastatin under the reference pricing system, and there was an increase in thrombotic vascular complications [12].

## IMPACT OF REFERENCE PRICING: ON CONTROL

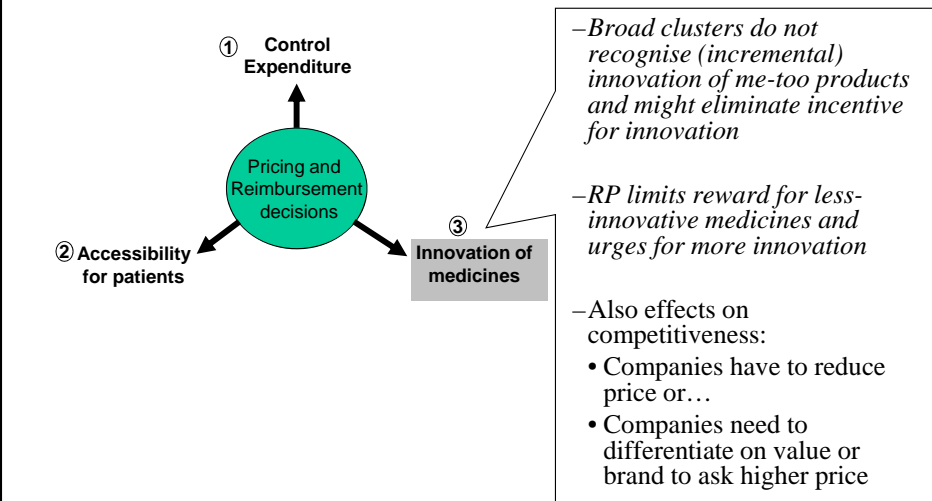




## IMPACT OF REFERENCE PRICING : ON ACCESS



## IMPACT OF REFERENCE PRICING: ON INNOVATION



## Toolbox

Practice: Reference Pricing		
Description: A financing mechanism that establishes a maximum level of reimbursement for a group of drugs assumed to be bio and/or therapeutically equivalent. The share of the price above the reference price is borne by the consumer. (To be distinguished from referring national prices to cross-border prices of the same products)		
Modalities: <ul style="list-style-type: none"> <li>Grouping of medicines (clusters): variant 1 – narrow clusters (ATC level 5); variant 2 – broad clusters (ATC level 4) of originators; variant 3 – broad clusters (ATC level 4) of originators + generics</li> <li>Fixing common reimbursement-value: variant 1' – in function of cheapest product; variant 2' – in function of average</li> </ul>		
Application in EU: BE, CY, DE, DK, ES, NL, ES, HU, IT, LT, LV, NL, PL, PT, SK, SI, SK		
Impact on:		
	Benefits	Risks
<b>Cost containment</b>	<ul style="list-style-type: none"> <li>Medicinal cost reductions up to 50%</li> <li>Net healthcare-savings up to 18%</li> <li>Allows promotion of generics</li> <li>Creates cost-awareness in patients and doctors</li> </ul>	<ul style="list-style-type: none"> <li>Might create a shift to other expensive medicines (out of controlled clusters)</li> <li>Fixed reimbursement-values can hamper further price-competitions and reductions</li> </ul>
<b>Reward for innovation</b>	<ul style="list-style-type: none"> <li>Potential to incentivize valuable innovative products through exemptions</li> <li>Potential to create headroom for innovation</li> </ul>	<ul style="list-style-type: none"> <li>Incremental value not always recognised (in case of variant 2 and 3), through exemptions possible</li> </ul>
<b>Access to medicines</b>	<ul style="list-style-type: none"> <li>If one co-payment free medicine is foreseen per cluster, affordable access is ensured</li> <li>Transparent presentation of alternatives to patients, pharmacists and doctors</li> </ul>	<ul style="list-style-type: none"> <li>In case not all medicines align prices to Reference Price, for some individual patients extra information might be needed to avoid confusion when shifting treatments.</li> <li>In this case, price-sensitive (poorer) patients are most affected</li> </ul>

Auginsky et al 2006 (14%)  
Savings reported: CY: -20% in 1 year (-11mEUR); HU: -5% in 6 months; IT: basis for price cut in 2004 with 500-600MEUR saving; LV: -0 kmEUR in 6 months; DE: 100mEUR  
PT, Asensal et al 2006

## Some conclusions

- “The international literature about the **benefits** of therapeutic reference pricing is **inconclusive**”.
- “The results of therapeutic reference pricing **depend on the classess of drug incorporated**, and..
- ...the **short-term savings** might not extend into the long-term”

Thank you for your attention

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