Organización Panamericana de la Salud
Oficina Regional de la Organización Mundial de la Salud

Reunión sobre Políticas Farmacéuticas e Indicadores de Evaluación

Experiencias sobre evaluación y desarrollo de instrumentos de apoyo a la implementación de Políticas Farmacéuticas en la Unión Europea

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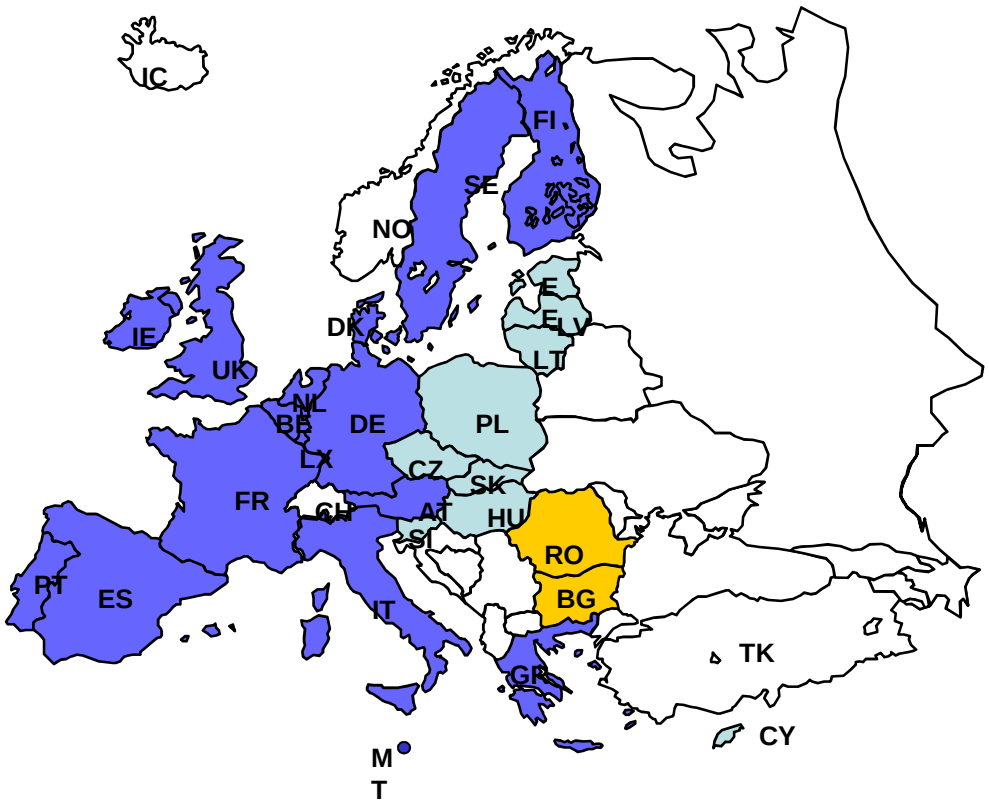
CONSEJERÍA DE SALUD

Washington, 10 de Diciembre 2009

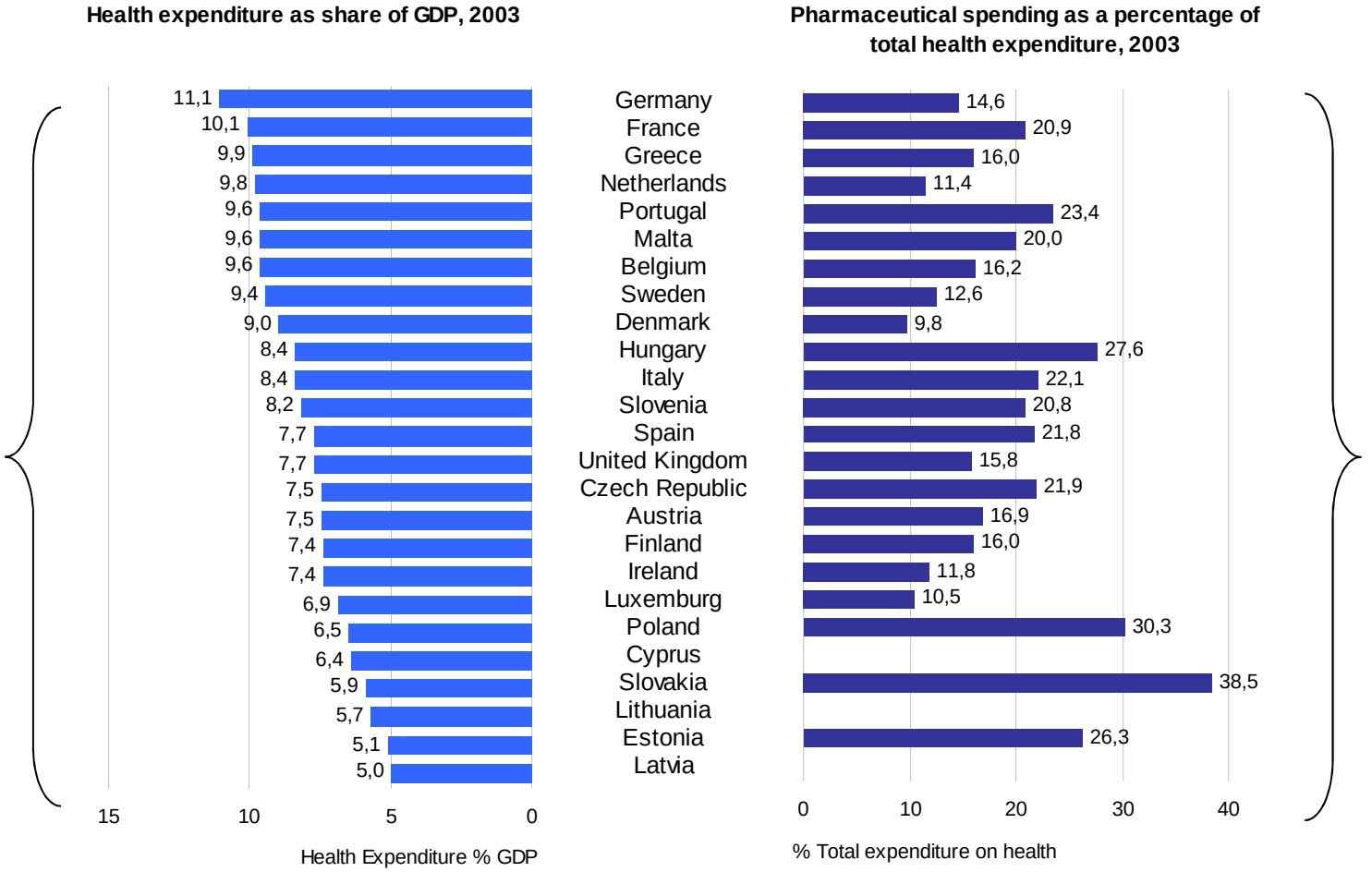
Contexto Europeo



- Intregración gradual
- Libre circulación de mercancías
- Distintas políticas farmacéuticas

Gasto en salud y farmacéutico UE- 25

x 2

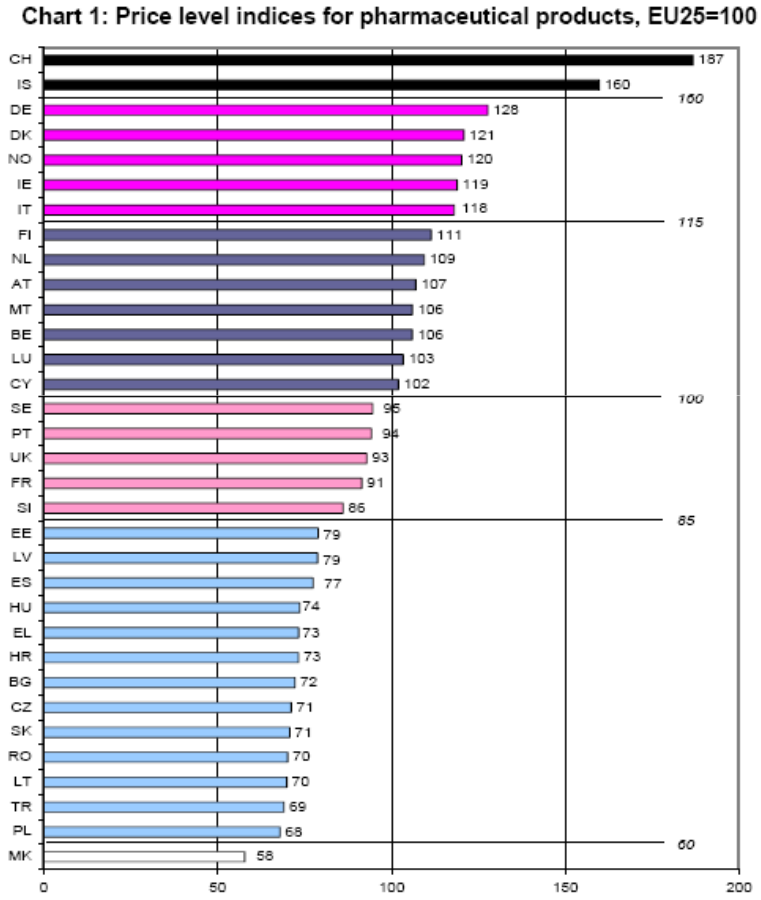


x 4

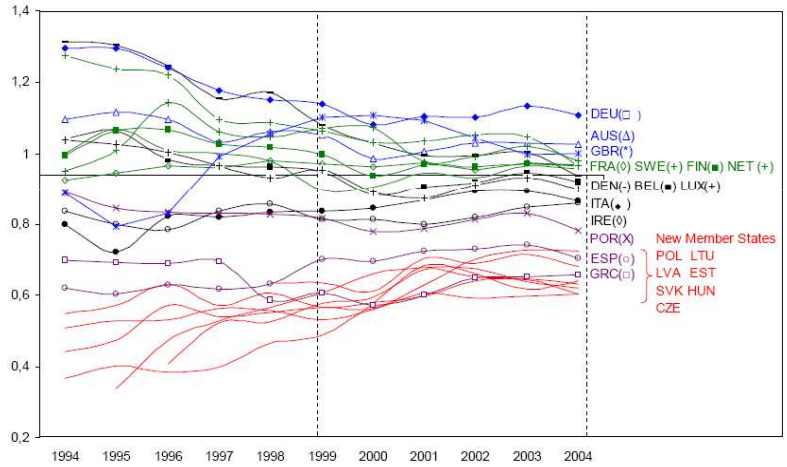
Source: The data are mainly from OECD Health Data 2005 and Health for All Database (HFA-DB). WHO/Europe . 2005.

Data of some countries are different from 2003.

La diferencia de precios de los medicamentos llega a ser el doble según los países, tras un largo período de convergencia (principalmente por el comercio paralelo)



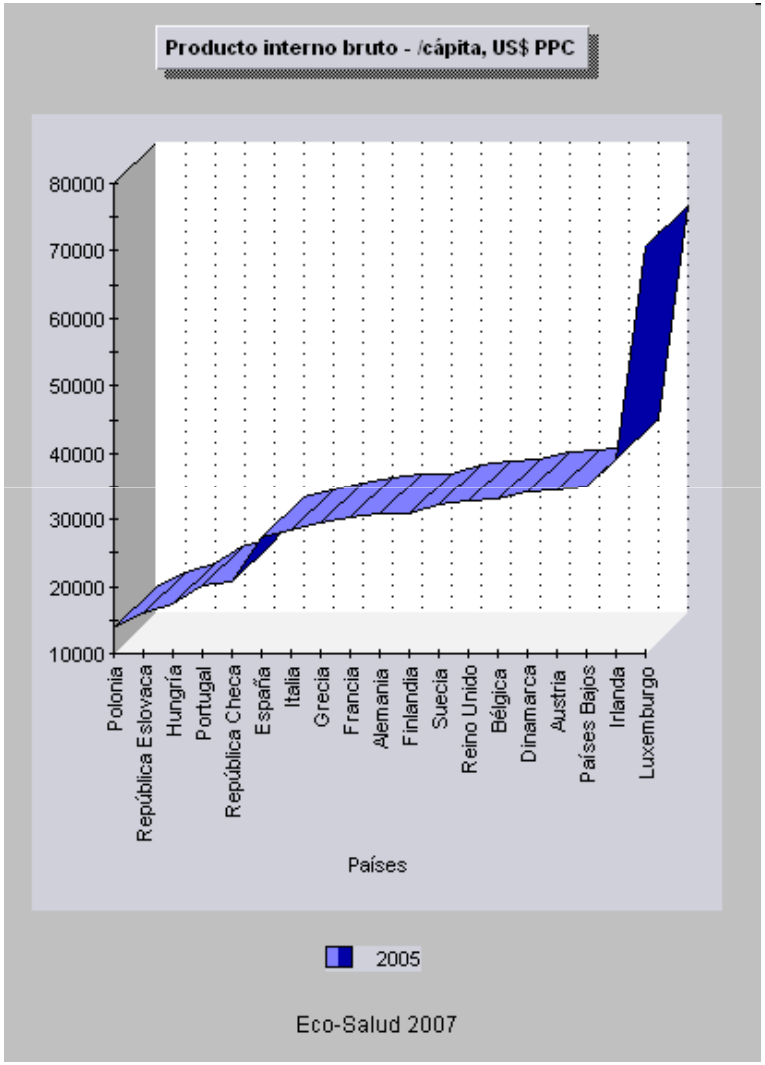
Convergencia de precios en UE 25
entre 1994-2005



Fuente Commission staff working document, accompanying the communication from the commission. "Economic reforms and competitiveness. Key messages from the European Competitiveness Report 2006" (com (2006) 697 final)

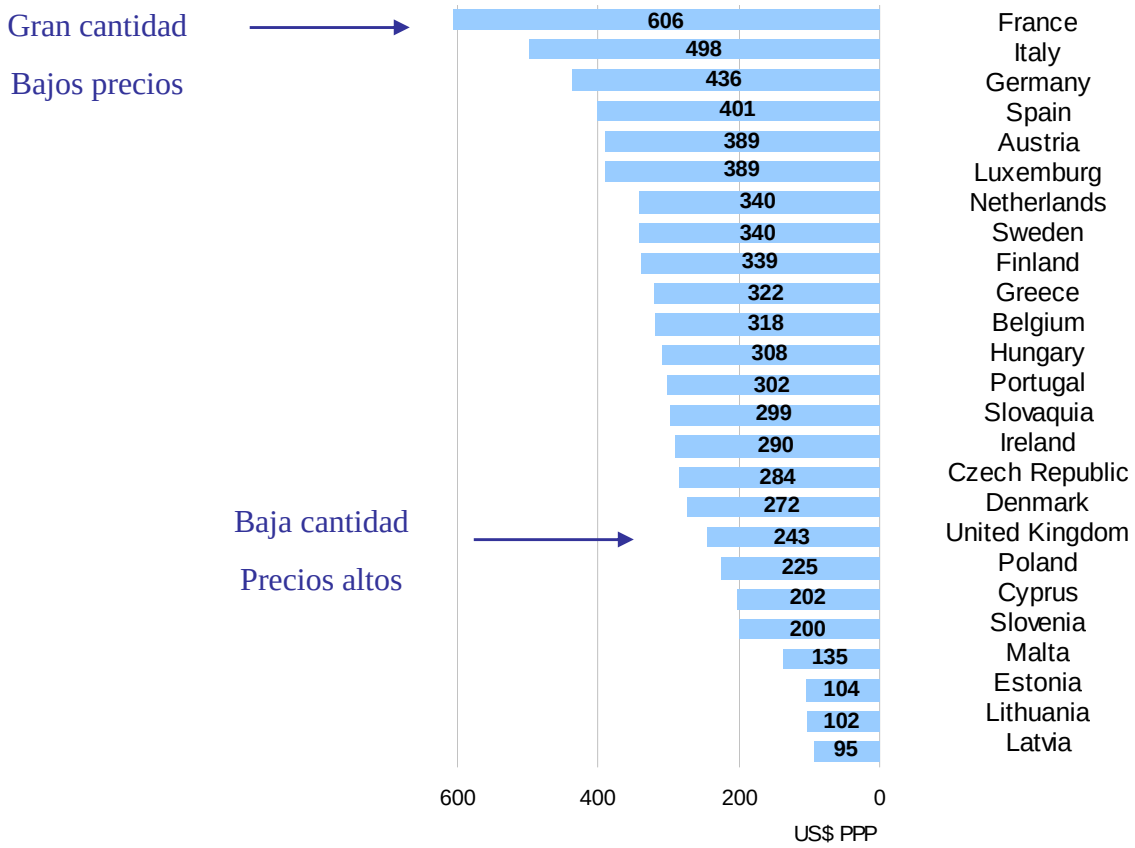
Fuente: Eurostat

… pero la diferencia de PIB / per cápita llegar a ser de 7 veces



Gasto en farmacia, per capita*, 2003**

Gasto Total= Cantidad * Precio

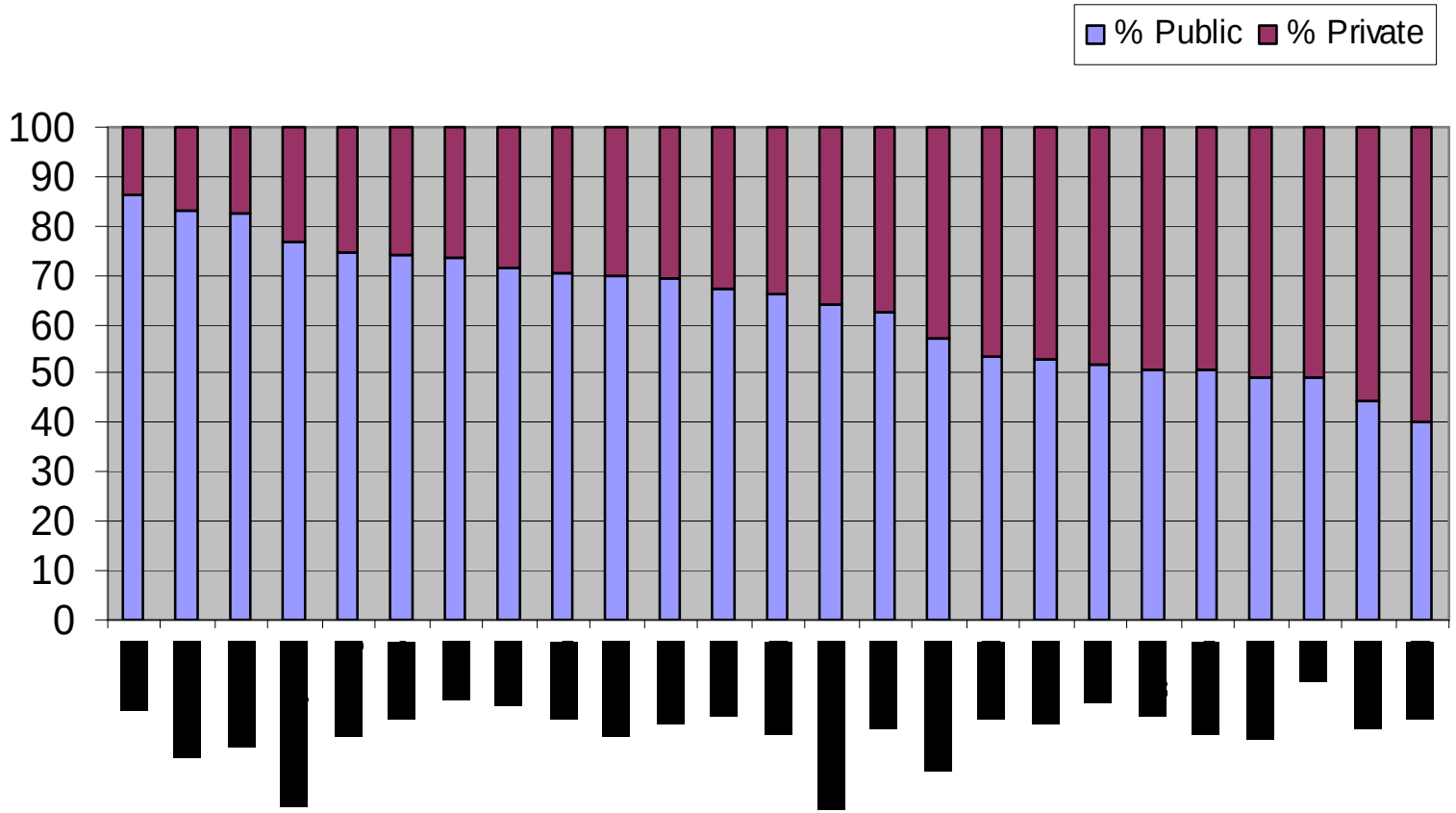


Source: The data are mainly from OECD Health Data 2005 and Health for All Database (HFA-DB). WHO/Europe . 2005.

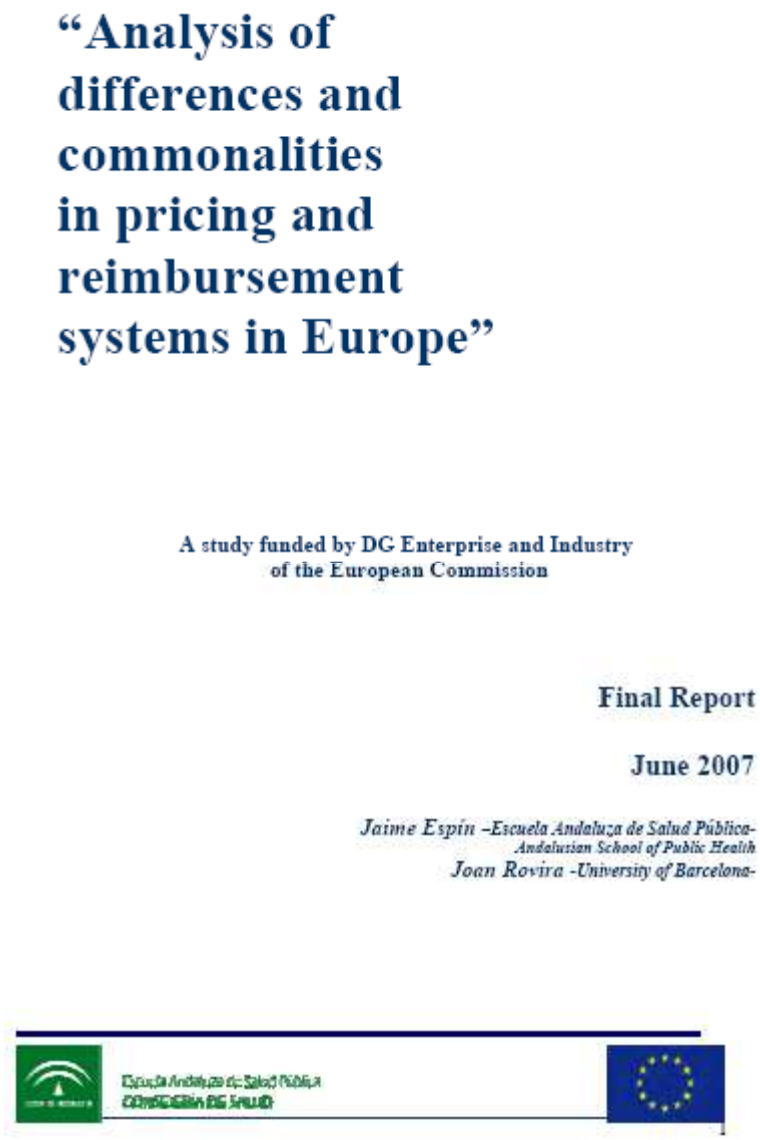
* The OECD definition is applied. It includes the consumption of pharmaceutical products supplied on prescriptions and obtained for self-medication (often referred to as over-the counter products), as well as pharmaceuticals consumed in hospitals. The expenditure includes VAT and sales taxes, where applicable.

** Data of some countries are different from 2003.

Gasto farmacéutico público y privado



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



http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm.

Objetivos del estudio

- Evaluar el uso de las distintas políticas de precio y reembolso de medicamentos en la Unión Europea y su impacto en
  - Control de gasto
  - Acceso a los pacientes
  - Incentivo y compensación a la innovación

- Identificar los factores de éxito y de riesgo

- Ayudar a los Estados Miembos a aprender acerca de las experiencias de otros Estados Miembros

Fases del estudio

- El estudio constaba de tres fases:
  - Fase I: Diseñar un esquema general de los sistemas de precios de reembolso de los medicamentos en la UE-25
  - Fase II: Evaluar el impacto para los gobiernos, pacientes, industria y otros actores
  - Fase III: Resaltar las condiciones y factores de éxito, así como oportunidades para el intercambio de experiencias

Metodología

- Encuesta mediante cuestionario y contactos personales a representantes de organismos gubernamentales de P&R de los Estados Miembros de la UE
  - Prácticas de política de medicamentos aplicadas
  - Descripción detallada de seis practicas seleccionadas
  - Evidencia del impacto de las dichas prácticas
- Revisión de la literatura internacional sobre impacto de las seis políticas seleccionadas

Fase I

Tabla 1. DIFERENCIAS Y SIMILITUDES EN LOS SISTEMAS DE PRECIOS Y REEMBOLSOS EN LA UE-15 (SALVO LUXEMBURGO)

	Algunas medidas enfocadas a la oferta						Algunas medidas enfocadas a la demanda					
	Regulación de precios	Control de gasto		Regulación de la industria		Políticas de reembolso	Médicos			Farmacéuticos		
	Fijación de precios basada en evaluación económica	Uso de descuentos	Acuerdos precio/ volumen	Control de beneficios	Tasa por beneficios	Reembolso basado en evaluacion económica	Techos de gasto	Cuotas de prescripción	Incentivos financieros	Sustitución por genéricos	Incentivos financieros	Recuperación de descuentos (Claw-back)
Alemania		√						√	√	√		
Austria	√	√				√			√			√
Bélgica	√				√	√		√	√			√
Dinamarca			0			√				√		
España		√	0		√		√	√	√	√	0	
Finlandia	√					√				√		
Francia		√	√							√	√	
Grecia		√				0						
Irlanda	√	√				√					√	
Italia	√	√		√		√			0	√	√	√
Países Bajos						√			√	√	√	√
Portugal	√		√		√	√				√		
Reino Unido				√	√		√		√		√	√
Suecia	√	0	√			√	√		√	√		

√: medidas actualmente aplicadas 0: medidas que han sido aplicadas, pero no han tenido continuidad

Fuente: Escuela Andaluza de Salud Pública.

Fase II- Políticas seleccionadas

- **Control de precios**
- **Co-pago**
- Políticas de genéricos
- **Precios de referencia**
- Instrumentos e incentivos para una buena prescripción
- **Presupuestos prospectivos con devolución (payback)**

Control de precios

- La **mayoría** de los países de la UE fijan el precio de sus productos farmacéuticos. Algunas **excepciones** son Alemania, Reino Unido, Dinamarca, Malta y Suecia
- En el 50% de los casos, la decisión del precio está ligada al reembolso.
- Existen **diversos criterios** para fijar el precio de los medicamentos y la mayoría son fijados de modo simultáneo: coste del tratamiento existente para la misma patología, eficacia, precios del mismo medicamento en el entorno europeo, evaluación económica,etc

Control de precios

	Regulación de precio						
	Precio inicial basado en utilidad terapéutica	Precio inicial basado en la evaluación económica	Precio inicial basado en el coste de tratamiento existentes	Precio inicial basado en calculos cost-plus	Precio inicial basado en precio internacionales	Actualización de los precios actualizados	Otros
AT	✓	✓	✓		✓		✓
BE	✓	✓	✓		✓	✓	
CY				ⓘ	✓		
DE							
DK							✓
EE		✓	✓		✓		
EL				✓ ⓘ	✓	✓	
ES	✓		✓	✓	✓	✓	
FI	✓	✓	✓		✓	✓	✓
FR	✓		✓		✓		
HU			✓		✓		
IE	✓	✓	✓		✓		
IT	✓	✓	✓		ⓘ	✓	
LT					✓	✓	
LV	✓	✓	✓			✓	
MT							
NL					✓		
NO					✓		
PL	✓				✓		
PT	✓	✓	✓		✓	✓	✓
RO					✓	✓	
SE	ⓘ	✓	ⓘ		ⓘ		✓
SK	✓	✓			✓	✓	
SI		✓			✓	✓	✓
UK						✓	✓

Countries USED as International RF

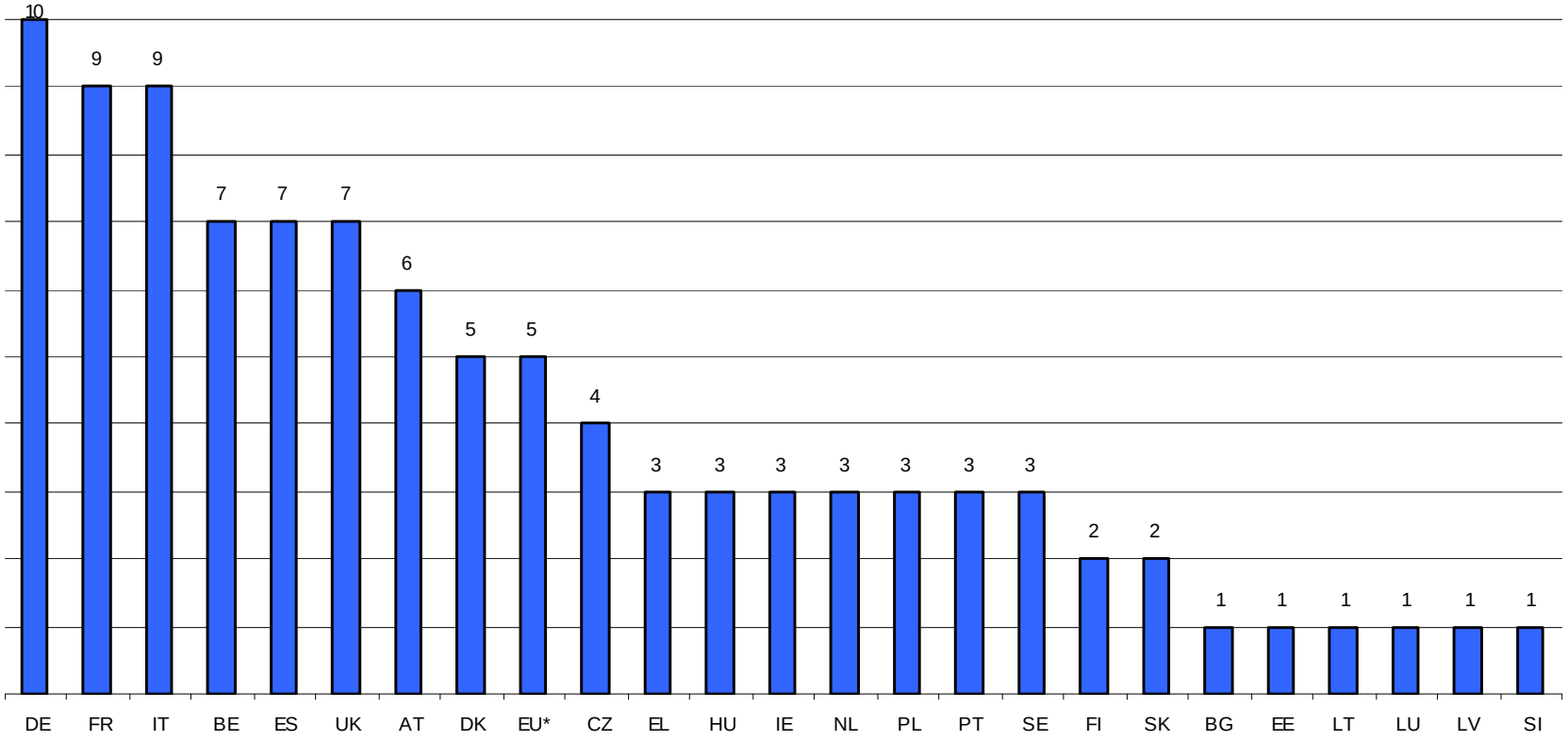
Countries USING International RF

	AT	BE	CY	EL	ES	FI	FR	HU	IE	LT	LV	NL	NO	PL	PT	RO	SK	SI
CRITERIA	AVERAGE	AVERAGE & MIMUM	AVERAGE	AVERAGE	MINIMUM	OTHERS	OTHERS	MINIMUM	AVERAGE	AVERAGE (95%)	OTHER	AVERAGE	AVERAGE (THREE LOWEST)	OTHER	MINIMUM	MINIMUM	AVERAGE (LESS 10% 3 LOWEST)	AVERAGE
COMPARE	EX-FACTORY & WHOLESALE	EX-FACTORY	WHOLESALE	EX-FACTORY	EX-FACTORY	WHOLESALE	EX-FACTORY	EX-FACTORY	EX-FACTORY	EX-FACTORY	EX-FACTORY	EX-FACTORY	PHARMACY	EX-FACTORY	EX-FACTORY	EX-FACTORY	EX-FACTORY	WHOLESALE
COUNTRIES REFERENCE	AT	BE	CY	EL	ES	FI	FR	HU	IE	LT	LV	NL	NO	PL	PT	RO	SK	SI
AT			■			■		■	■				■			■	■	
BE			■		■	■		■	■			■	■					
BG																■		
CY																		
CZ								■		■						■	■	
DE			■			■	■	■	■			■	■			■	■	■
DK			■			■			■				■			■		
EE										■								
EL			■			■		■										
ES			■			■	■	■							■		■	
FI													■					
FR			■		■	■						■			■		■	■
HU										■						■	■	
IE						■							■					
IT			■		■	■		■							■	■	■	■
LT																■		
LU						■												
LV										■								
MT																		
NL						■			■				■					
NO																		
PL										■						■	■	
PT			■			■		■										
RO																		
SE			■			■							■					
SK								■		■						■		
SI								■										
UK					■	■	■		■			■	■			■		
EU*	■	■		■							■			■				

AN UPDATING IS NEEDED

* EU as one country

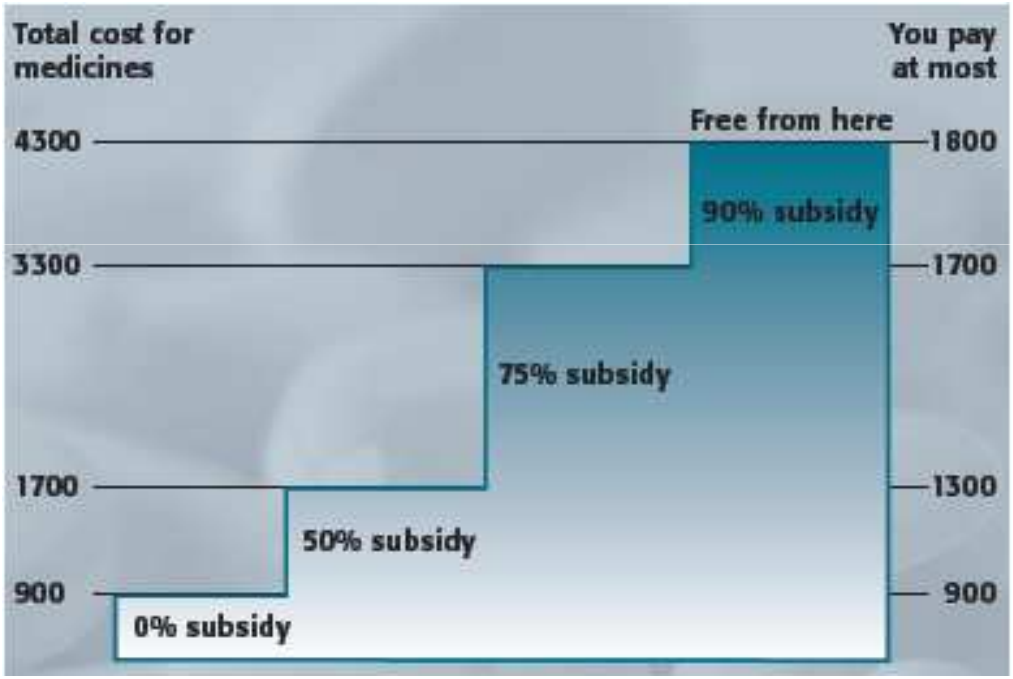
Países mas utilizados en en las referencias de precios internacionales



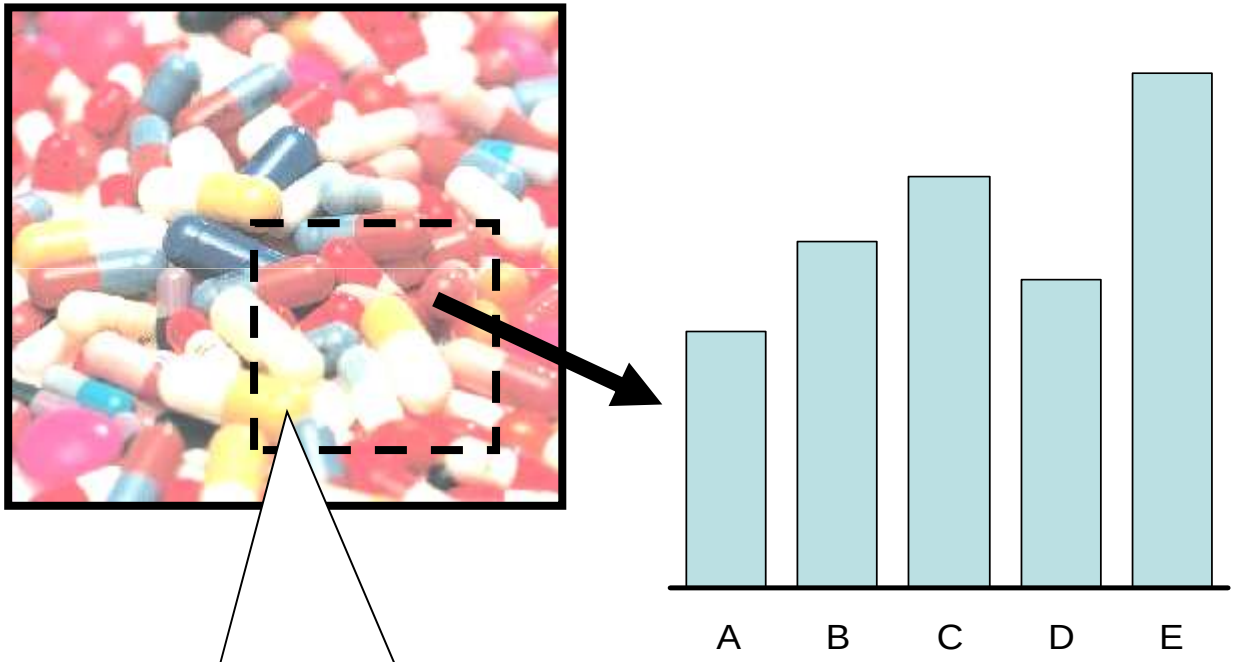
Participación en el pago

- Múltiples formas: Co-pago (fijo); AT, IT, UK (bono de pre-pago); Co-seguro con porcentajes distintos por medicamento y por otros factores: (BE, EE, ES, LV, LT, PL, PT, SK,SL)
- Excepciones para **mejorar acceso**
- Experimento de la RAND la **evidencia** existente apunta a que la participación en el coste tiene **efectos negativos** sobre el acceso y la equidad y que no discrimina entre tratamientos de distinta efectividad.

Copago-Experiencias interesantes

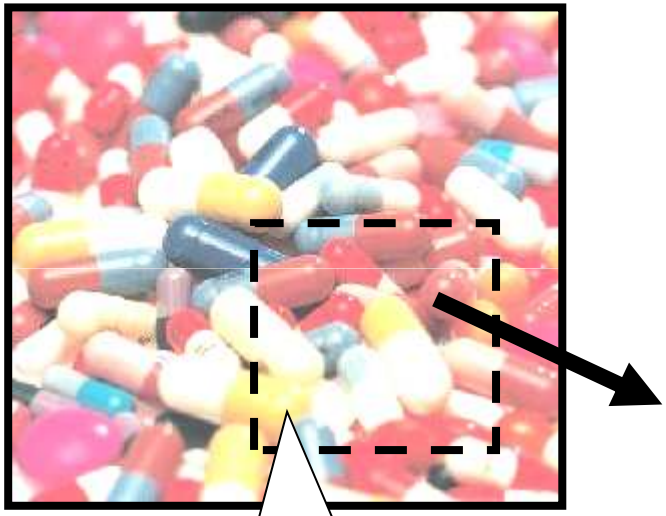


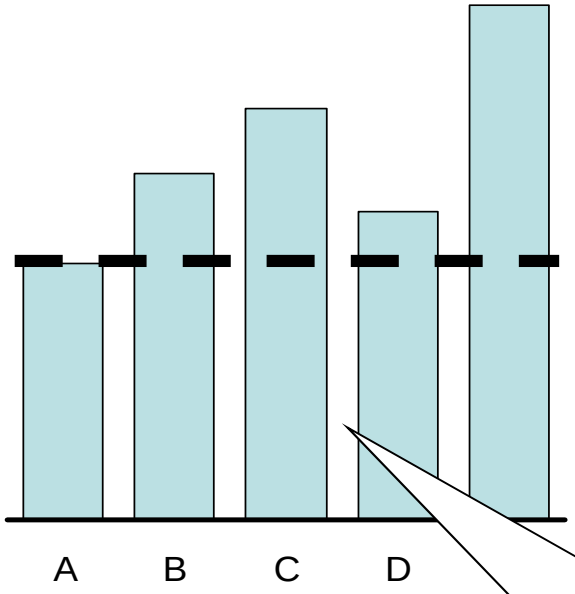
Precios de referencia - Funcionamiento



1. Se definen grupos de medicinas terapeuticamente equivalentes

Precios de referencia - Funcionamiento

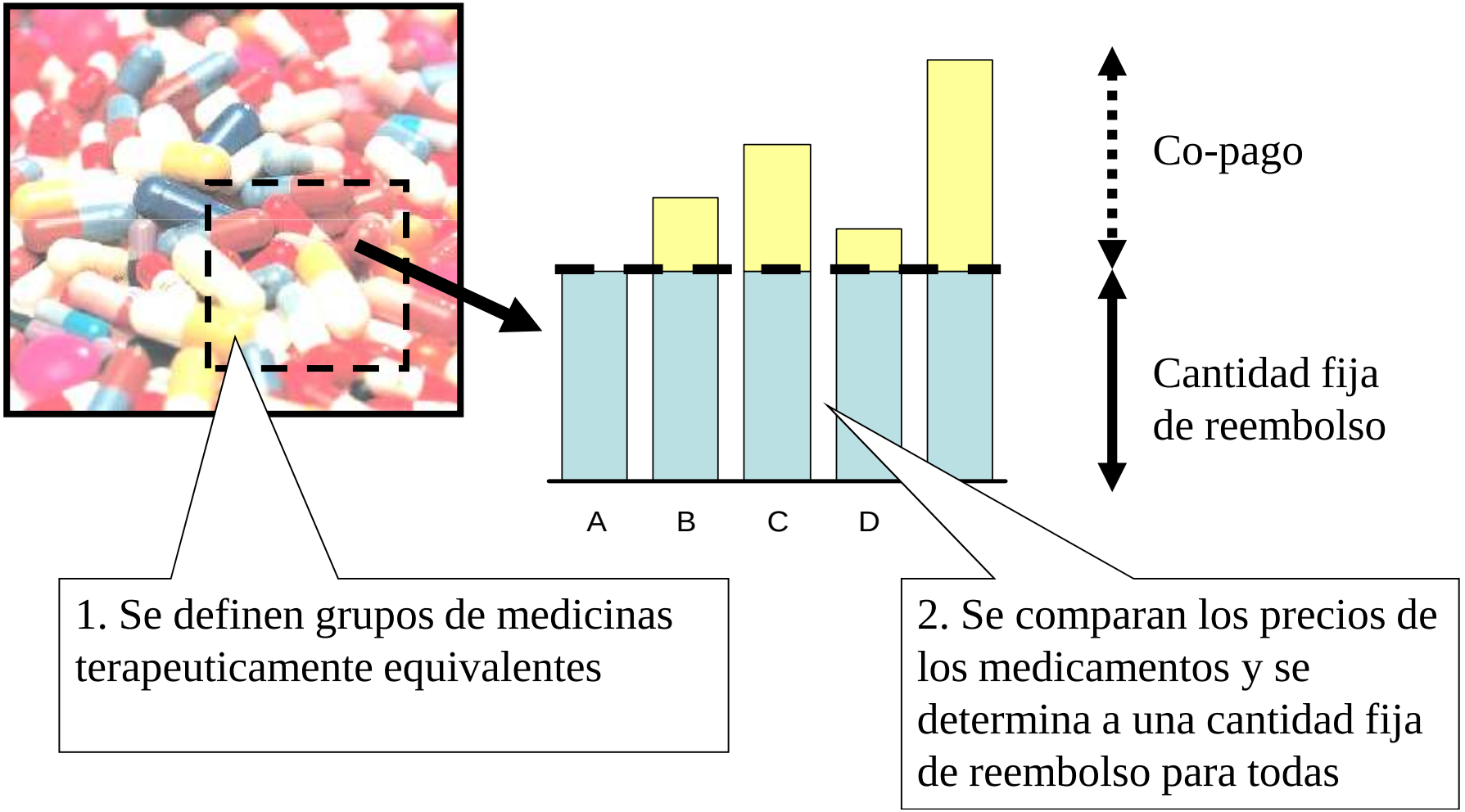




1. Se definen grupos de medicinas terapeuticamente equivalentes

2. Se comparan los precios de los medicamentos y se determina a una cantidad fija de reembolso para todas

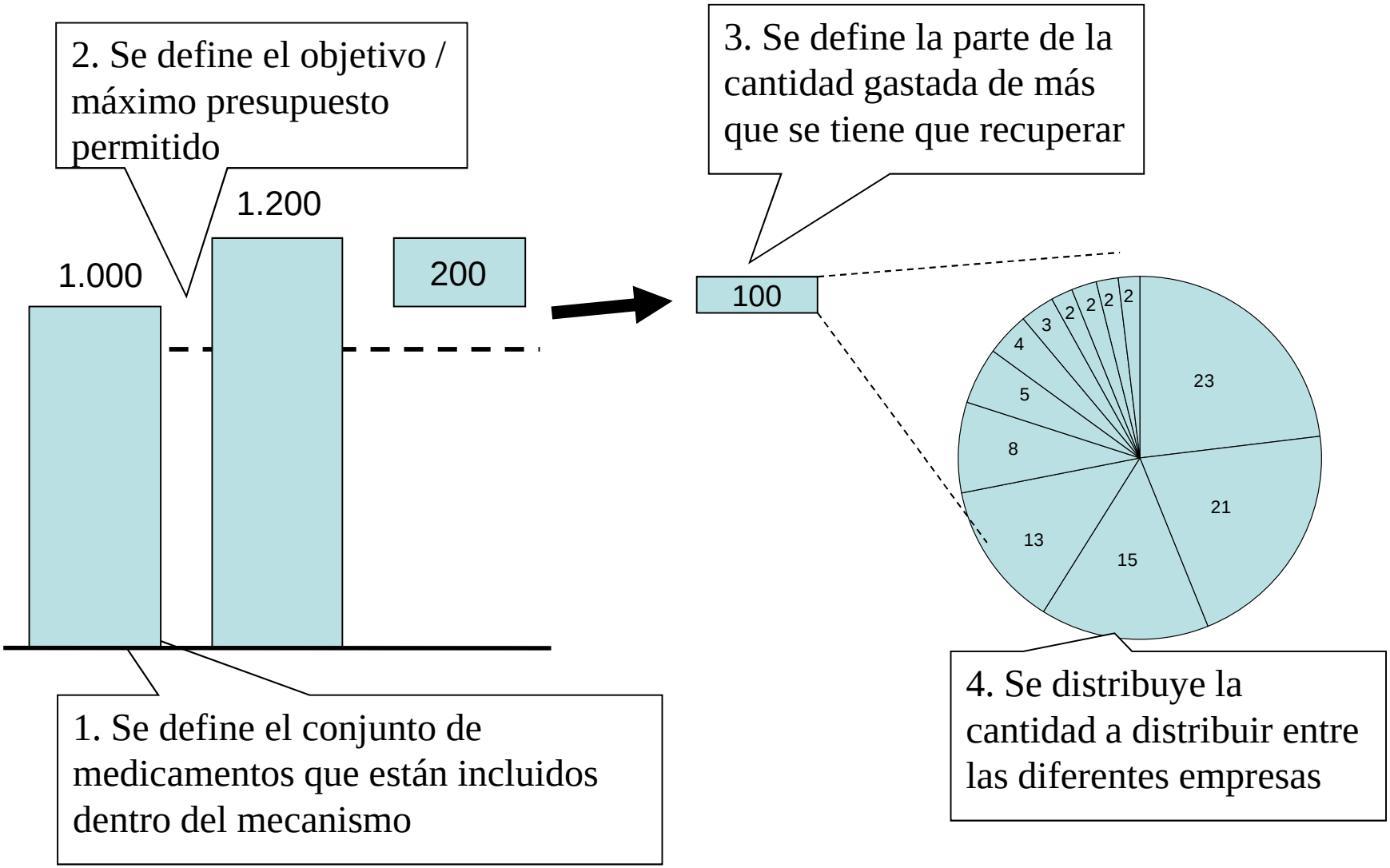
Precios de referencia - Funcionamiento



Precios de referencia – Algunas conclusiones

- Los PR parecen tener **mayor impacto en el gasto en países con libertad de precios** o con **sistemas débiles de control de precio** en que los nuevos medicamentos tienen precios relativamente altos y en los que existe una **industria de genéricos muy competitiva**.
- Desde posiciones de la **industria** se argumenta que cuando los grupos de un sistema de PR se basan en la equivalencia terapéutica, **se desincentiva la innovación incremental**, que se supone constituye la forma normal de progreso del conocimiento y la innovación en el campo de los medicamentos.
- Se afirma, finalmente, que algunas modalidades de sistemas de PR **limitan la competencia** en precios por debajo del nivel en que se establece el PR.

Presupuestos prospectivos con devolución - Payback



Presupuestos prospectivos con devolución - Payback Experiencias Europeas

	Belgium	France	Hungary	Italy	Portugal
Year Started	2002	2002	2003	2002	1997
System working level	Pharmaceutical budget	Per group of (therapeutically related) products	Per product & pharmaceutical budget	Pharmaceutical budget	Pharmaceutical budget
Target	Estimation	Target voted by parliament	Fixed amount of money	13% budget healthcare	Nominal Growth of GDP
Amount due	72% extra spending	Around 50%		100%	69,60%
Contribution	Pharmaceutical industry (72%) & Insurance organisms (25%)	Pharmaceutical industry (according to spending and growth)	Pharmaceutical industry (according to market share in reimbursement)	60% industry & 40 % regions	Pharmaceutical industry (according to its market share & responsibility in NHS' expenditure growth)
Exemption		Innovation, Generics and Orphan drugs			

Fase II – Algunas conclusiones

Hasta la fecha, **se dispone de poca evidencia para los decisores clave sobre el impacto de estas diferentes prácticas**. Este estudio resume algunas de las evidencias obtenidas de la literatura y ha reunido y comparado hallazgos iniciales de Estados Miembros individuales. De todas formas, está basado en aportaciones fragmentadas y sólo refleja la situación existente en un periodo de tiempo determinado, otoño 2006. Pudiera ser interesante, por tanto, **considerar adoptar un enfoque de mayor duración, intercambiando evidencia sobre un número mayor de prácticas entre las autoridades nacionales.**

Fase III

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: • 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 • Fixing common reimbursement-value: variant 1' – in function of cheapest product; variant 2' – in function of average		
Application in EU: BE, CY, DE, DK, EE, EL, ES, HU, IT, LT, LV, NL, PL, PT, SI, SK		
Impact on:	Benefits	Risks
Cost containment	• Medicinal cost reductions up to 50%[1] • Net healthcare-savings up to 18%[2] • Allows promotion of generics[3] • Creates cost-awareness in patients and doctors	• Might create a shift to other expensive medicines (out of controlled clusters) • Fixed reimbursement-values can hamper further price-competitions and reductions
Reward for innovation	• Potential to incentivize valuable innovative products through exemptions • Potential to create headroom for innovation	• Incremental value not always recognised (in case of variant 2 and 3), though exemptions possible
Access to medicines	• If one co-payment free medicine is foreseen per cluster, affordable access is ensured • Transparent presentation of alternatives to patients, pharmacists and doctors	• 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. • In this case, price-sensitive (poorer) patients are most affected

[1] Augurzky et al 2006 (14%)
[2] Savings reported: CY: -20% in 1 year (-11mEUR); HU: -5% in 6 months; IT: basis for price cut in 2004 with 500-600 MEUR saving; LV: -0.6mEUR in 6 months; DK: 100mDKK
[3] PT, Aserud et al 2006

Fase III

Toolbox

6. The Toolbox exercise (page 110)

Member States increasingly look to the same range of practices to balance budgets with access and reward for innovation. Nevertheless there is need for more evidence of the benefits and risks of different practices. This increases the interest of the Member State participants in sharing their experiences and evidence on different practices.

The aim of the toolbox exercise is therefore, for six selected practices, to collect expertise from Member States and stakeholders and to provide answers to questions like: real benefit(s), potential risks and interferences with other practices, driving factors of such risks or successes, practical set-up.

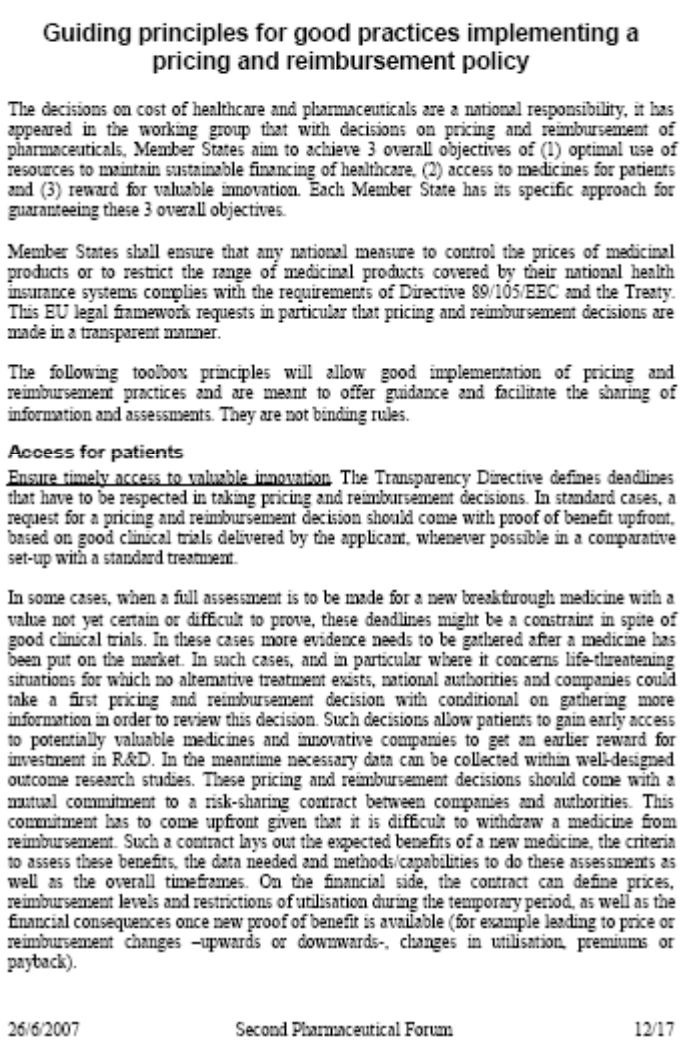
Guiding principles for good practices implementing a pricing and reimbursement policy

1. Guiding principles for good practices implementing a pricing and reimbursement policy (page 84)

With decisions on pricing and reimbursement of pharmaceuticals, Member States aim to achieve 3 overall objectives of (1) finding the optimal use of resources to maintain a sustainable financing of healthcare, (2) ensuring access to medicines for patients and (3) rewarding valuable innovation. Each Member State has its specific approach for balancing these 3 overall objectives.

The guiding principles and ideas in the document aim to help Member States obtain such a balance, through implementation of national pricing and reimbursement practices.

Fase III



Annex A.

Guiding principles for good practices implementing a pricing and reimbursement policy

The decisions on cost of healthcare and pharmaceuticals are a national responsibility, it has appeared in the working group that with decisions on pricing and reimbursement of pharmaceuticals, Member States aim to achieve 3 overall objectives of (1) optimal use of resources to maintain sustainable financing of healthcare, (2) access to medicines for patients and (3) reward for valuable innovation. Each Member State has its specific approach for guaranteeing these 3 overall objectives.

Member States shall ensure that any national measure to control the prices of medicinal products or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of Directive 89/105/EEC and the Treaty. This EU legal framework requests in particular that pricing and reimbursement decisions are made in a transparent manner.

The following toolbox principles will allow good implementation of pricing and reimbursement practices and are meant to offer guidance and facilitate the sharing of information and assessments. They are not binding rules.

Access for patients

Ensure timely access to valuable innovation. The Transparency Directive defines deadlines that have to be respected in taking pricing and reimbursement decisions. In standard cases, a request for a pricing and reimbursement decision should come with proof of benefit upfront, based on good clinical trials delivered by the applicant, whenever possible in a comparative set-up with a standard treatment.

In some cases, when a full assessment is to be made for a new breakthrough medicine with a value not yet certain or difficult to prove, these deadlines might be a constraint in spite of good clinical trials. In these cases more evidence needs to be gathered after a medicine has been put on the market. In such cases, and in particular where it concerns life-threatening situations for which no alternative treatment exists, national authorities and companies could take a first pricing and reimbursement decision with conditional on gathering more information in order to review this decision. Such decisions allow patients to gain early access to potentially valuable medicines and innovative companies to get an earlier reward for investment in R&D. In the meantime necessary data can be collected within well-designed outcome research studies. These pricing and reimbursement decisions should come with a mutual commitment to a risk-sharing contract between companies and authorities. This commitment has to come upfront given that it is difficult to withdraw a medicine from reimbursement. Such a contract lays out the expected benefits of a new medicine, the criteria to assess these benefits, the data needed and methods/capabilities to do these assessments as well as the overall timeframes. On the financial side, the contract can define prices, reimbursement levels and restrictions of utilisation during the temporary period, as well as the financial consequences once new proof of benefit is available (for example leading to price or reimbursement changes –upwards or downwards-, changes in utilisation, premiums or payback).

26/6/2007 Second Pharmaceutical Forum 12/17

Apoyo a la elaboración de los principios que guían para la buena implementación de una política de precios y reembolso

Guiding principles…

- **Access for patients**
  - Ensure timely access to valuable innovation.
  - Provide affordable medicines.
  - Ensure equal availability of medicines.
- **Optimal use of resources**
  - Limit price control to where it is needed to contain the public budget.
  - Set-up a consistent package of supply and demand-side measures.
  - Create the right environment for price competition.

Guiding principles

- **Reward for Innovation**
  - Set expectations.
  - Recognise innovation.
  - Be consistent when giving

Algunas conclusiones

- Este tipo de estudios que intentan **buscar evidencia de impacto** y **ayudar en el intercambio de experiencias** son aplicables a otros regiones con características comunes (América Latina, Asia, África, etc)
- Aprender de los errores y de las buenas prácticas es necesario, y necesario para la implementación de **políticas basadas en la evidencia**

Muchas gracias por vuestra atención

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"Analysis of differences and commonalities in pricing and reimbursement systems in Europe"

A study funded by DG Enterprise and Industry
of the European Commission

Final Report

June 2007

Jaime Espín –Escuela Andaluza de Salud Pública-
Andalusian School of Public Health
Joan Rovira -University of Barcelona-

http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm.