

PHARMACEUTICAL PRICING & REIMBURSEMENT SYSTEM IN SPAIN

PPRI Conference
29-30 September 2011, Vienna

Piedad Ferré

Dirección General de Farmacia y Productos Sanitarios




**Pharmaceutical offer in Spain
some features**

- High coverage and rapid accessibility
- Pharmaceutical expenditure and pharmaceutical consumption relatively high in the EU context representing up to 25% of total health care costs
- Prices relatively low in the EU context with a trend to equal them in high cost products
- Basically centralised regulations; budget management at a regional level
- The Spanish Agency of Medicines and Medical Devices is competent in the medicines authorisation process, the Directorate General for Pharmacy and Health Care Products is competent in pricing & reimbursement decisions

Dirección General de Farmacia y Productos Sanitarios






PRICING

- **Competent authorities and legal background:**
 Ministry of Health, Social Policy & Equality (MoH), Directorate General for Pharmacy and Health Care Products (DGFPS)
 Interministerial Pricing Committee (led by MoH ,Economy & Finance, Industry) (IPC)
 Medicines Act 29/2006 art 90, 91, 92, 93
- **Procedure:**
 Company price application (pricing proposal, production costs, estimated sales, comparative costs with similar products in Spain, price in other EU countries)
 A technical staff team in the DGFPS performs a therapeutic utility report (place in therapy, alternatives, applicability) followed by a pharmacoeconomic assessment (cost comparisons, budget impact) to support pricing negotiations and IPC decisions
 IPC fix maximum ex factory prices for reimbursed medicines

Timing:
 6 months since the submission, fast track for generics
 IPC meetings / month


Dirección General de Farmacia y Productos Sanitarios





REIMBURSEMENT

- **Competent authorities and legal background:**
 Ministry of Health, Social Policy & Equality, Directorate General for Pharmacy and Health Care Products (DGFPS)
 Interterritorial Board of the NHS
 Medicines Act 29/2006 art.89, RD 1348/2003, RD 1030/2006
- **Decision criteria for granting reimbursement:**
 Severity of disease, certain patient needs, therapeutic & social value, incremental clinical benefit considering cost effectiveness, rational pharmaceutical expenditure and budget impact, alternatives availability, innovation degree
- **Reimbursement categories & rates, predefined by ATC pharmacotherapeutic groups**
 - 60% (majority of reimbursed medicines)
 - 90% (products for chronic diseases)
 - 100% (pensioners, hospital medicines)

Dirección General de Farmacia y Productos Sanitarios






REFERENCE PRICING SYSTEM

- Grouped by active ingredient and route of administration, each group including at least a generic or biosimilar. Reference price is the lowest cost/treatment/day by DDD
- Possibility for relevant galenic innovations to be excluded from the system during a five year period or until generic availability
- The system covers 179 active ingredients. 55,4% of reimbursed medicines are included in the reference price system
- Additional interchange groups of identical products for substitution
- External price referencing only for innovative medicines, not in the context of reference pricing system

Dirección General de Farmacia y Productos Sanitarios




PRICING & REIMBURSEMENT PUBLIC ACCESS

- <http://www.mspsi.gob.es/profesionales/farmacia/frmNom-enclator.jsp>
NHS reimbursed pharmaceuticals information: Identification data, gross retail price, reimbursement category, subject or not to internal reference pricing, subject or not to mandatory discounts. Lower prices information
- <http://www.mspsi.gob.es/profesionales/farmacia/financiacion/home.htm>
Interministerial Pricing Committee fixed maximum ex factory prices
- http://www.mspsi.gob.es/profesionales/farmacia/pdf/formulario_solicitud_precio_EN.xls
Pricing application form for Companies

Dirección General de Farmacia y Productos Sanitarios





COST CONTAINMENT

- In 2010, two RD Laws were issued about urgent modifications to reduce expenditure and to ensure NHS sustainability: measures included price cuts and discounts, reference pricing modifications, interface dispensing conditions, centralised procurement. Some of these measures came into force in 2011
- Reference Pricing groups are currently updated by Ministerial Order once a year, last one was published on 26 nov 2010 and came into force by march 2011 reflecting further expenditure reductions since that date.
- Additional regional initiatives regarding rational use, medicines selection or purchasing

Dirección General de Farmacia y Productos Sanitarios





COST CONTAINMENT

- In 2011, further cost containment measures have been agreed in the Interterritorial Council of 21 July and adopted by RD Law 9/2011 in the Council of Ministers of 19 August:
 - Prescription by active ingredient
 - Only lower priced products will be dispensed
 - The procedure to create new reference pricing groups will be speed up and graduality eliminated
 - 15% discount for innovative medicines more than 10 years in the market without a generic
 - Reinforce mechanisms to promote selective reimbursement, including more value based approaches. Participation of regions is foreseen in this context
 - Small retail pharmacies compensation

Dirección General de Farmacia y Productos Sanitarios






Pharmaceutical expenditure 2005- 2011

Year	NHS pharmaceutical expenditure, millions € gross retail price	% Δ previous year
2006	10.636,06	5,82
2007	11.191,07	5,22
2008	11.970,96	6,97
2009	12.505,69	4,47
2010	12.211,10	-2,36
2011 (march)		-5,77
2011 (june)		-9,42


Dirección General de Farmacia y Productos Sanitarios





Generic market share

	% per volume	% per value
2005	14,10	7,35
2006	16,72	8,54
2007	20,94	9,23
2008	21,81	9,20
2009	23,82	9,38
2010	27,39	10, 91
2011 (jan)	31,40	12,43

Dirección General de Farmacia y Productos Sanitarios





FINAL COMMENTS

- Sustainability has been a key issue during these last years. Pharmaceutical expenditure has been subject to restrictive measures reaching an annual costs reduction up to 2500 millions euros that may be doubled with the recently approved reforms
- The future will be more focused on value based approaches and reinforced interregional coordination

Dirección General de Farmacia y Productos Sanitarios

