

SPAIN

Recent changes in pharmaceutical policy measures and developments in pharmaceutical expenditure

Major changes in pharmaceutical policy in 2012-2013

Pricing

- Urgent measures to guarantee NHS sustainability- RD Law 16/2012
- Lower prices for NHS reimbursed products. Prices for non-reimbursed products need to be notified to the Ministry of Health
- Obligation to dispense the lowest price product. Lowest prices adjusted on a monthly basis (voluntary decreases subject to a minimum of 10% decrease)
- Centralised procurement platform - applied in 2012 to influenza vaccine, children calendar and some adult vaccines. Products approved recently:
 - Medicinal products: epoetins, monoclonal antibodies anti-TNF
 - Medical devices: examination and surgical gloves, blood glucose strips, material to control incontinence
- Increase in VAT of Medical Devices from 8% to 10%

Reimbursement

- Delisting of medicines - 417 medicines for minor ailments, 90 of which maintain reimbursement for certain severe or chronic indications in order to avoid treatment gap.
- Co-payment now linked to income (from € 18.000/year):
 - Active workers: ranges between 40-60%
 - Retired: ranges between 10%-60% up to a maximum per month
- Changes/modifications to the reference price system:
 - Ability to create groups without generics if medicine or API approved in an EU Member State for more than 10 years.
 - Reference groups must ensure the supply of lower price medicines
 - Independent groups for hospital medicines (including hospital packs)
 - Medicines declared Galenic Innovations would no longer be excluded from the system

Other changes

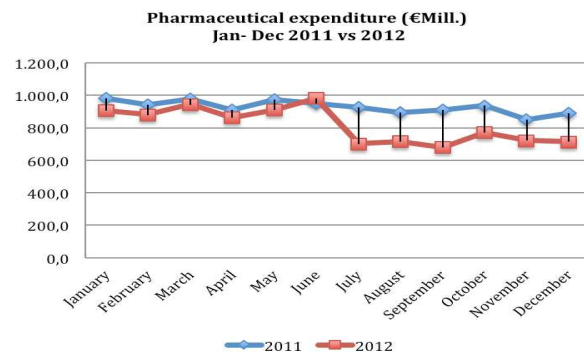
- Mandatory prescription by active ingredient. Lowest price product dispensing favouring generics (brand name possible for chronic diseases or non substitutable medicines)
- Encourage e-health: common health card, e-prescription, electronic medical record
- Value based approaches: The Spanish Agency of Medicines has begun to elaborate therapeutic positioning reports in connection with the Regions for pricing and reimbursement decisions
- Pricing decisions based in cost-effectiveness analysis and budget impact
- The Interministerial Pricing Committee now includes two rotating members from the Regions in addition to the existing representatives of the Ministries of Health, Economy, Finance and Industry

Outlook

Development of pharmaceutical expenditure in the last 5 available years

Year	NHS pharmaceutical expenditure, € million gross retail price	% Δ previous year
2007	11,191.07	5.22
2008	11,970.96	6.97
2009	12,505.69	4.47
2010	12,221.10	-2.36
2011	11,135.40	-8.78
2012	9,769.7	-12.26

From July 2012 to January 2013 € 1,2bn have been saved in the pharmaceutical spending



(Source: Spanish Ministry of Health)

Impact of measures Given the broad pharmaceutical coverage of the NHS, there has been scope to implement cost containment measures to ensure the sustainability of the system. However access to medicines for vulnerable groups have been guaranteed: 0% co-payment is applied for lowest social pension, unemployed without benefits and occupational diseases



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Pharmaceutical Pricing and Reimbursement Information