

# Pharmaceutical pricing and reimbursement policies

## SPAIN

### Ministry of Health



Directorate General (DG) for Common NHS Services Portfolio and Pharmacy  
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Total population= 48.59 Million € (INE (2024))  
GDP 28,162 € (INE (2023))  
Tax funded system = NHS  
Public Health expenditure: 92,072 million € (2022)  
Pharmaceutical expenditure 29,687 million € (2023)

### Pricing of medicines

**Competent authority for pricing and reimbursement:** Ministry of Health (MoH) is in the out-patient and in-patient sector.

**Pricing decisions:** Price & Reimbursement Committee: Members: Representatives from the MoH, the Ministry of Finance, Ministry of Industry, Ministry of Economy and Competitiveness, and of all Regional Governments (payers). No price fixing by P&R Committee for non-reimbursed medicines.

**Price regulation:** At ex-factory price level.

**Pricing procedures:** All prescription-only medicines (unless in negative list) are subject to P&R prior to marketing. Price established centrally for both out-patient and in-patient (though additional tendering may be applied at regional or hospital level for in-patient medicines). Criteria applied: Internal Price Referencing (list updated yearly), cost-effectiveness and cost-minimisation, general rule of 40% discount for first generic and 30% for first biosimilar, external reference pricing (used only as an additional criterion).

**VAT:** 4% (reduced)

**Reforms:** Since 2010, mandatory discounts as cost-containment measures. Discounts are of 7.5% for originator medicines, 4% for orphan and 15% for medicines reimbursed for more than 10 years and without a generic, Discounts granted jointed by manufacturers, wholesalers and pharmacies to the NHS for all reimbursable. Exemption: Products included in the internal reference price system.

#### Margins

**In-patient:** Wholesale and pharmacy remuneration not applicable in the in-patient sector.

#### Out-patient:

Wholesale remuneration	Pharmacy margins
Ex-factory price ≤91.63 €, margin = 7.6% of wholesale price.	Ex-factory price ≤91.63 €, 27.9% of pharmacy retail price.
Ex-factory price >91.63 €, fixed wholesale margin of 7.54 €	Ex-factory price >91.63 € and ≤ 200 €, fixed pharmacy margin of 38.37 €/pack.
	Ex-factory price >200 € and ≤ 500 €, fixed pharmacy margin of 43.37 €/pack.
	Ex-factory price is >500 €, fixed pharmacy margin of 48.37 €/pack.

Since August 2000, pharmacy claw-back in place. Retail pharmacies payments based on a percentage of their annual sales of reimbursable medicines at manufacturer prices.

### Coverage / Reimbursement

**Competent authority for pricing and reimbursement:** Ministry of Health (MoH).

**Internal Price Referencing (IPR):** Reference assigned by ATC level 5. Yearly updates.

**Number of medicines included in the positive list:** Over 18,000 medicines (both in-patient and out-patient)

#### Co-Payment:

OUT-PATIENT	IN-PATIENT
Both positive and negative lists are national. Positive list updated monthly and available at: <a href="https://www.sanidad.gob.es/profesionales/nomenclator.do">https://www.sanidad.gob.es/profesionales/nomenclator.do</a> .	Full public coverage. (No co-payment apply)
<b>Co-payment (applied to retail selling price):</b> 60% of medicine price for people earning ≥100,000 €/year 50% for people earning ≥18,000 and <100,000 and, 40% for the remaining employed citizens. Specific medicines for long term treatment benefit from reduced co-payment of 10% of selling price with a max. fee of 4.24 €/pack. Co-payment for retired people is 10% with a max. monthly co-payment depending on earnings (4.24€, 8.23€, 18.52€ and 61.75€ respectively). Special vulnerable collectives are exempt from co-payment.	In terms of coverage and reimbursement, consideration of in-patient medicines is given to drugs dispensed only in hospitals regardless of whether the patient is formally admitted or is ambulatory

**National governmental programs for optimisation in the use of:** Generics and biosimilars, Opioids for non-oncological pain and Chronic hepatitis C.

### LINKS TO PUBLIC INFORMATION

- 🔍 Search tool for retail price (VAT included) of all out-patient medicines reimbursed (monthly update): <https://www.sanidad.gob.es/profesionales/nomenclator.do>
- 🔍 **Reimbursement info (BIFIMED):** a web search tool for public reimbursement status and conditions information: <https://www.sanidad.gob.es/profesionales/medicamentos.do>
- 🔍 **VALTERMED:** NHS information system to gather information on real world data for decision making. Specially aimed for high priced medicines. <https://www.sanidad.gob.es/areas/farmacia/infoMedicamentos/valtermed/home.htm>
- 🔍 Internal Price Reference list. Available at: <https://www.boe.es/boe/dias/2023/11/01/pdfs/BOE-A-2023-22303.pdf>

### HTA

New HTA specific legislation on development. Foreseen in 2024.