



# SPAIN

## Ministry of Health, Consumer Affairs and Social Welfare

Directorate General (DG) of Services of the National Health System Basic Portfolio and Pharmacy

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### Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

Total population= 46,72 Millions (World Bank (2018))  
 GDP per capita (USD) =40,854.6 (World Bank (2018))  
 Organisation of health care sector = NHS  
 Health expenditure per capita= 2,389.89 USD (World Bank (2016))  
 Health expenditure in % of the GDP= 8.96% (World Bank (2016))  
 Pharmaceutical exp. (%current health exp.) = 22,3 %.(OECD 2016)

PRICING

The Ministry of Health, Consumer Affairs and Social Welfare (MoH) is the competent authority for pricing and reimbursement in the out-patient and in-patient sector. Payers are the regional governments and decisions are made by a Price & Reimbursement Committee (P&R committee), whose members are representatives of the MoH, as well as representatives of the Ministry of Finance and Civil Service, Ministry of Industry, Trade and Tourism, Ministry of Economy and Competitiveness, and of all Regional Governments health representatives.

#### Pricing in the out-patient sector and in-patient/hospital sector

Ex-factory price is established by the P&R committee for all reimbursable medicines (both out-patient and in-patient). External price referencing is used as supportive pricing policy. Policies for generic and biosimilars are in place. Conditional pricing is also applied (capping, MEAs). Reference price system (RPS) is also applied for out-patient price fixing. VAT for medicines is a reduced rate of 4%

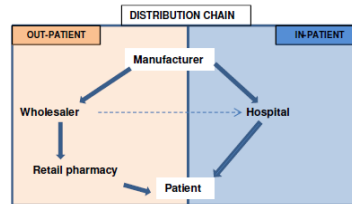
#### OUT- PATIENT

**Wholesale remuneration**  
 Ex-factory price ≤91.63 €, wholesale margin is 7.6% of the wholesale price. Ex-factory price >91.63 €, fixed wholesale margin of 7.54 €  
**Pharmacy margins**  
 Ex-factory price ≤91.63 €, 27.9% of pharmacy retail price. 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.

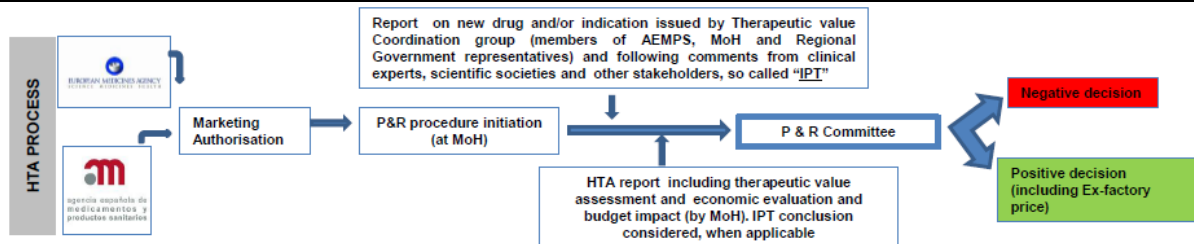
A pharmacy claw-back system has been in place since August 2000, with pharmacies making payments based on a percentage of their annual sales of reimbursable medicines at manufacturer prices

#### IN - PATIENT

Wholesale remuneration and pharmacy remuneration are not applicable in the in-patient sector  
Tendering for medicines in the in-patient sector in addition to pricing policies is also applied.



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



COVERAGE / REIMBURSEMENT

#### Coverage / reimbursement out-patient sector

There are both positive and negative lists. Medicines included in the positive list are updated monthly and available at: <http://www.mscbs.gob.es/profesionales/nomenclador.do>

#### Co-payment

60% of selling price of medicines 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 have a reduced co-payment of 10% of the price with a maximum fee of 4.26 €/pack. Co-payment for retired people is 10% with a maximum monthly co-payment depending on earnings (6€, 18€ and 60€, respectively). Special vulnerable collectives are exempt from co-payment.

**Coverage / reimbursement in-patient sector:** 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.

**NEW:** A new search tool informing on whether a medicine is reimbursed or not (including both out-patient and in-patient), is currently under development. Availability foreseen in November 2019.

#### Co-payment:

There is full coverage of reimbursed medicines with no co-payment by patients in the in-patient sector