SPAIN

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

No changes to pricing made since last update. However, changes to pricing for generics and biosimilars are foreseen.

Volume sales are regularly monitored, and price reviews are negotiated by a specific team to adapt prices to the real volume sales within NHS, in case of excess.

CHANGES IN REIMBURSEMENT

A new P&R national legislation is under development. Foreseen in 2025.

OTHER CHANGES

CHANGES ON TRANSPARENCY: Public reports containing details and grounds for reimbursement publishing was started in the first quarterly 2015 for some new medicines. This transparency measure will start with reimbursement decisions only. At the end of first semester 2025, reports for all reimbursed new medicines from september 2024 onwards should be available (sorted by ATC code) at: https://www.sanidad.gob.es/areas/farmacia/precios/comisionInteministerial/informesPublicos/home.htm

PHARMACEUTICAL STRATEGY: The new Pharmaceutical Industry Strategy (2024-2028) was published with participation of 4 Ministries: Health; Revenues; Industry and Tourism; and Science, Innovation and Universities and the main Pharmaceutical Industries Associations. The strategy aimes at promoting equitative access to medicines, the sustainability of the NHS and the promotion of innovation and competitiveness in the industry. Framed within the Recovery and Resilience Facility (RRF) and also meant as a contribution to the Pharmaceutical Strategy for Europe.

WORK LINE 1: Access for patients, unmet medical needs coverage and NHS sustainability.
This line contains a number of measures including:

- **Creation of a HTA, Price & Reimbursement System;**
- **Improvements in the following areas: HTA; timely access to medicines; current reimbursement procedure; Internal Reference Pricing System; and Procurement of medicines.**
- **National consumption information systems**
- **Completeness of biomarkers and genetic testing incorporation to the NHS Services.**
- **Plan for the promotion of biosimilars and generics**
- **Plan for access to innovative medicines**
- **Update of National sustainability tool**

(Full document available at: https://www.sanidad.gob.es/areas/farmacia/infoIndustria/docs/Estrategia_de_la_industria_farmaceutica.pdf)

NEW LEGISLATION: New Medicines and Medical Devices Law is under development. Expected to be approved and published during 2025.

SPECIAL TOPIC:
Current advances in HTA
(for EU Member States: Implications from EU-HTA Regulation)

Positioning reports (similar to clinical HTA) were elaborated by the Spanish Medicines and Medical Devices Agency and approved jointly by a group of experts in Spain since 2013, to support P&R decisions. These Positioning reports will continue to be elaborated for those medicines, for which Joint HTA assessments are not mandatory.

Joint HTA reports should be used instead to support P&R decisions for those medicines with Joint HTA Assessments available.

Changes needed within the process are being identified and will be reviewed and included in the new HTA national legislation under development. This dedicated legislation is being developed, and it is foreseen to be published during 2025.

CHALLENGES: Expertise (specially in non-clinical aspects) and need for Human and Financial Resources are the biggest challenges encountered. ⚠