PPRI
Pharmaceutical Pricing and
Reimbursement Information

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Infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde, I.P.

PORTUGAL

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

- **Reference countries** (Jan25): Spain, France, Italy and Belgium (Belgium took Slovenia's place this year)

- **Annual price review (APR):** (Jan25)
  - **Exceptional measures** – Price increase for medicines with a Max Retail Price (MRP) ≤ €16.00 ➜ May increase up to **2.6%** (based on MRP of 15/11/2024)

  - **APR for Non-Generics & Non-Biosimilars**

A. Outpatient Market	B. Hospital Market
o MRP ≤ €16.00 ➜ **Exempt**	o Acquisition Price ≤ €75.00 ➜ **Exempt**
o €16.00 < MRP ≤ €30.00 ➜ Max reduction: **5%**	o Acquisition Price > €75.00 ➜ Max reduction: **5%**
o MRP > €30.00 ➜ Max reduction: **10%**	

  - **APR for Generics & Biosimilars**

A. Outpatient Market	B. Hospital Market
o MRP ≤ €16.00 ➜ **Exempt**	o Price ≤ €75.00 ➜ **Exempt**
o MRP > €16.00 ➜ **Price decreased to align with reference medicine**	o Price > €75.00 ➜ **Price decreased to align with reference medicine**

CHANGES IN REIMBURSEMENT

Recent changes:

- **Full reimbursement of medicines for elderly with lowest income** (Jun24)
  ➜ **100%** reimbursement for all medicines prescribed within the NHS

- **Reinforced reimbursement for Former Military** (Jan25)
  - **Pensioners: 100%** reimbursement
  - **Non-Pensioners: 90%** reimbursement for psychotropic drugs

- Reimbursement for **Endometriosis Medicines** (Jan25)
  ➜ **69%** reimbursement

- **Exceptional co-payment scheme update - Pneumococcal Vaccine** (Mar25)
  - Targeted benefeciaries:
    ➜ Focus on **at-risk populations: all individuals >= 65 years**
  - Expanded coverage: **included new pneumococcal vaccines**

- **Revision of the Portuguese HTA system** (on-going)

OTHER CHANGES

- **Creation of specific internal teams to support the promotion of prescription/use of generic and biosimilar medicines** (Ongoing)
- **Reference pricing system for biological medicines for out-patient sector** (ongoing)

- **New Government–Pharmaceutical Industry Agreement** (Mar25) signature aimed at:
  - Strengthening the financial sustainability of the National Health Service (NHS)
  - Enhancing access to innovation and medicine availability
  - Stimulating research and development
  ➜ sets a maximum public medicines expenditure growth cap of 7%

> **Spending Review**

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

Overview of the HTA Process in Portugal

- HTA is coordinated by **INFARMED, I.P.**, with the support of Health Technology Assessment Commission (CATS)
- The process plays a central role in **pricing and reimbursement (P&R) decisions** for medicines and health technologies within the **NHS**
- Assessment focus **on clinical benefit (therapeutic added value)**, **quality of evidence**, **cost-effectiveness** and **budget impact**.
- Final decisions on P&R are made by the Ministry of Health, based on INFARMED's assessments and recommendations

Impact of the EU HTA Regulation (EU 2021/2282)

- Introduction of **Joint Clinical Assessments (JCAs)** will streamline early-phase evaluations of new health technologies across the EU
- Portugal is adapting national processes to ensure **alignment with EU-wide methodologies (but only minor changes needed)**
- Expected benefits:
  • **Reduced duplication** of clinical assessments
  • **Faster access** to innovative medicines
  • Enhanced **transparency and consistency** in evaluations

Looking ahead

Portugal remains committed to an effective implementation of the EU HTA Regulation, with an emphasis on collaboration, transparency, and sustained patient access to innovation

Institutional and Methodological Adjustments

- Reinforced collaboration between INFARMED, I.P., and EU HTA bodies.
- National procedures are being adapted to **integrate EU JCA outputs** into the reimbursement pathway.
- Training (participation in HAG insight capacity building) and internal alignment to ensure application of **EU methodological guidelines**.

Challenges and Barriers

- Ensuring **timely integration** of EU-level assessments into national timelines.
- Balancing **national priorities** with the **standardised EU approach**.
- Need for ongoing investment in **resources**, **digital tools**, and **cross-border coordination**.