# PORTUGAL

## Recent and planned developments in pharmaceutical policies 2025/2026

### CHANGES IN PRICING

- **2026 Annual price review (APR)**:
  **1) APR for non-generics & non-biossimilars** (jan/26)
  A. Outpatient: MRP (Maximum Retail Price) ≤ €30.00 ➔ Exempt;
  MRP > €30.00 ➔ Max reduction: 20%;
  B. Hospital: Exemption for medicines with Acquisition Price ≤ €75.00
  **2) APR for Generics** (feb/26): Price decreases only to align with the reference medicine;
  **3) Essential medicines of critical nature** in the outpatient market: exempt from APR;
- **Change on the biosimilar price** (planned) » linking to the price of the medicine of reference, replacing the external referencing currently used

### CHANGES IN REIMBURSEMENT

- **Obesity Focus:** An impact study regarding the reimbursement of obesity medicines was completed and will be used for decision-making (dez/25)
- **Exceptional Reimbursement Schemes** (ongoing): review for specific diseases - harmonization on the content and update on the reimbursed pathologies

### OTHER CHANGES

**Revision of the Portuguese HTA system** (awaiting approval and publication in the official journal):

- **EU HTA:** Full alignment with Regulation (EU) 2021/2282 for joint clinical assessments and scientific consultations, integrating it at national level.
- **Expanded Scope:** Strengthening the evaluation of other technologies (e.g., medical devices, digital app).
- **Priorisation:** Early identification of disruptive technologies through the Horizon Scanning to ensure timely access.
- **Real-World Evidence (RWE)**: Use of clinical and administrative data to monitor effectiveness and reassessment purposes.
- **Stakeholder Engagement:** Independent participation of patient associations and other stakeholders in the assessment process.
- **Streamlined processes:** faster decision-making for paediatric extensions and vaccines. Priorisation for economic assessment (with major added therapeutic value). Exemption from clinical evaluation (new presentations of already funded medicines). Automatic pricing for generics and biosimilars.
- **Transparency & Data:** Public information on the submission and decision dates regarding the reimbursement applications. Ensure that INFARMED, I.P. has timely access to health data through the interoperability of national registries and information systems, aligned with the European Health Data Space.
- **Low clinical evidence**: it cannot exceed 5% of the comparator's price. Moreover, additional evidence can be submitted later for reassessment.

### SPECIAL TOPIC:
### Regulation, pricing and reimbursement of pharmaceutical combination products

**1. Definition**

Combination products are drug associations that may involve different Marketing Authorization Holders (MAH). This concerns innovative medicines where at least one of the drugs (Drug A) has an approved "in-label" indication for use in combination with a passive partner drug (Drug B), that might be already be on the market.

**2. Pricing**

Each medicine has an individual price, but for reimbursement is considered the total cost of the treatment (Drug A + Drug B).

**3. Reimbursement & Contractual Challenges**

- **Absence of Joint Responsibility:** Lack a mechanism for joint contractual liability between different MAH. While a combination (Drug A + Drug B) benefits both companies through increased revenue, the "passive" partner (Drug B) usually retains its original contract without revisions to its price or expenditure limits (LE).
- **Economic Burden on Requesting MAH:** To demonstrate the required "economic advantage" based on total treatment cost, the requesting MAH (Drug A) may be asked to reduce its own price, especially if it is comparable with the alternative.
- **Liability for Expenditure Limits (LE):** It is difficult to review the cap of the Drug B.

**4. Regulation**

Under the new legislation it will be possible to review the financing conditions of any medicine within a combination that is already funded, regardless of whether the drugs belong to the same or different MAH, to manage shared expenditure and ensure sustainable access to these innovative therapies. This will involve mandatory negotiations with both MAHs to mitigate risks to the NHS.