

Portugal

Recent and planned developments in pharmaceutical policies 2023

CHANGES IN PRICING

- **Annual price review in 2023:**
 - Suspension for all medicines in the in-patient sector (03/2023)
 - Applicable only to medicines in the out-patient sector (03/2023)
 - retail price (RP) < 10 € » 5% **price increase***
 - 10 € ≤ RP ≤ 15 € » 2% **price increase ***
 - RP > 15 € - maximum price reduction of 5% (exceptional brake mechanism in order to guarantee the sustainability of the SNS and simultaneously avoid the erosion of prices)
 - for generic medicines only with price RP >15 € above the reference medicine (04/2023)
- *Note: **exceptional criteria** are introduced to allow an increase in the lowest prices in order to preserve their distribution in the market.
- Establish a mechanism to identify medicines with excessive cost, which may lead to a downward revision of their price, indexing this option to increase its market share, under conditions to be defined by legislation (01/2023)
 - The elaboration of an essential medicines list, of high criticality, which will be subject to specific measures (e.g., price increase), in order to ensure, its supply without interruption (within 90 days after 26/01/2023)

CHANGES IN REIMBURSEMENT

- Update on the methodology for pharmacotherapeutic assessment version 3.0 (08/2022)
- Reinforcement of HTA Committee (11/2022)
- Simplification of the HTA assessment for specific products (e.g., vaccines and others) (planned)
- Reimbursement of Evrysdi (risdiplam) indicated for the treatment of spinal muscular atrophy (SMA), based on performance managed entry agreement and supported by a register developed to follow-up SMA patients (01/2023)
Special conditions applied to Evrysdi:
 - ✓ NHS reimbursement in case worsening of motor or respiratory function
 - ✓ Special conditions applied in case of death or permanent intensive ventilation
 - ✓ Specific platform developed for SMA

OTHER CHANGES

Agreement with Pharmaceutical Industry under review

SPECIAL TOPIC:

Developing and implementing pharmaceutical policies in view of the current challenges (soaring inflation, medicine price increases, increasing no. of medicine shortages)

- 1) **Medicine shortages:** Problems with shortages have increased especially during and after COVID times. Most of the policies were implemented before it.
 - National register to report shortages in place, managed by INFARMED, I.P. MAH shall report shortages for any medicine with 2 months in advance.
 - Medicine reserves supplies in place, obligatory and sanctions may be applied in case of non-compliance. MAH and wholesalers shall stock, based on average monthly sales.
 - Export ban / notification for medicines targeted by shortage: for some medicines included in the "**Ex ante notification list**" (published in a Decree-Law) and medium/ high impact shortages, there's an obligation to notify export.
 - Regulatory measures: In case of shortages of medium and high impact in public health, MAH must submit a shortage prevention plan with a specific set of actions and assessment of national and international supply. MAH and wholesalers have specific obligations regarding safety stocks (two months) and the notification of a shortage two months in advance. Additionally, there are several measures that can be put into place, depending on the medicine, its relevance, the type of shortage or its duration, namely the exceptional use of foreign language packages, issuance of therapeutic guidelines, controlled distribution, export ban, etc. The Agency works in close cooperation with the National Commission of Pharmacy and Therapeutics in order to identify valid alternatives for high impact shortages.
 - Financial measures: The price of medicines has been decreasing over the past years. In the current year the price of cheaper medicines was increased to prevent availability problems.
 - Stakeholder involvement: The close contact with stakeholders, namely MAH, manufacturers and wholesalers, is key to avoid shortages or, at least, to minimise its impact. Therefore, in Portugal this involvement occurs on a daily basis.
 - Other: discussion on unsustainably low prices; shortages of antibiotics are closely monitored; a medicine shortage does not automatically mean that there are no treatments for patients available. A list of essential medicines is under preparation.
- 2) **Price increases:**
 - **Exceptional Review of prices** - Consist in the authorization, on an exceptional basis, of higher prices than those that are approved by reasons of public interest or at the initiative of MAH.
 - Applicable to reimbursed medicines subject to medical prescription. The pharmaceutical company submits an application to INFARMED, I.P. after its 1st Annual Price review.
 - The application is evaluated within 75 working days. Clock-stop in case there are requests to companies.
 - **Criteria:** Indispensability of the product considering the relative effectiveness; Economic advantage; Productive and Economic Viability and Budget affordability.
 - **In case of a grant of an REP application:** only allowed a new REP application within three years from the notification of approval of a decision on the REP application immediately prior for the same medicine.
 - **In case of a refusal of a request** for REP application: only allowed a new REP application provided that:
 - Have elapsed six months of the notification of the decision given on the REP application immediately prior for the same drug, and
 - If you make a subsequent change regarding the factors that contributed to the decision.
 - Increase in price increase requests was observed.
 - **Annual Revision of prices** – exceptionally during 2023 was possible to increase prices of medicines in the outpatient sector for medicines with RP below 15 € per package
 - **Medicines outside out-patient reimbursement list:** free pricing, **price notification procedure (max 10% increase and not higher than 2,5 €)**
- 3) **Price level freezing during this crisis situation:** despite the suspension of the RAP in 2023 for the maximum prices of medicines in the in-patient sector, prices might be reviewed within the scope of contract monitoring
- 4) **Introduction or discussion of other measures related to current challenges (high inflation rates, budget caps, high-priced medicines, introduction of production sites in Europe, etc.):** Managed entry agreements under review (around 348 contracts) – price negotiations, NHS caps and outcome-based – monitored every two years