BRAZIL

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

Our main regulation on medicine pricing (Resolução CMED nº 02/2004) is under revision. Status: under Regulatory Impact Assessment.

- **General goals**: promote Pharmaceutical Assistance to the population, through mechanisms that stimulate the supply of medicines and the competitiveness of the sector.

In Brazil, a technical group is currently working on analysing the following topics, which may be submitted to the CMED Executive Technical Committee for deliberation and, subsequently, to the Council of Ministers:

1. Definition of an updated list of reference countries for External Reference Pricing (ERP), to consider the current reality of the global pharmaceutical market.
2. CMED proposes clearer rules for granting provisional prices, allowing reviews based on new clinical and economic data so that drugs enter the market with prices closer to their real effectiveness.
3. Public consultation and participation in the sector - all proposed changes will be submitted to a public consultation before implementation.
4. Improving the pricing model for new medicines through dialogic processes for innovative medicines registered in Brazil which are under development (undergoing studies).
5. Formally consolidate CMED's understandings regarding the interpretation and application of CMED Resolution No. 02/2004, through its inclusion in the new regulatory proposal and provide for reinforced advertising obligations in the new regulatory alternative.

OTHER CHANGES

- CMED has published targeted consultation on pricing of advanced therapy medicinal products- ATMPs (Edital de Chamamento 01/2025): from feb/10th to mar/28th. Status: under evaluation of the proposals.
    - Targeted stakeholders: healthcare professionals, patients, pharmaceutical industry representatives, researchers, government entities and all other interested parties.
    - Pricing advanced therapies involves specific challenges and directly impacts the viability of these treatments. Thus, contributions from society will help build an appropriate regulatory instrument, promoting a more transparent, participatory and innovation-friendly regulatory environment.

SPECIAL TOPIC:
HTA process in Brazil