

BRAZIL

Recent and planned developments in pharmaceutical policies 2026

CHANGES IN PRICING

Our main regulation reviewing on pharmaceutical pricing was finished and the Resolution CM-CMED n. 3/2025 was published in December/2025. Status: in preparation for entry into force on April 29th.

Incremental innovation: a) new combination; b) new single drug; c) new route of administration; d) new concentration; e) new pharmaceutical form; f) new packaging; or g) other incremental innovation.

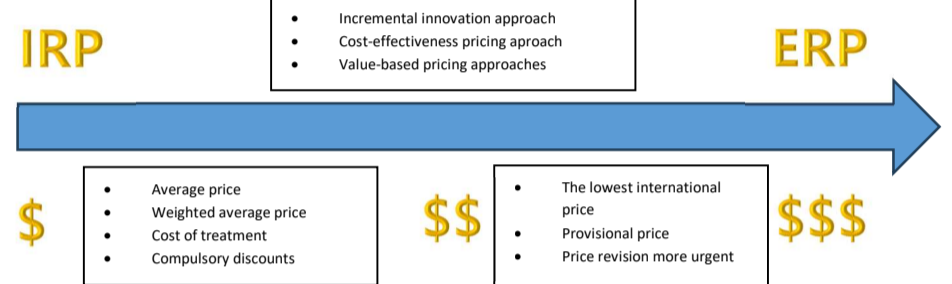
- Incremental innovation can provide a bonus regarding the comparator if it brings additional clinical benefit, increased patient safety, or gains on health system efficiency through reduced costs associated with treatment administration.
- Rewarding the national production and the Brazilian R&D > possibility of special pricing for local development.
- Flexible pricing in more competitive markets.
- Pre-submission meeting: the pricing rational negotiation between laboratory and regulator (dialogic processes).

New ERP basket (15): South Africa, Germany, Australia, Canada, Spain, United States of America, France, Greece, Italy, Japan, Mexico, Norway, Portugal, United Kingdom and Origin > Always the lowest price (\$).

Provisional price is established if price is available in less than 4 countries or in cases where registration is conditional upon the submission of additional data and evidence after registration has been granted.

Biosimilars: compulsory 20% discount regarding the originator. Moreover, the originator price will be cut off in 20% with the first biosimilar entry.

Generics: compulsory 35% discount regarding the reference medicine.



OTHER CHANGES

Advanced therapy medicinal products (ATMPs): we've launched a targeted consultation (Edital de Chamamento 01/2025). Objective: to collect data, information, opinions, and suggestions regarding pricing criteria for advanced therapy products, in order to support a proposed regulation. Moreover, in March/2026, we've organized a 3-day workshop in order to discuss and test value-based pricing approaches for ATMPs, such as the Pharmaceutical Innovativeness Index (PII) and the efficiency frontier. Currently, there is a Working group preparing a draft which will be submitted to public consultation.

Price revision regulation: Establish criteria for extraordinary adjustments (positive or negative) to pharmaceutical prices. The draft will be submitted to public consultation this year.

Radiopharmaceuticals price regulation: Technical discussions aimed at developing a methodology for pricing radiopharmaceuticals, following guidelines for quality improvement and greater regulatory legal certainty.

Pharmaceutical judicialization: criteria for setting and adjusting drug prices in sales to government to meet court orders for the supply of medicines.

SPECIAL TOPIC:

Value-based approach for ATMPs pricing - The Pharmaceutical Innovativeness Index (PII) and the efficiency frontier

