

# BRAZIL

## Recent and planned developments in pharmaceutical policies 2023

### CHANGES IN PRICING

A public consultation is underway in Brazil on a reform of the country's drug pricing framework.

Main proposed changes:

- Biosimilars: their prices may not exceed 80% of the reference product's price.
- Products with incremental innovation: bonus up to 35% of their internal referential price comparators

The public consultation is still ongoing and the proposals have not been implemented.

### CHANGES IN REIMBURSEMENT

In Brazil, the public health system provides services and products free of charge (Law n. 8080/1990).

The Ministry of Health evaluates the incorporation of new products to be made available to citizens, considering scientific evidence regarding safety, efficacy and effectiveness.

### OTHER CHANGES

- Changes in the incidence of taxes will reduce some drug prices.

### SPECIAL TOPIC:

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

- 1) The problem of **medicine shortages** (i.e. especially in certain product groups like antibiotics) seems to have intensified:
  - The logistics problems arising from the COVID pandemic have also affected the Brazilian market. In 2022, the Drug Market Regulation Chamber (CMED) evaluated several reports of medicine shortages. Considering that the Chamber is responsible for the economic regulation of the medicine market, it was studied which shortages resulted from insufficient ceiling prices. The selected medicines were temporarily released from price control.
    - AMICACIN SULFATE (250 MG/ML SOL INJ);
    - AMINOPHILINE (24 MG/ML SOL INJ);
    - DOPAMINE CHLORIDATE (5MG/ML SOL INJ);
    - DIPIRON (500 MG/ML SOL INJ);
    - HUMAN IMMUNOGLOBULIN (5,0 G);
    - MAGNESIUM SULPHATE (10% E 50% SOL INJ);
    - FITOMENADION (10 MG/ML);
    - SALBUTAMOL SULFATE (0,5 MG/ML);
    - OCYTOCIN (5 UI/ML SOL INJ);
    - SWINE SODIUM HEPARIN (5.000 UI); and
    - BOVINE HEPARIN SODIUM (5.000 UI).

The price control release will end on June 30th, 2023. After this date, the ceiling prices of these products will be defined through a new pricing procedure, the criteria of which will be determined by CMED.
- 2) **Price increases:**
  - Since the 1990s, inflation has been controlled in Brazil. However, the formula for annual price adjustment has the accumulated inflation of the previous year as one of their parameters, so the ceiling prices of medicines are adjusted upward annually.
  - In 2020, at the beginning of the COVID pandemic, the price adjustment scheduled for the end of March was exceptionally postponed until the second half of that year.
- 3) Products classified as **advanced therapies** (gene therapies) are very expensive and represent a challenge for the Brazilian health system and for the pricing process.