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## OBJECTIVES:

To analyze international regulatory practices regarding the use of provisional drug pricing and to compare them with the Brazilian strategy.

## METHODS:

This is an exploratory, documentary study with a comparative analysis of regulatory practices on the use of provisional prices in 15 countries, conducted in December 2025.

## CONCLUSIONS:

Few countries adopt provisional pricing, and when they do the timeframe is predictable. Ensuring predictability and legal certainty in regulation is essential to guarantee access and the sustainability of the health system.

## RESULTS:

Country	Is there state regulation of prices?	Is there provisional pricing?	Duration of provisional price
South Africa	Yes	No	-
Germany	Yes	Yes	Up to 6 months
Australia	Yes	No	-
Canada	Yes	Yes	Up to 3 years
Colombia	Yes	No	-
Spain	Yes	No	-
USA	Yes	No	-
France	Yes	Yes, through <i>Autorisation Temporaire d'Utilisation - ATU</i>	Up to 1 year
Greece	Yes	No	-
Italy	Yes	No	-
Japan	Yes	No	-
Mexico	Yes	No	-
Norway	Yes	No	-
Portugal	Yes	No	-
UK	Yes	No	-

**REFERENCES:**