Opportunities of Innovative Agreements for Incorporating Advanced Therapy Medicine Products (ATPM) in Brazil

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OBJECTIVE

- To understand the regulatory framework for innovative agreements in Brazil.
- To evaluate Brazil's maturity in adopting innovative agreements for ATPM.

METHODS

- Collection and analysis of normative acts and government technical documents, including reports and previous RSA attempts.
- Monitoring and assessment of statements by health managers, researchers, and officials from the Ministry of Health at public events.

INTRODUCTION

- Advanced therapies in Brazil face access barriers, due to uncertainties around their efficacy and high cost.
- As an example, Conitec, the health technology assessment (HTA) body, denied the incorporation of an ATPM for Hereditary Retinal Dystrophy, that costs around US$300 thousand, in 2021, arguing for its high financial impact and uncertainties on its long-term effectiveness.
- In 2019, the Ministry of Health (MoH) attempted to sign a first risk-sharing agreement for a drug for Spinal Muscular Strophy (SMA). It was not put into effect due to lengthy discussions on real-world data collection and the MoH's inability to bring the agreement into line with the current legal basis, which was perfected for performance-based contracts.
- Ever since, the public debate on the matter has been intensified, with several events about ATPM, especially gene therapies, and innovative agreements.

RESULTS

- The Brazilian new law on bids encourages innovative agreements as it makes the legal framework even more certain for public administration to (i) request the industry for innovative solutions and (ii) establish variable payment fees according to the service's performance. These and other provisions of the new law can strengthen the basis for formalizing innovative agreements based on performance.
- The analysis of the number of events and the discourse promoted by public managers suggests that the topic has gained space and supporters in the public policy arena. A recent development was the confirmation by Conitec's manager that the body's internal rules will be updated to regulate RSAs.
- This political interest in innovative agreements is enforced by the second attempt to implement an RSA, for a drug for Multiple Sclerosis based on a financial cap. The contract was signed in September 2022, but the risk-sharing terms remain unclear.

CONCLUSIONS

- Considering the current legal framework and discussions propelled by government stakeholders, it was verified that accessing advanced therapies in the Brazilian public health system via innovative agreements, especially RSA, has increasingly gained the attention and affinity of public officials.
- Such arrangements can address access barriers for ATMP in Brazil by supplying the therapy while conditioning the incorporation to its real-life performance.
- The research findings are supported by the Multiple Sclerosis drug RSA's recent attempt, which aims to ensure that the cost spent by the government does not exceed the estimated limit. However, its terms and possible replications to other drugs still lack transparency and assessment.