



# COMPARATIVE ANALYSIS ON ACCESS TO ADVANCED THERAPY MEDICINE PRODUCTS (ATPM) IN LATIN AMERICA

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## INTRODUCTION

- In recent years, the discussion and construction of access policies to ATPM (specifically gene therapies) have gained ground in Latin America, but the regulatory access route to these new technologies still has gaps.
- At the same time, pharmaceutical companies are preparing to launch new gene therapies in the region’s countries.




## OBJECTIVE

- To describe policies for ATPM access, specifically gene therapies, in three Latin American countries; and highlight trends in the effort to establish the path of access to these technologies.

## METHODS

- For this study, three Latin American countries selected: Brazil, Colombia, and Mexico.
- Review and analysis of official documents, normative acts, and publicly available records of the discussions that guided the elaboration of these documents.
- The objective is to identify the regulatory framework for ATPM access, specifically to gene therapy, in three axes: (i) drug registration; (ii) genetic testing; and (iii) financing schemes to provide access to gene therapy.

## RESULTS

	REGISTER	CARE	
	Drug registration	Genetic testing	Financing schemes and innovative agreements
<b>Brazil</b> 	In 2018, Brazil established a registration request process for ATPM.	Access to genetic testing is provided by private and public health systems, but mainly by the Universal public Healthcare system (SUS).	<p>There is no specific financing system for advanced therapies. Innovative agreements are under discussion as an option to include gene therapy, and ATPM in general, within SUS. Nusinersen to treat SMA, despite not being an ATPM, is a landmark case in Brazil.</p> <p>Gaps in the legal framework caused the negotiation of the agreement to stall. Patients usually appeal to lawsuits to request specific treatments from the public health network (SUS) or the private plan operators, as an extraordinary path to ensure access to therapies.</p>
<b>Colombia</b> 	There is no specific regulatory framework for advanced therapies in Colombia. Despite the specific regulatory updates expected, right now, any therapy to be introduced in the country should comply with the general regulation for the registry of medicines.	Access to genetic testing is provided by public and private health systems. In Colombia, the most recognized health service are placed in main cities.	There is no specific financing system for advanced therapies. The Maximum Budgets, mechanism used for financing high-cost diseases, has played an important role in financing access to advanced therapies. Like the Brazilian case, court orders are mobilized as a tool to ensure access.
<b>Mexico</b> 	There is no specific regulatory framework for advanced therapies in Mexico. In order to be registered, advanced and gene therapies are evaluated by the same registration request process for drugs classified as innovative/biotechnological.	Access to genetic testing is fragmented, once each health system has its own institutions and laboratories, making it harder to consolidate a national system.	There is no specific financing system for advanced therapies. The Health Institute for Welfare (INSABI), which is used to finance the treatment of high-cost diseases, has played an important role to ensure access to advanced therapies. Like the Brazilian case, court orders are mobilized as a tool to ensure access.

## CONCLUSIONS

- Financing resources and schemes to ensure access to gene therapy as well as providing genetic diagnostic testing are still challenges for all countries. The adoption of regulatory frameworks for ATPM register in Brazil , however, seems to be the first step to reducing legal uncertainty and making room to guarantee access to therapies.
- Despite having a regulatory framework for ATPM register, Brazil still have few precedent cases. The Brazilian regulatory agencies is gaining experience putting the regulatory framework in practice – the country has just guaranteed the registry for a Cart-Cel Therapy
- In Mexico and Colombia, on the other hand, there is no specific regulatory framework. Thus, advanced therapies are licensed through their general drug license process. This scenario makes the industry still afraid of how a request for licensing ATPM will be evaluated and if health systems could effectively provide medicine access to patients.