Are Managed Entry Agreements a feasible approach to improve patient access to innovative therapies in Latin America?

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OBJECTIVES

- Review health policies in Latin America that consider Managed Entry Agreements (MEAs) as a solution to reimburse innovative medicines.
- Compare MEAs adoption in public settings to inform countries implementation.
- Provide recommendations based on findings.

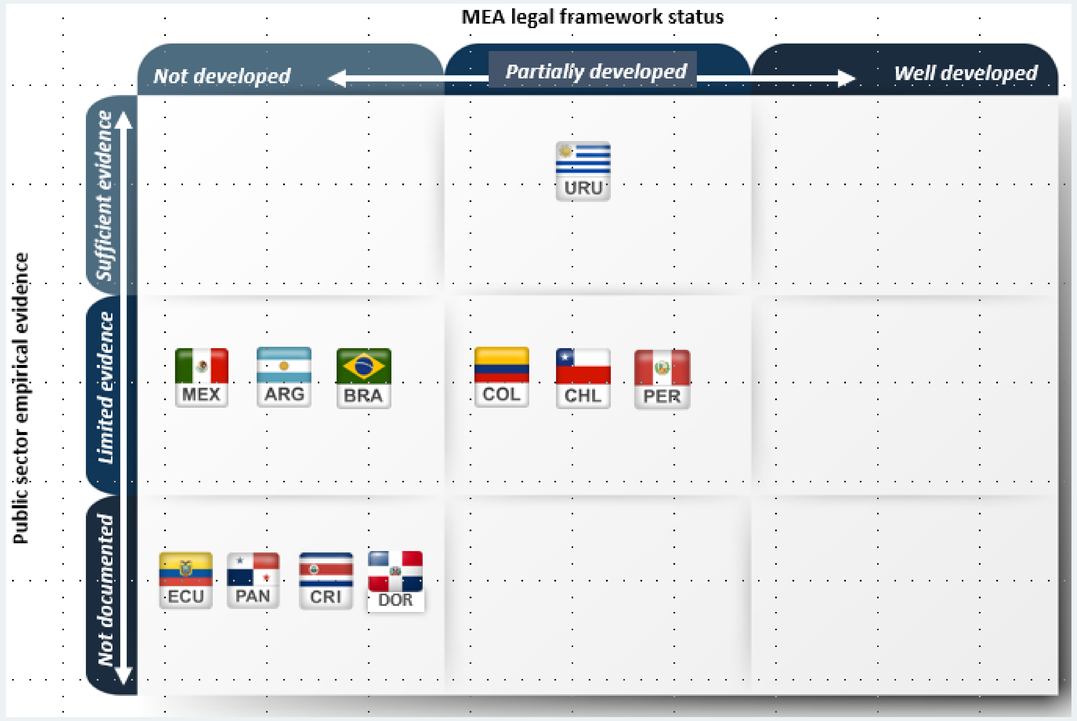
METHODS

- Between 6/21 to 6/22, six country workshops on ten affordability policies (1) were held in Colombia, Costa Rica, Peru, Dominican Republic, Ecuador, and Panama.
- In addition, a scoping literature review was conducted in MEDLINE using the terms: risk-sharing agreements and managed entry agreements. Articles from 6/12 to 6/22 were selected and analyzed by two independent reviewers. The search was updated in October 2022. Articles that did not provide empirical evidence were excluded.
- Other sources such as Google Scholar and Global Data were used to identify other potentially relevant documents.

RESULTS

- Colombia, Costa Rica and Peru prioritized MEAs during their workshops.
- Colombia's MoH conducted socialization meetings in 10/21 that resulted in a draft MEAs decree 6/22 sent for comments from civil society for "**Acuerdos de Acceso Administrado**". The decree is still in revision by the new government.
- Peru's congress passed Cancer Law 31,336/21 including "**Mecanismos Diferenciados de Adquisicion**" to incorporate cancer medicines in the national formulary. The MoH issued Decree 189/22 announcing 4 pilot MEAs in Lung ca., Breast ca. and Multiple Myeloma.
- The MEDLINE search retrieved 1 article while the Google Scholar and Global data yield 50 relevant articles. After reviewing the publications title and abstract, 18 articles were retained and a summary of 24 MEAs was created. MEAs were predominately financial based in Oncology and rare diseases, and most were biologics.
- Chile's congress passed Rare Diseases Law 20,850/15 followed by Decree 13/17 mandating "**Mecanismos de Riesgo Compartido**" be included as part of the manufacturer submissions. 27 diseases had been listed but gaps in the procurement rules had impeded the implementation of MEAs to date.
- Uruguay's National Resources Fund has been leading the implementation of "**Acuerdos de Riesgo Compartido**" in the region with 4 MEAs including 6 medicines using 2 approaches: one disease, multiple drugs or one drug, multiple diseases (2). MEAs in Uruguay had been implemented by the payer with no national regulation.
- We found empirical evidence of MEAs implemented in the public sector in (1) Mexico: Bortezomib in Multiple Mieloma, (2) Brazil and Argentina: Nusinersen in SMA, to mention the most cited (3, 4, 5).
- Despite interest in Costa Rica, limited progress has been made to date. We could not find empirical evidence for Costa Rica, Dominican Republic, Ecuador or Panama.

Figure 1. MEA legal framework & Public sector empirical evidence in Latin America



Argentina (ARG), Brazil (BRA), Chile (CHL), Colombia (COL), Costa Rica (CRI), Dominican Republic (DOR), Ecuador (ECU), Mexico (MEX), Panama (PAN), Peru (PER), Uruguay (URU)

CONCLUSION

- MEAs are perceived by stakeholders as a solution to reconcile access to innovative therapies with the health system sustainability. Level of development, implementation and evaluation varies between countries.
- Technical assistance by Multilateral Organizations and/or Think-tanks involving interested parties is critical to ensure the success of MEAs as a policy solution. Success depends on health system capacity/capabilities and regulations
- Political will seems to be more relevant than legal frameworks to ensure successful implementation, as seen in Uruguay.
- Legal frameworks defining MEAs are preferred but not sufficient for successful implementation as evidenced in Chile.
- Colombia's HMOs and manufacturers had implemented MEAs without regulation form the MoH. Peru is about to launch 3 pilots to bring the regulation into practice.
- There is empirical evidence of MEAs implemented in Argentina, Brazil and Mexico, however policy gaps and/or decision maker changes had turned mixed results.

References: (1) Castro HE. Et at (2021) Value in Health 24:S87; (2) Gilardino R. et al (2020) Value in Health Regional Issues 23(C):6–12; (3) ISPOR LA Conference 2017 IP 7: Risk Sharing Agreements: perspectives and Challenges for their implementation in Latin America (4) Global Data (2019) Brazil to reimburse Spinraza for type 1 SMA; (5) Global Data (2019) Argentine MoHSD signs reimbursement agreement with Biogen for SMA drug Spinraza.