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ASCERTAIN

Exploring Managed Entry Agreements: A Scoping Review of Country-Specific Approaches

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Background

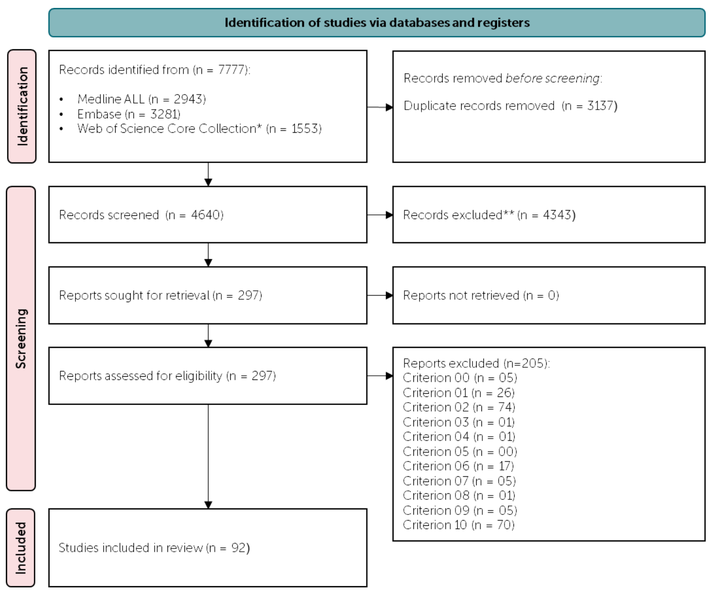
Innovative health technologies (IHTs) often struggle to gain market access due to high costs and uncertainties around their effectiveness, posing financial challenges and risks for healthcare systems. Managed Entry Agreements (MEAs) offer a solution by allowing payers and technology developers to share risks and manage costs. MEAs can be finance-based, focused on cost control, or outcomes-based, where reimbursement depends on treatment performance. Whereas financial MEAs are common and can enhance access and financial sustainability, outcomes-based agreements are less common due to high transaction costs and challenges in monitoring outcomes.

Objective

This study aims to explore the variation in MEA utilization, interpretation, and application.in the different healthcare settings of the European Economic Area (EEA), United Kingdom, Australia, Switzerland, and Canada.

Methods

A scoping review of scientific literature published between 2013 and September 2023. Only English-language publications were included, with searches conducted in MedLine, Embase, and Web of Science Core Collection. Studies were selected based on their focus on MEA utilization, interpretation, and application in the EEA, United Kingdom, Australia, Switzerland, and Canada.



0 - Publications < 2013
1 - Publication not in English
2 - Publication consist of abstract only
3 - Publication is an opinion paper
4 - Publication is conference paper
5 – Publications focus market regulations outside Healthcare
6 - Publications not about country specific regulations
7 - Publications about market authorization only
8 - Publications focusing on market access of no IHTs
9 - Publications focusing on countries outside EEA (except for Australia, Canada and UK)
10 - Publications not on Market entry strategies/ policies

MEA in practice

This review identifies 24 countries from scientific publications using finance-based, outcome-based, or combined MEAs within the EEA, Australia, Canada, Switzerland, and the UK. Finance-based schemes are the most common due to their simplicity and lower resource requirements, with Switzerland being the only country not reporting their use.

Outcome-based schemes, such as CED, are used in 20 countries to address clinical uncertainty, but face challenges related to data infrastructures and collection. Outcome-based schemes are mostly used in cases involving rare severe diseases with high unmet need or in the field of oncology.

While finance-based MEAs are favored for their straightforwardness and resource efficiency, outcome-based MEAs are increasingly recognized as essential for navigating uncertainties in clinical benefits and costs, especially for medicines with potentially long-lasting effects.

Types of MEA

Finance-based agreements are financial arrangements designed to control costs. They include:

- Discounts and Rebates: Collaborative negotiations that reduce the costs, while keeping net prices confidential.
- Volume or Expenditure Caps: Predetermined limits on volume or cost, often leading to net price reductions or free treatments once the cap is exceeded.
- Price-Volume Agreements: Prices are tied to volume purchased or a predetermined budget, with prices decreasing if volume and sales increase.

Advantages: Simple to implement, low administrative burden, predictable costs, and enhanced access to costly treatments.

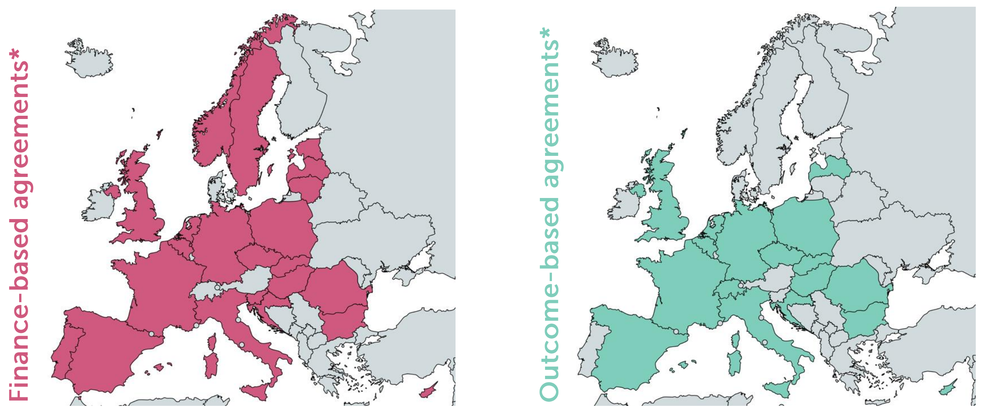
Disadvantages: Lack of transparency, reduces and inequality in access once caps are met, and risks of inequities in healthcare access.

Outcome-based agreements link reimbursement to actual clinical outcomes, ensuring value for money. They include:

- Coverage with Evidence Development (CED): Temporary coverage while gathering real-world evidence to reduce clinical uncertainty.
- Pay-by-Result: Reimbursement based on meeting predefined health outcomes.
- Conditional Treatment Continuation (CTC): Reimbursement only for patients achieving specified treatment milestones.

Advantages: Ties reimbursement to real-world value, encourages innovation, and provides transparency on treatment effectiveness.

Disadvantages: Uncertainty in budget impact, high administrative burden, costly data collection, and difficulties in evidence generation and outcome monitoring.



*The identified countries were derived from scientific publications and, therefore, may not reflect the actual situation.

This research highlights the widespread adoption of MEAs but underscores key challenges in implementing outcome-based agreements. The decision to pursue outcome-based agreements often involves balancing transaction costs with the need for robust evidence on treatment effectiveness.

Conclusion

To support implementation, standardizing methods and frameworks for MEAs is essential—especially for outcome-focused agreements. This includes:

- *Enhanced Disease Registries:* Promote comprehensive data registries to enable accurate tracking of outcomes and improve cost-effectiveness analysis.
- *Stakeholder Engagement:* Foster collaboration among healthcare professionals, patients, and payers to address practical hurdles in design and execution.

Further research on existing MEAs will provide valuable insights for future agreements. By focusing on standardized methods, improved data infrastructure, and active stakeholder involvement, healthcare systems can better balance cost-effectiveness with patient access to innovative therapies, supporting improved health outcomes.

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