Performance-Based vs. Finance-Based Managed Entry Agreements: Global Trends and Challenges

HPR185

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Introduction

- National healthcare payers are exploring innovative reimbursement methods to ensure timely access to new health technologies while maintaining affordability and value for money.[1]
- Managed entry agreements (MEAs) are confidential deals between pharmaceutical manufacturers and payers, used when there is uncertainty about a medicine's clinical benefit, but high public spending is involved.[2]
- MEAs aim to improve patient access to novel treatments, particularly in cases where traditional reimbursement models may not adequately address the uncertainties surrounding new drugs.
- MEAs benefit different stakeholders (payers, patients, companies) by balancing objectives such as budget control, patient access, and undisclosed pricing arrangements based on financial or performance outcomes.[2]
- MEAs are categorized into performance-based agreements (PBAs) and finance-based agreements (FBAs).[3]
- FBAs primarily aim to mitigate financial risk through discounts, price-volume agreements, or capping treatment costs. In contrast, PBAs tie reimbursement to real-world outcomes, thereby addressing uncertainties regarding the clinical effectiveness of new treatments.[4]
- With the growing demand for innovative therapies and rising costs of healthcare across the globe, understanding the evolving role of MEAs is critical for ensuring sustainable access.

Objective

- To investigate emerging trends in MEAs focusing on FBAs and PBAs and their impact on market access, cost-effectiveness, and outcomes associated with new drugs.

Methods

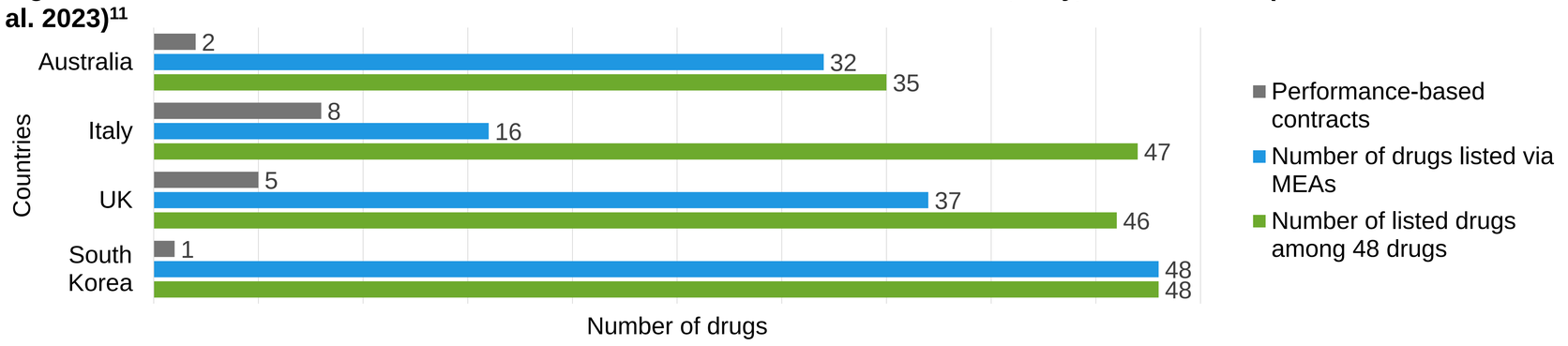
- A targeted literature review was conducted on May 24, 2024, to identify the most recent peer-reviewed journals, policy reports, and expert opinions from PubMed and Google.
- Search terms included keywords for “managed entry agreements”, “performance-based agreements”, “finance-based agreements", combined with keywords for emerging trends. Records published between 2018 and 2024 and in English language were included.
- The review focused on describing FBAs and PBAs, including their trends across regions and countries, and measurable outcomes.
- A descriptive analysis was used to evaluate the effectiveness and challenges associated with MEAs.

Results

- Of the 20 identified records, 12 records highlighting MEA trends across Europe, North America, and other regions were included.
- Excluded records either did not report on the country of interest, contained duplicate information, or fell outside the 2018-2024 timeframe
- Among included records, five were from Europe, four from Asia (Japan, Korea, Malaysia), and three from the USA. Records consisted 10 reviews (of which four were systematic), one survey, and one expert opinion.
- **Trends of MEAs by countries**
- FBAs have been the dominant type of MEA, especially in Europe[5] and North America.[6]
- According to Global Data’s Risk-Sharing Database, 79% of over 1,000 Risk Sharing Agreements (RSAs) across 28 countries from 2012-2022 were FBAs.[7]
- The growing preference for FBAs is attributed to their ability to provide immediate financial relief to healthcare systems by directly lowering drug costs.
- FBAs have been in place for several decades in France through rebate, price-volume agreements, and future price decreases previously agreed upon.[6]
- However, there has been a noticeable shift towards PBAs, particularly in England and Italy:
  - 44% of MEAs in England were PBAs.[8]
  - 59% of MEAs in Italy during the same period were PBAs.[8]
  - UK and Italy have been leaders in adopting PBAs due to their robust health technology assessment (HTA) frameworks that support outcomes tracking.
- There is a growing use of PBAs in the US, mainly due to increasing use of value-based care models, and the introduction of expensive, innovative therapies like gene therapies and immunotherapies.
- Trends are also starting to shift in Japan, South Korea, and Taiwan towards PBAs.[9,10] This shift is driven by an increased emphasis on linking payment to patient outcomes, reflecting a global movement towards value-based healthcare.

Results

Figure 1: Trends in MEA Utilization for 48 Medicines Across South Korea to UK, Italy, and Australia (Recreated from Kim et al. 2023)[11]



- A 2023 review by Kim et al. provides a valuable comparison of MEA trends for 48 medicines across four countries: South Korea, Australia, Italy, and the United Kingdom. The study found that 77.1% and 66.7% of these medicines were listed under MEA contracts in the United Kingdom and Australia, respectively, compared to only 33.3% in Italy. Among the medicines listed via MEAs, South Korea had the fewest PBAs at 2.1% (1 out of 48), while Italy had the most at 50.0% (8 out of 16). These findings are illustrated in **Figure 1.**[11]

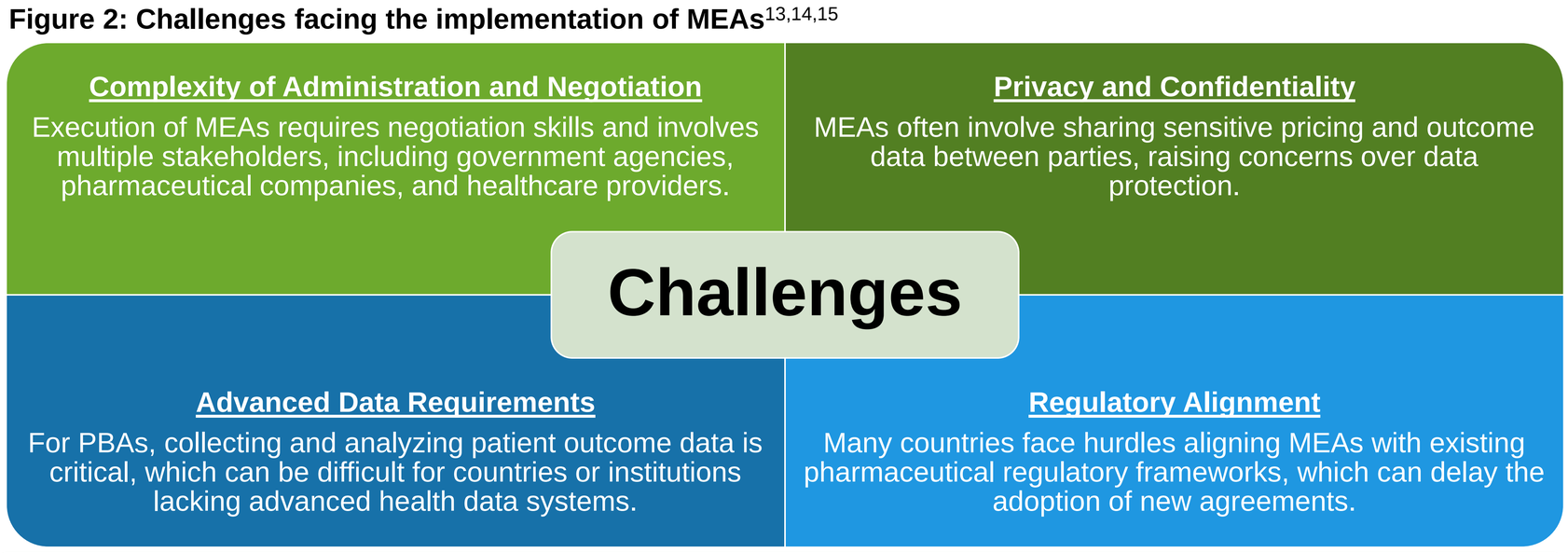
MEA application by therapeutic area

- MEAs have been applied disproportionately across different therapeutic areas, with the majority targeting high-cost treatments.[12]
  - >50% of MEAs are applied to anticancer therapies, reflecting the high cost and innovation associated with oncology drugs.
  - Endocrinology represents 9.5% of MEAs, with a focus on diabetes and other chronic conditions that require long-term management.
  - Neurology comes in at 6.8%, often focusing on expensive treatments for conditions like multiple sclerosis and Alzheimer’s disease.
- This uneven distribution highlights how MEAs are primarily used for diseases with substantial treatment costs and evolving therapeutic advancements.
- A review of MEAs for gene therapies showed a significant variation by country.[11] In France all gene therapies received PBAs, whereas in Canada they received FBAs.
- FBAs are more common in chronic, high-prevalence conditions where cost containment is the priority. Whereas PBAs are used more for innovative, high-cost therapies with uncertain long-term outcomes, where effectiveness needs to be proven through real-world results.[12]

Challenges in MEAs implementation

- The implementation of MEAs faces multiple challenges[13,14,15] summarized in **Figure 2**.

Figure 2: Challenges facing the implementation of MEAs[13,14,15]



Discussion

- Increasing complexity of healthcare systems and high costs of innovative therapies have driven the adoption of MEAs to ensure patient access while managing uncertainties in clinical and economic outcomes.
- PBAs are gaining popularity as they link reimbursement to actual real-world performance of a therapy, thus reducing financial risk for payers. Therapies with high upfront cost like gene therapies and biologics necessitate performance-based agreements to justify long-term value.
- Confidentiality of critical components, including performance metrics, financial terms, eligibility criteria, and outcome evaluation methods, limits the ability to measure and compare the effectiveness of MEAs.
- Although PBAs are becoming more popular, FBAs remain widely used because they are simpler and easier to implement. FBAs typically involve price discounts, cost caps, or limits on budget impact, making them more straightforward for healthcare systems to manage.

Conclusions

- Our findings indicate that FBAs and PBAs are vital for market access by reducing uncertainties in costs and clinical outcomes.
- FBAs are primarily used to manage costs and outcomes, though their success depends on effective data collection, collaboration, and adaptability to local healthcare environments.
- Emerging trends, such as the increased use of real-world evidence, may drive greater adoption of PBAs over time, supported by improved systems for capturing and measuring outcomes.
- Future research should further quantify the long-term impact of PBAs on health outcomes and sustainability across healthcare systems.

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