Abstract No. 132725

The Use of Managed Entry Agreements (MEAs) for Accessing Innovative Health Technologies

Kodjamanova P[1], Bennetts L[2], Bellaoui Y[3], Ciritel A[4], Bagnall R[4], Atanasov P[4]

[1]Amaris Consulting, London, UK, [2]Amaris Consulting, Montreal, QC, Canada, [3]Amaris Consulting, Paris, France, [4]Amaris Consulting, Barcelona, Spain

INTRODUCTION

- Clinical and financial uncertainty associated with new innovative therapies for serious and life-threatening diseases presents a major challenge in the market access landscape[1,2]
- Market access and reimbursement have become increasingly challenging for manufacturers, payers, and decision makers due to factors including:
  1. High prices and budget impact of new medicinal products
  2. The use of accelerated regulatory approvals, which increase uncertainty regarding efficacy and long-term safety due to limited data[1,2]
- Managed entry agreements (MEAs) were developed as a response to these challenges. MEAs are arrangements between the manufacturer and payer/provider that allow patient access to innovative new medicinal products while managing uncertainty around their financial impact or performance[1,3]
  - MEAs shift post-approval uncertainties and responsibilities from the payers to the manufacturers[2]

The main types of MEAs include financial-based agreements (FBAs) and performance-based agreements (PBAs) (Figure 1).

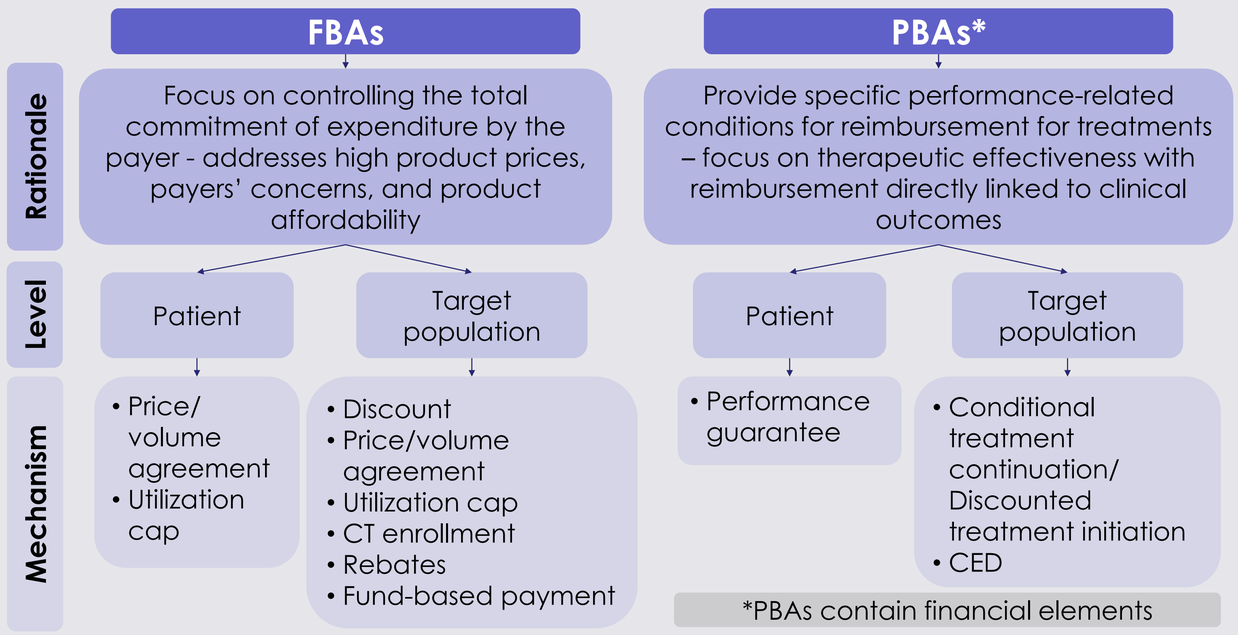

Fig 1. Financial- and performance-based agreements: the two main types of MEAs.
This flow chart describes the purpose and rationale for each MEA. Each arrangement can be made at the population-level, or patient-level (individual basis). This figure illustrates the mechanisms that can be used for each type and level of MEA. Figure was adapted from Dabbous et al. 2020[2]
Abbreviations: CED: coverage with evidence development; CT: clinical trial; FBA: financial-based agreement; PBA: performance-based agreement.

OBJECTIVES

This study aimed to understand the use of MEAs in the healthcare industry, any critique on previous financial-based submissions, and investigate potential recommendations for future MEA submissions

METHODS

- EMBASE and Medline were searched from inception until June 7th, 2023.
- We considered articles of interest to be those assessing feasibility of financial-based MEAs, impact of successful agreements, and the time taken to final decision outcome. In addition, we sought information on key recommendations, good practices, critiques, and potential ways to improve MEAs

RESULTS

The main use of MEAs[1]

Oncology and rare diseases, with the most common product/indication areas being:

1. **Neoplasms**
2. **Eye and adnexa diseases**
3. **Skin and subcutaneous tissue diseases**
4. **Endocrine, nutritional, and metabolic diseases**

- All the identified evidence was from Europe
- Most countries in Europe have tended toward FBAs, while PBAs have been more often seen in England and Italy[1]. Simplicity and discount are the leading drivers and direction for MEAs[2]

Challenges associated with FBAs

No account for product performance
- FBAs approaches do not usually address outcome uncertainties. Thus, reimbursement of medicinal products can occur for which original claims of safety, efficacy, or cost-effectiveness are later unconfirmed[1,2,4,5]

Inequity
- FBAs may provide an advantage to larger, wealthier markets, but they put a disproportionate burden on smaller, less wealthy markets[2]

Unreliable list pricing
- Confidential discounts or other savings to payers, resulting from all forms of FBAs, are not reflected on list prices. This could negatively impact the external reference pricing because prices are set based on official listed prices rather than on the actual net ones[2,6]

Guidance for the use of FBAs, PBAs, or a combination

- With the apparent preference toward FBAs, formal guidance for the use of PBAs vs. FBAs, or their use in combination, are necessary.
- Some European counties, including France and England, have recommendations or conditions for the use of PBAs[1], but we could not identify any for the use of FBAs

Recommendations for future financial-based MEA submissions:

A combination of MEAs could lead to successful and sustainable reimbursement of expensive innovative products. Many options for combining MEAs into a reimbursement mechanism exist[7]

Utilising PBAs to account for product performance comes with added challenges and does not always address performance uncertainty

- PBAs aim to manage the cost-effectiveness of a new technology depending on its performance; therefore, data related to clinical outcomes are gathered and analysed[1]
- However, formal evaluation of PBAs from Belgium and Sweden, as well as European expert interviews have found that, despite their intent, PBAs did not reduce uncertainty around the performance of the products in terms of comparative and cost-effectiveness[1]
- Currently, PBAs are less commonly used due to difficulties implementing them and measuring relevant clinical outcomes, leading to a high administrative burden associated with their execution[2]

CONCLUSIONS

- MEAs have the potential to positively impact patient access to innovative medicines, though adjustments are needed to address current challenges
  - A strategy for guiding the use of financial-based MEAs must be defined. This will ensure that the advantage of new evidence on product performance overcomes the cost of negotiating and implementing MEAs
  - Uncertainties in each coverage selection and building MEAs must be identified. This includes that data sources and study designs are suited to meet the uncertainties at hand

REFERENCES

1. Wenzl M, Chapman S. Performance-based managed entry agreements for new medicines in OECD countries and EU member states. How they work and possible improvements going further. 2020. **2.** Dabbous M, Chachoua L, Caban A, Toumi M. Managed Entry Agreements: Policy Analysis From the European Perspective. Value Health 2020;23(4):425–33. **3.** World Health Organization. Regional Office for Europe. (2015). Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. World Health Organization. Regional Office for Europe. https://iris.who.int/handle/10665/159405 **4.** Efthymiadou O, Kanavos P. Impact of Managed Entry Agreements on availability of and timely access to medicines: an ex-post evaluation of agreements implemented for oncology therapies in four countries. BMC Health Serv Res 2022;22(1):1066. **5.** Reckers-Droog V, Federici C, Brouwer W, Drummond M. Challenges with coverage with evidence development schemes for medical devices: A systematic review. Health Policy Technol 2020;9(2):146–56. **6.** Young KE, Soussi I, Toumi M. The perverse impact of external reference pricing (ERP): a comparison of orphan drugs affordability in 12 European countries. A call for policy change. J Mark Access Health Policy 2017;5(1):136981. **7.** Vreman RA, Broekhoff TF, Leufkens HG, Mantel-Teeuwisse AK, Goettsch WG. Application of Managed Entry Agreements for Innovative Therapies in Different Settings and Combinations: A Feasibility Analysis. Int J Environ Res Public Health 2020;7(22):8309.

Disclosures

Authors have no conflict of interest to declare

Presented at ISPOR Europe 2023; 12-15 November 2023; Copenhagen, Denmark.