Managed Entry Agreements

Overview, trends & potential financial outcomes

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October 2026

Rationale for putting MEAs on the agenda

EAS, MEA & patient access to high-priced medicines

PPRI Query

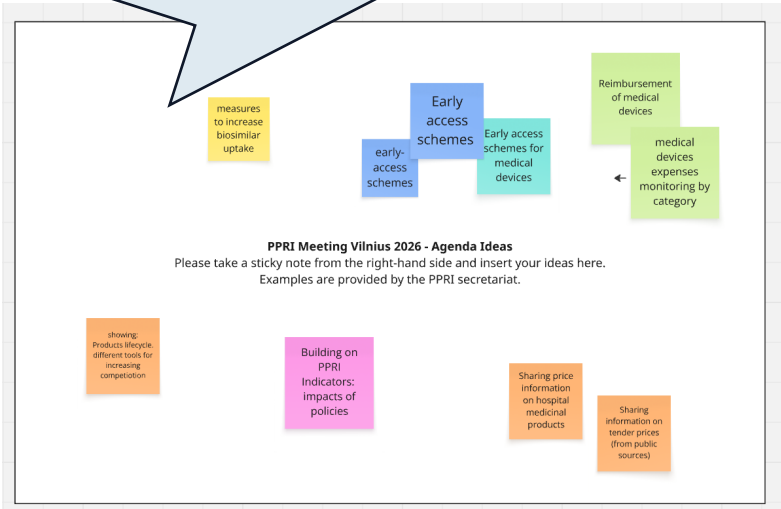
Dear PPRI colleagues,

- Does your country use Managed Entry Agreements that include confidentiality of prices? If yes, which of the below options apply:

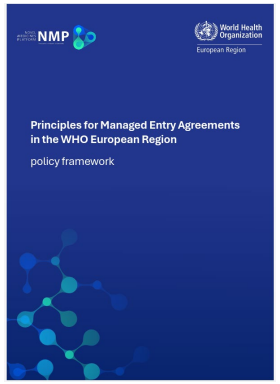
1. Confidentiality of prices/price information is legally binding for payer/governmental body only
2. Confidentiality of prices/price information is legally binding for both the manufacturer and the payer/governmental organization

- If 2 applies:

1. Are there any additional clauses for the manufacturer regarding sharing confidential pricing information with a third party, or foreign governmental organization? If so, wh
2. What is the legal consequence of the manufacturer breaking confidentiality?



Work by collaborating institutions (WHO, EFPN):



The European Journal of Health Economics
https://doi.org/10.1007/s10198-026-01942-3

ORIGINAL PAPER

A comparative analysis of managed entry agreements in Europe: trends, reporting practices, and financial outcomes

N. Franzen[1,4] · J. Vancoppenolle[1,2,3] · V. P. Retèl[1,4] · S. Vogler[5,6] · W. H. van Harten[1,3]

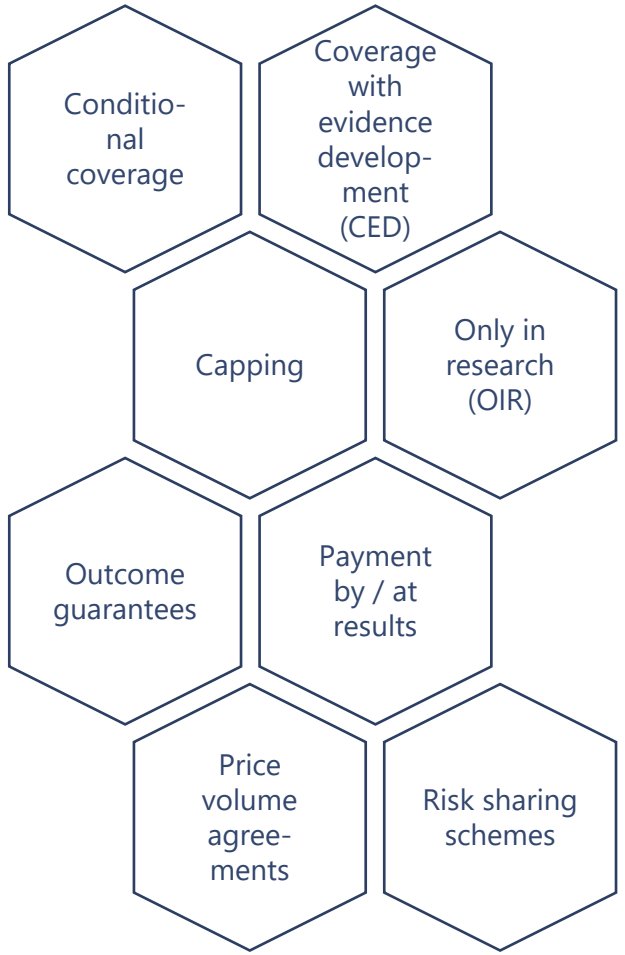
Received: 5 December 2025 / Accepted: 18 May 2026
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What are we talking about?

New high-priced medicines
Innovation?

Definition:
"An **arrangement between a manufacturer and payer/provider** that **enables access** to (coverage/reimbursement of) a health technology subject to specified conditions.
These arrangements can use a **variety of mechanisms** and are usually classified into **financial-based and performance-based MEA**.
The latter links price (reward for manufacturers) to health outcomes."
(PPRI Glossary: https://ppri.goeg.at/MEA)

Examples of common types



Outline

Potential financial outcomes

What we know about MEAs
(and what we do not know)

Potential financial outcomes
Do MEAs bring savings?

Conclusions
Take-aways for the future

1 — 2 — 3 — 4 — 5

Concerns
Issues about MEAs

Good practices in MEAs
Learnings

Internal PPRI presentation
Do not share!

Feel free to use information from listed (public) sources

Overview & trends

What we know about MEAs

And what we do not know

Gesundheit Österreich GmbH

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

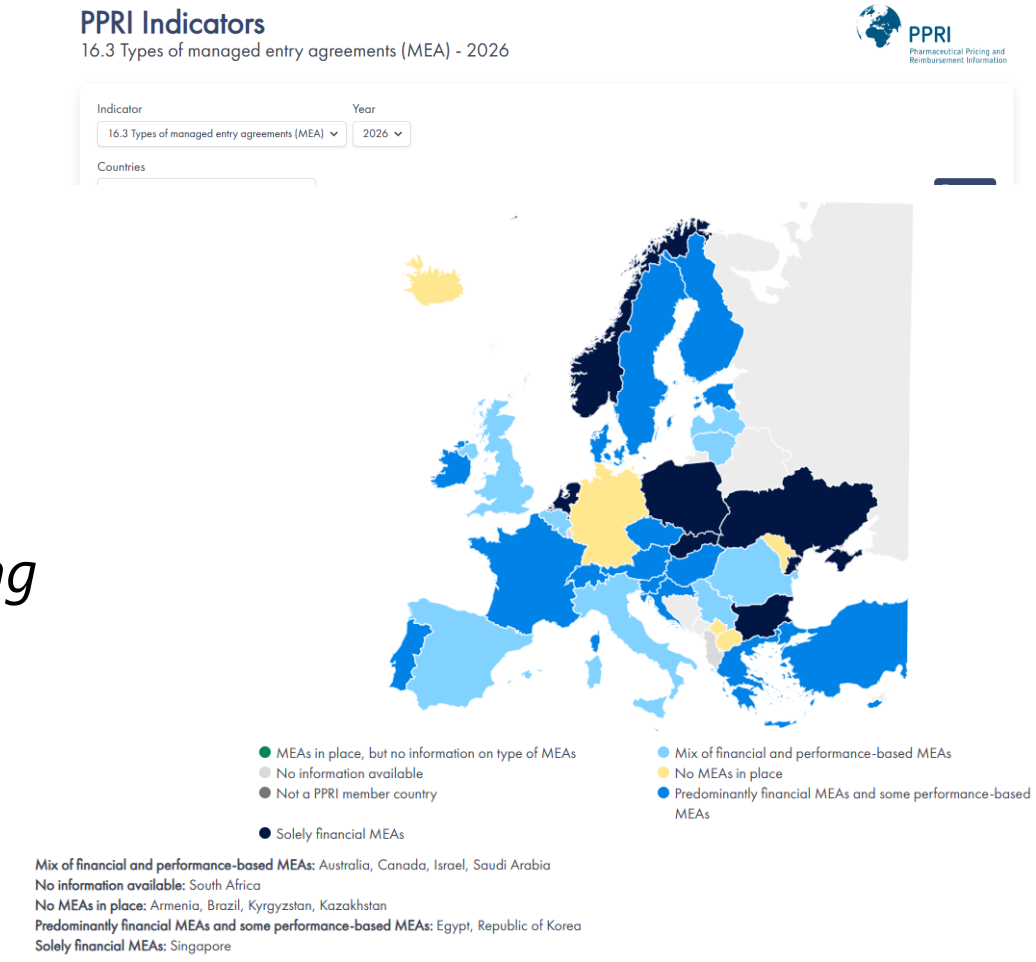
PPRI Pharmaceutical Pricing and Reimbursement Information

What we appear to know about MEAs

"MEAs are commonly used for new medicines in European countries and globally."

"While financial-based remain the dominant type, performance-based MEAs have been rising in recent years."

PPRI Indicators
currently accessible only for PPRI members (PW protected)



What we believe to know about MEAs

When and why it was started to conclude MEAs

What MEAs are

Why MEAs are needed

MEAs are always confidential

What we do not know about MEAs (and would like to know …)

How many MEAs are in place in each country?

Which types of MEAs?

Which medicines are covered?

How high are the discounts / savings?

How are MEAs designed ….?

What is their impact?





Concerns

What are key issues about MEAs?

Major concerns



Major concerns: "Outside the standard system"?

Silo

MEA?

Risks:
- Lower evidence requirements
- Fairness and governance issues
- Increasing budgets

MA

"Standard P&R procedure"
HTA, pricing (setting, negotiation), reimbursement decision

Market entry → Patient access

Innovation funds

Add-on lists

DRG carve-outs

"Judicialisation" (public funding upon court decisions)

Major concerns: Information asymmetry



thebmj

BMJ 2018;360:k840 doi: 10.1136/bmj.k840 (Published 26 February 2018)

EDITORIALS

Check for updates

Removing the blindfold on medicines pricing

Increased transparency would enable more evidence based policy making

Suerie Moon *director of research*

Global Health Centre, Graduate Institute of International and Development Studies, Geneva, Switzerland

Asym-metry

weakens

negotiation power

Major concerns:
Lack of evaluations on the impact of MEA

Impact?



1.3 A difficult process due to data confidentiality and threat of legal proceedings

KCE's main priority was to evaluate the existing conventions to provide well-considered advice to the policy makers to improve their policy. The analysis was nevertheless limited by the confidential character of the appendices of the conventions, encompassing the precise outcome of the negotiation process (for instance the exact amounts or percentages of discounts, budget caps, etc.). KCE committed from the beginning of this project to respect the confidential nature of the conventions (with anonymous aggregated reporting and with a final check by the RIZIV – INAMI to verify the respect of the confidentiality and the validity of all observations and statements).

This was nevertheless not approved by the representatives of the pharmaceutical industry. Even after having invited them to participate in the study as external stakeholders, in full transparency, Pharma.be, a Belgian organisation representing part of the (non-generic) pharmaceutical industry, threatened to take legal action against KCE if the study was continued. We unfortunately had no other choice than to stop the collaboration and to base our analysis on public information only. Details on the compensation mechanisms available in the appendices of these conventions could not be used (neither directly, nor indirectly).

Gerkens S, Neyt M, San Miguel L, Vinck I, Thiry N, Cleemput I. How to improve the Belgian process for Managed Entry Agreements? An analysis of the Belgian and international experience. Health Services Research (HSR) Brussels: Belgian Health Care Knowledge Centre (KCE). 2017. KCE Reports 288. D/2017/10.273/41. https://kce.fgov.be/sites/default/files/2021-11/KCE_288_Improve_Belgian_process_managed_entry_agreements_Report.pdf

Major concerns:
Lack of shared experience and SOP

Best deal?



FIGURE 4
Assessing whether participants' perception of their prices relative to others within their country are (in) correct. A difference of 5% from the average price level was chosen as a cut-off point for the similar price level. Note that in France, only two hospitals were included.

"Hospitals' perceptions of their negotiated prices frequently did not align with reported price levels. Among 20 hospitals included in this analysis, ten had incorrect perceptions. **Several hospitals perceived their prices as lower than those of peers.**"

Good practice?

Contract clauses

Financial specifica-tions

Procedures (milestones, exit)

Reinventing the wheel?

Vancoppenolle J, Franzen N, et al. (2026): Price transparency of cancer medicines: a crucial step towards informed pricing negotiations in the European region . Front. Pharmacol. 17:1736741. doi: 10.3389/fphar.2026.1736741

Potential financial outcomes

Do MEAs bring savings?

Financial outcomes from MEA being publicly known?

How high are net price reductions?

€ 4.4 billion (FR)
€ 1.0 billion (BE)
€ 0.95 billion (DK)

Average discounts / price reductions?

45% (DK)
46% (NL)
3-5% (IT)

Reductions in spending on medicines covered by MEA as share of TPE?

FR: 49% → 38%
DK: 95 % → 55%

Data retrieved from: Franzen N, Vancoppenolle J, Retèl VP, Vogler S, van Harten WH. A comparative analysis of managed entry agreements in Europe: trends, reporting practices, and financial outcomes. The European Journal of Health Economics. 2026. 10.1007/s10198-026-01942-3

Financial outcomes from MEA published?

Country	Financial outcomes	2016	2017	2018	2019	2020	2021	2022	Source
BE	Average discounts/ price reduction (%)	18.6	25.5	27.2	39.4	40.4	53.8	Changed methodology	(1)
CY	Average discounts/ price reduction	NA	NA	NA	NA	NA	NA	NA	Not reported
CZ									
DE									
DK									
ENG									
FR									
IE									
IT									agreements for pharmaceuticals in Italy'(5)
NL	Average discounts/ price reduction (%)	NA	NA	34.15	40.13	42.17	45.81	46.04	Calcualted using 'Voortgangsbrief financiële arrangementen geneesmiddelen'(6)
NO	Average discounts/ price reduction (%)	NA	NA	NA	NA	NA	NA	NA	NA
SE	Average discounts/ price reduction (%)		23.68	43.97	49.74	44.11	42.63	42.61	Calculated based on TLV: Besparingar från sidoöverenskommelser (7)
SK	Average discounts/ price reduction (%)	NA	NA	NA	NA	NA	NA	NA	NA
BE	Estimated expenditure without MEA excluding VAT(Billion EUR)	0.653	1.070	1.315	1.534	1.866	1.896	Changed methodology	(1)

1. RIZIV. MORSE-rapport gegevens 2021: Monitoring Of Reimbursement Significant Expenses 2021 [5-4-2026]. Available from: https://www.riziv.fgov.be/SiteCollectionDocuments/morse_rapport_gegevens_2021.pdf.
2. Amgros. Markedsovervågning 2018 [5-4-2026]. Available from: https://www.amgros.dk/om-amgros/presse-og-analyser/markedsovervaagning/.
3. CEPS. Rapport d'activité 2022 [Available from: https://sante.gouv.fr/ministere/acteurs/instances-rattachees/comite-economique-des-produits-de-sante-ceps/article/rapports-d-activite-du-ceps.
4. S. Prior RS, M. Hennessy, E. Walker. Spending Review 2021: Review of High-Tech Drug Expenditure 2021 [5-4-2026]. Available from: https://assets.gov.ie/static/documents/review-of-high-tech-drug-expenditure.pdf.
5. Trotta F, Guerrizio MA, Di Filippo A, Cangini A. Financial Outcomes of Managed Entry Agreements for Pharmaceuticals in Italy. JAMA Health Forum. 2023;4(12):e234611.
6. VWS. Voortgangsbrief financiële arrangementen geneesmiddelen 2023 [5-4-2026]. Available from: https://open.overheid.nl/documenten/0230958a-aae0-4088-9f3a-420bf4aa609c/file.
7. TLV. Prognos av besparingar från sidoöverenskommelser 2023 [5-4-2026]. Available from: https://www.tlv.se/publikationer/publikationer/2024-06-03-prognos-av-besparingar-fran-sidooverenskommelser-2024-2027.html?query=besparingar.
8. NHS. Cancer Drugs Fund activity update Q4 2023-24 2024 [5-4-2026]. Available from: https://www.england.nhs.uk/long-read/cancer-drugs-fund-activity-update-q4-2023-24/.
9. NIHO. Annual Report on the Activities of the Institute 2022 [5-4-2026]. Available from: https://niho.sk/en/zverejnovanie/.

5 pages of financial outcome data related to MEAs

Annex 5 based on public information published by authorities

Franzen N, Vancoppenolle J, Retèl VP, Vogler S, van Harten WH. A comparative analysis of managed entry agreements in Europe: trends, reporting practices, and financial outcomes. The European Journal of Health Economics. 2026. 10.1007/s10198-026-01942-3

WHA 72.8 resolution

urges Member States in accordance with their national and regional legal frameworks and contexts:

1. Take appropriate measures to **publicly share information on the net prices of health products**;
2. Take the necessary steps […] to **support dissemination of** and enhanced availability of and access to aggregated **results data** and […] **costs from human subject clinical trials** regardless of outcomes […];
3. Work collaboratively to **improve the reporting of information by suppliers** on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;
4. Facilitate improved public reporting of **patent status** information and **marketing approval** status of health products



SEVENTY-SECOND WORLD HEALTH ASSEMBLY WHA72.8

Agenda item 11.7 28 May 2019

Improving the transparency of markets for medicines, vaccines, and other health products[1]

https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

Approaches for implementing net price transparency

Requesting manufacturers to disclose net price

"Clearing House" (third party to collate data and share aggregate data)

Labelling MEAs

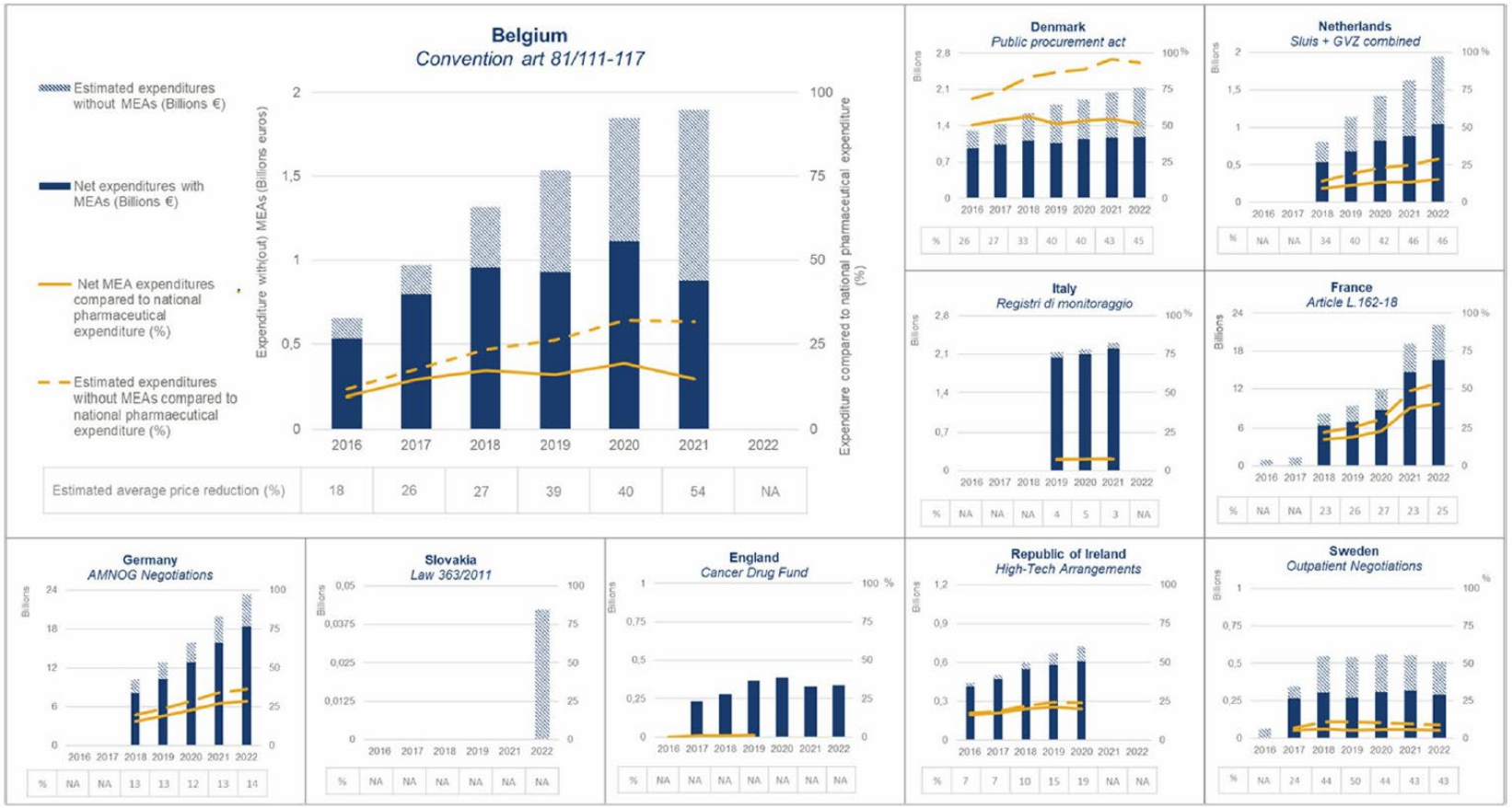
Publishing aggregate data

Webb E, Richardson E, Vogler S, Panteli D (2022):What are the implications of policies increasing transparency of prices paid for pharmaceuticals. World Health Organization, European Observatory on Health Systems and Policies

Perehudoff K, Mara K, Hoen E'. What is the evidence on legal measures to improve the transparency of markets for medicines, vaccines and other health products (World Health Assembly resolution WHA72.8)? [Internet] Copenhagen: WHO Regional Office for Europe; 2021. (Health Evidence Network Synthesis Report, No. 73.) https://www.ncbi.nlm.nih.gov/books/NBK572572/

Vogler S (2022): Access to information in markets for medicines in the WHO European Region. Oslo Medicines Initiative technical report. Copenhagen: World Health Organization, Regional Office for Europe

An initiative to be applauded, but …



Missing data

Comparability

Fig. 3 Financial Outcomes of MEA. Data based on sources specified in Table 2 and Appendix 5

Franzen N, Vancoppenolle J, Retèl VP, Vogler S, van Harten WH. A comparative analysis of managed entry agreements in Europe: trends, reporting practices, and financial outcomes. The European Journal of Health Economics. 2026. 10.1007/s10198-026-01942-3

Suggestion for harmonised reporting

Box 1: Harmonized reporting

- Products, subject to MEA
  - Sales revenue
  - List prices
  - Number of patients covered
- Types of MEA (financial-based / outcomes-based)
- Estimated expenditure at list price (pre-discount)
- Actual aggregated expenditure
- Average discounts
- Confidential vs public reductions
- Discounts per therapeutic class
- Key decision dates
  - Date of reimbursement application from manufacturer
  - Date of MEA decision
  - Date of reimbursement decision
  - Date of MEA renewal/revision
- Renewal criteria / conditions for continued reimbursement
- Outcomes (outcomes-based MEAs only)
  - Performance conditions met (aggregate)
  - Real world data generated/published
- Responsible reporting entity

All reporting in English and local languages with transparency regarding any aggregation or underlying calculations

Franzen N, Vancoppenolle J, Retèl VP, Vogler S, van Harten WH. A comparative analysis of managed entry agreements in Europe: trends, reporting practices, and financial outcomes. The European Journal of Health Economics. 2026. 10.1007/s10198-026-01942-3

MEAs may increase list prices

Abstract

Managed entry agreements (MEAs) have been used for several years, with the aim of curbing the growth of pharmaceutical expenditure and enhancing patient access to innovation. Yet, much remains to be understood about their economic implications. This paper studies the impact of MEAs on list prices, that is, prices before the deduction of any discount. Using a theoretical model, we show that, under most price setting regimes, the introduction of an MEA leads to a higher list price. This is confirmed by our empirical analysis of a sample of 156 medicines in six countries, providing a conservative estimate of the increase in price due to the MEA of 5.9%. A relevant policy implication is that payers may overestimate the financial gains that can be achieved through this tool.

KEYWORDS

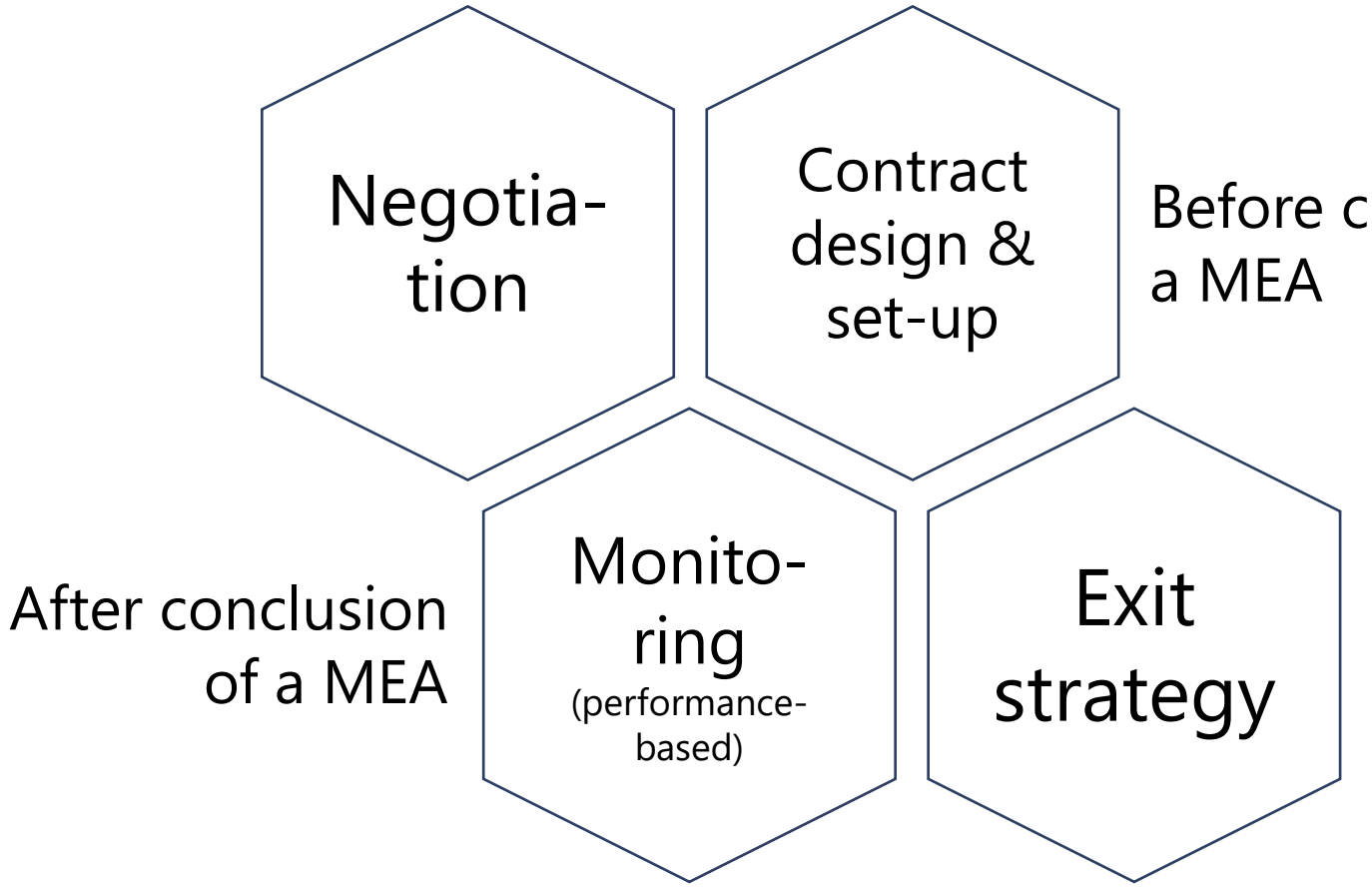
managed entry agreements, pharmaceutical prices, risk-sharing agreements

Gamba S, Pertile P, Vogler S. The impact of managed entry agreements on pharmaceutical prices. Health Econ. 2020;29(51):47-62

However, larger discounts do not necessarily indicate stronger negotiating performance. Instead, inflated list prices can create the illusion of substantial savings, complicating cross-country comparisons.

Franzen N, Vancoppenolle J, Retèl VP, Vogler S, van Harten WH. A comparative analysis of managed entry agreements in Europe: trends, reporting practices, and financial outcomes. The European Journal of Health Economics. 2026. 10.1007/s10198-026-01942-3

Additional costs of MEAs due to administrative burden



Lack of good practice examples / evaluations

Good practices in MEAs

Learnings

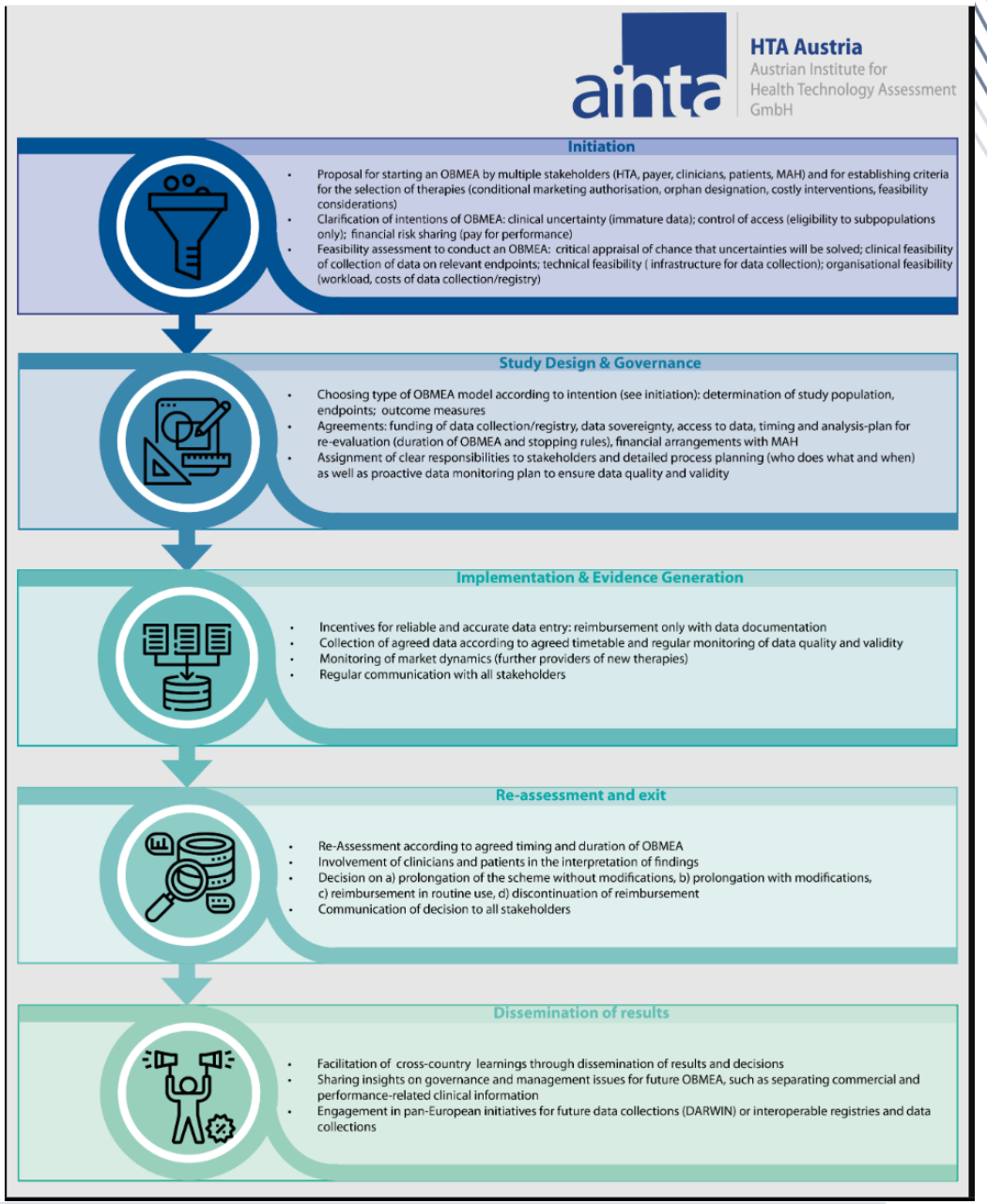
Guidance for improving MEAs



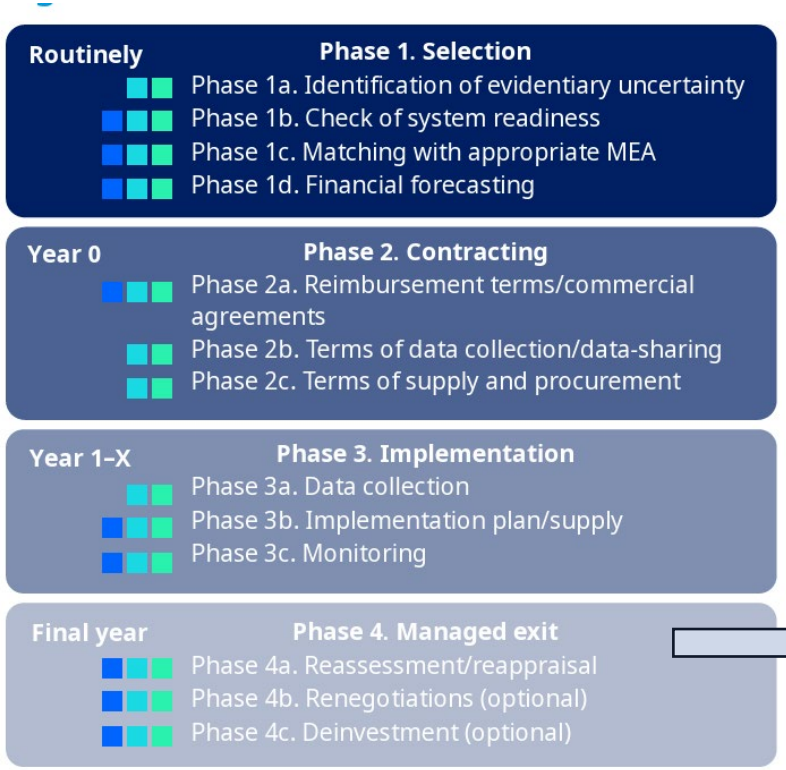
Conclusion

In theory, OBMEAs present an alternative pricing approach by sharing risks equally between private and public entities. Yet, an imbalance is caused by the lack of transparency around these agreements, hindering the successful implementation in practice. Therefore, a higher level of standardization could lead to more comparable results, facilitate data sharing and diminish the culture of the opaqueness of these agreements. Existing collaboration initiatives provide a good starting point for exploiting the potential of real-world data to advance decision-making in healthcare.

Wohlhöfner, K. (2021): (Gute) Praxis Organisationsmodelle für die öffentliche Finanzierung von hochpreisigen Therapien unter Verwendung von Anwendungsevidenz. HTA-Projektbericht 138 https://eprints.aihta.at/1329/
Highlights added by the presenter



Guidance for improving MEAs



4. Managed exit (final year)

Aim: to transparently execute the agreed upon terms (during the contracting phase) of exiting the MEA

4a. Reassessment/ re-appraisal (optional)	Criteria	☐ New regulatory information (EPAR) from EMA or MHRA ☐ Availability of post-launch evidence from: a. significant published literature from clinical trials, observational data, consumption data or other data sources b. outcome-based MEAs ☐ New national clinical guideline ☐ Reaching outcome-based MEA targets before the anticipated time frame, e.g. reaching OS in an ongoing clinical trial when the outcome-based MEA is based on uncertainty of PFS translating to OS
	Stakeholders	Initiated by: ☐ HTA agency Involved: ☐ clinicians ☐ health technology developers ☐ Ministry of Health/payer
	Sources of evidence	☐ Updated reimbursement submission from health technology developer, including additional clinical information and evidence from outcome-based MEA ☐ Published literature ☐ Unpublished clinical evidence from post-launch evidence ☐ Recommendations from national scientific association
	Transparency	☐ Publication of reassessment report
	Templates/tools	☐ No templates available



Principles for Managed Entry Agreements in the WHO European Region: policy framework. Copenhagen: WHO Regional Office for Europe; 2026. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/694cd151-3020-426b-8030-cd112552bda5/content

Conclusions

Take-away learnings for the future

In continued use of MEAs as a tool to make medicines more affordable and thus contribute to patient access, it should be aimed at

- documenting and publishing as much as possible,
- working on standardised reporting and contractual terms,
- generating evidence, including on its effectiveness, strengths and limitations,
- improving MEAs based on the learnings,
- sharing evaluation results and experience across countries.

Before your well-deserved coffee break…

Please switch on your camera for our group photo



Enjoy your coffee break!



We will be back in 10 minutes!

Gesundheit Österreich GmbH

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information