Managed entry agreements and the clinical value of newly reimbursed medicines in Finland

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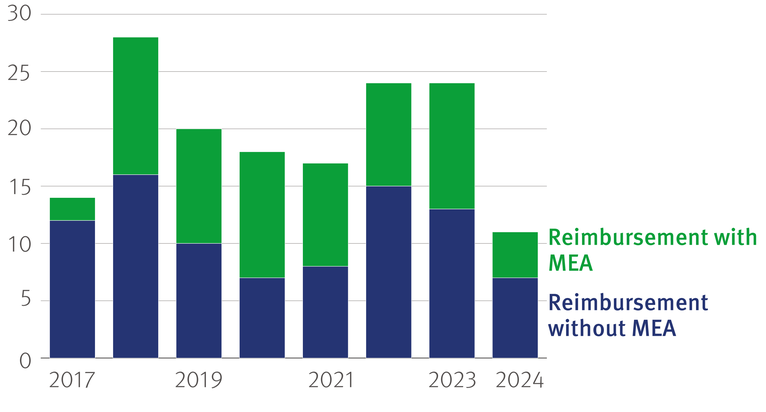
Background

Over the past decades, the pharmaceutical market has undergone significant structural and clinical changes that have reshaped outpatient medicine use. Costs of outpatient care medicines have increased substantially over the past decades, largely driven by the introduction of new, higher-priced pharmaceutical products. Managed entry agreements (MEAs) have become an increasingly common tool for payers and manufacturers to navigate uncertainties related to clinical effectiveness, the rising costs, and the rapid market entry of new health technologies. Although MEAs originally intended to link reimbursement more closely to real-world performance and provide patients with faster access to medicines with still-uncertain evidence, it appears that the agreements—particularly those based on financial criteria—function primarily as cost-containment mechanisms rather than genuine outcome-based contracts.

Purpose

This study describes newly reimbursed medicines covered by MEA in Finland. We examine the characteristics of these medicines and assess whether these newly introduced medicines provide measurable clinical added value compared with previously available therapeutic options.

Fig 1. Annual number of newly reimbursed medicines covered and not covered by managed entry agreements (MEAs) in Finland, 2017–2024.



Methods

Newly reimbursed medicines were identified from the nationwide register of outpatient medicine dispensations reimbursed under the National Health Insurance Scheme and maintained by the Social Insurance Institution of Finland. Information on which medicines were subject to MEAs was obtained from publicly available documents issued by the Pharmaceutical Pricing Board. Using published assessments from The French National Authority for Health (Haute Autorité de santé) each medicine was assigned a 'clinical added value' rating. Additionally, clinical added value was approximated by evaluating whether the medicine was the first in its therapeutic group to receive reimbursement.

Results

Between 2017 and 2024, a total of 156 new medicines were included into the public reimbursement scheme in Finland. MEAs has been made for approximately half of them (n=76). Almost half of these medicines with MEAs belonged to therapeutic classes comprising antineoplastic and immunomodulating agents, which are used, for example, in the treatment of cancer. Also, nearly half of these medicines held an orphan designation granted by the European Medicines Agency. Only a small number of newly reimbursed medicines – even those under a MEA – were first-in-class in their mechanism of action or offered a clinically meaningful additional benefit.

Fig 2. Distribution of medicines by Clinical Added Value and First-in-Class status (%, N=76). Most medicines covered by managed entry agreements were neither first-in-class nor associated with meaningful clinical added value.

	First-in-class	
HAS Clinical Added Value (CAV)	Yes (20%)	No (80%)
CAV I-III Meaningful clinical added value (42%)	11 %	32 %
CAV IV-V Low/no clinical added value (53%)	8 %	45 %
No HAS assesment available (5%)	1 %	4 %

Conclusions

Each year, approximately half of the new medicines accepted into the reimbursement system fall under a managed entry agreement. The added therapeutic value of these new medicines appears relatively modest, and a substantial proportion does not seem to address an unmet medical need, despite their high price. However, it is possible that they still contribute to increased competition within their therapeutic classes. The agreements are long in duration and often renewed repeatedly until the market situation changes — for example, when market exclusivity expires. These results highlight the need for continued evaluation of MEAs to ensure that reimbursement decisions align with meaningful therapeutic improvements and support sustainable pharmaceutical expenditure.

Key findings

- Every second new reimbursed medicine in Finland is subject to a managed entry agreement.
- MEA-covered medicines were predominantly high-cost oncology, immunology, and orphan medicines.
- One in five medicines covered by MEA was first-in-class.
- Meaningful clinical added value was demonstrated by 40% of medicines covered by MEA.

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