IMPLEMENTATION OF MANAGED ENTRY AGREEMENTS ACROSS THE NORDIC REGION

HTA196

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ISPOR Nordic Chapter

BACKGROUND

Global pharmaceutical spending is expected to increase due to rising medicine use and the high cost of innovative treatments, posing affordability challenges for healthcare systems—particularly for rare disease and cancer therapies. In many cases, new treatments enter the market with limited evidence of long-term effectiveness, making it difficult for payers to determine their true value at launch. To manage uncertainty around the real-world effectiveness of new drugs, managed entry agreements (MEAs) as a policy tool to facilitate access to high-cost medications while managing financial risk have been widely adopted in Europe, Australia, and parts of Asia (1,2). These agreements are negotiated between pharmaceutical market authorization holders (MAH) and payers such as national health authorities or insurance funds and typically include provisions for price discounts and performance-linked reimbursements.

OBJECTIVE

On behalf of the ISPOR Nordic Chapter, this study aims to outline the evolved processes for setting up confidential MAEs in each of the Nordic countries—known for their strong health technology assessment (HTA) systems—and to categorize the types of agreements implemented.

METHOD

Processes and MEA characteristics are described based on publicly available information for January 2023 to June 2025, sourced from public ally available information, sourced from relevant authority website. Data for hospital drug MEAs in Finland are sourced from data- on-file. The categories for MEAs are based on the taxonomy suggested by ISPOR see Figure 1 (3).

RESULTS - country wise processes for MEAs

The processes and main stakeholders for MEA negotiations differs across the Nordic countries.

In Sweden MEAs for prescription drugs can be negotiated as a result of a tripartite deliberations between the manufacturer, the region and the Dental and Pharmaceutical Benefits Agency (TLV). Hospital drugs lack a formal national process and are procured regionally. Since 2014, the New Therapies Council (NT-rådet) has coordinated national guidance for certain hospital drugs through the National Managed Introduction process, with input from TLV. MEAs are used for both outpatient and managed introduction products. the New Therapies Council can issue a recommendation to the regions to use the pharmaceutical for hospital care. All regions who wish to can then sign agreements with the company according to the negotiated terms.

In Finland, prescription drug MEAS may be negotiated with the Pharmaceutical Pricing Board (Hila). Hospital medicines are assessed by Fimea and reviewed by Cohere, which issues recommendations that guide price negotiations by hospital pharmacies. All MEAs for outpatient drugs are financial in nature while the number of type of MEA for hospitals drugs is not publicly available.

In Norway the Norwegian Medicines Agency (DMP) makes reimbursement decisions for prescription drugs on behalf of the National Insurance Scheme (NIS), often leading to a lower price than the statutory maximum price. The Decision Forum of the Regional Health Authorities (RHA) makes reimbursement decisions for the specialist care sector. The Hospital Procurement Trust (Sykehusinnkjop HF) manages price negotiations for hospitals through tenders and for the NIS. The Directorate of Health can enter into MEAs with MA-holders for medicines reimbursed by NIS, first introduced in 2017 and used for high-need, cost-effective treatments with limited budgets. A 2020 framework allows the Decision Forum and RHA to approve flexible pricing models, such as price-volume or outcome-based contracts, with Sykehusinnkjop HF leading negotiations (4). More complex models must be pre-approved by the Decision Forum.

In Denmark primary care medicines are assessed by the Danish Medicines Agency (DMA), while hospital medicines are evaluated by the Danish Medicines Council (DMC). Amgros, the central procurement body, negotiates hospital drug prices and supports flexible pricing models, including outcome-based and cost-sharing agreements. Since 2023, DMC and Amgros have allowed alternative pricing proposals to address uncertainty. In primary care, pilot risk-sharing agreements began in 2018, where companies cover usage above a cap (5,6). A new 2025–2028 pilot will allow confidential price negotiations for select reimbursed outpatient drugs, targeting high-cost or transitioning medicines.

Figure 1: Taxonomy, adopted from (3)

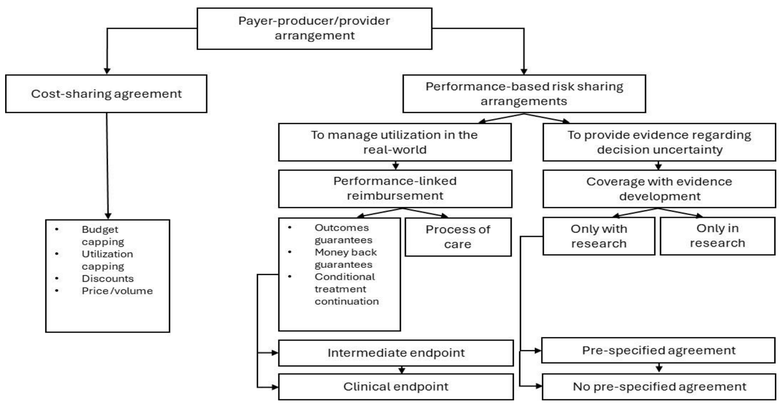


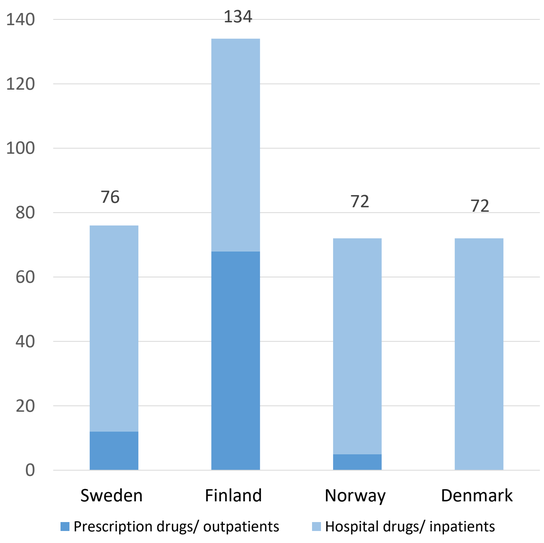
Table 1: Main stakeholders for MEAs negotiations

	Prescription drugs/ outpatients	Hospital drugs/ inpatients
Sweden	Tripartite deliberations requested by manufacturer or region and hosted by the TLV	National managed introduction through the NT council
Finland	MEAs negotiated with HILA	Negotiated with hospital pharmacies (non-public info)
Norway	MAEs negotiated with Helse-direktoratet / Sykehusinnkjøp	Flexible pricing to be negotiated (pre-approval) with RHA / Sykehusinnkjøp
Denmark	MEA pilot underway with DMA / Amgros	Negotiated with DMC/Amgros

Abbreviations: DMA = Danish Medicines Agency, DMC: Danish Medicines Council, HILA =the Pharmaceuticals Pricing Board; MEA=managed entry agreement; NT: New Treatment; TLV: the Dental and Pharmaceutical Benefits Agency; RHA = Regional Health Authorities

RESULTS - country wise number and categorization of MEAs

Figure 2: Number of MAEs per country



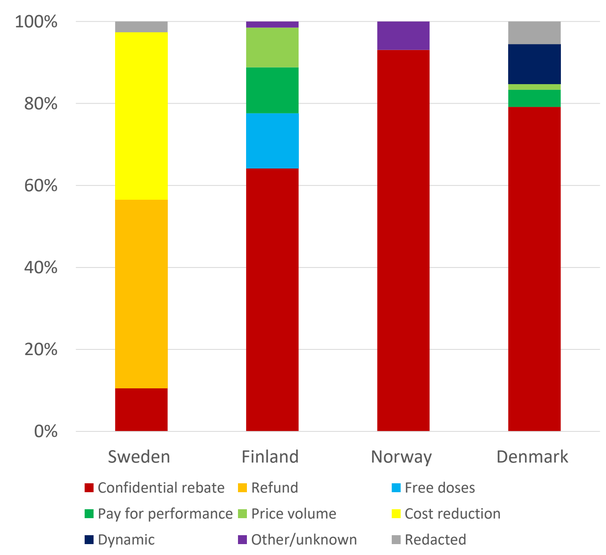
Sources: Sweden (7), Finland (8,9), Norway (10,11), and Denmark (12)

Figure 2 presents the total number of MAEs contracted in each of the Nordic countries. The data indicate that MAEs are considerably more frequent in hospital settings across all countries, with the exception of Finland, where their distribution appears to be more balanced between settings.

Figure 3 illustrates that cost-sharing agreement, particularly those involving confidential discounts to the list price, remain the most common form across all countries except Sweden. In Norway, this model is almost entirely dominant, with only five contracts employing alternative, undisclosed structures. In Sweden, the most prevalent arrangement involves manufacturers refunding costs to the regions or cost reductions not further specified. Evidence from several studies suggests that some refund-based and cost-reduction contracts in Sweden may also operate under price–volume frameworks, where volume is measured by the number of patients treated and treatment duration (13, 14). In Finland, the second most common MEA type consists of free-dosing contracts, while price, volume agreements are also frequent. Dynamic contracts, commonly seen in Denmark, typically cover immunotherapies and allow for contract updates in response to market changes.

Confirmed performance-based risk-sharing contracts were observed only in Finland and Denmark during the study period.

Figure 3: Proportion of MAE types by country



Sources: Sweden (7), Finland (8,9), Norway (10,11), and Denmark (12)

DISCUSSION AND CONCLUSIONS

Pharmaceutical prices are often established early in development and critics argue that a large share of industry profits is directed toward shareholders rather than reinvested into R&D, resulting in prices that may not align with healthcare value benchmarks.

The current study shows that Nordic countries favour simple rebate models maybe for their predictability and administrative efficiency. In Denmark, DMC and Amgros have concluded two performance-based agreements, though both required considerable setup time. Leveraging national registries can help reduce this burden. A retrospective Amgros evaluation of “on-demand” pricing demonstrated substantial savings potential when existing registry endpoints are utilized (15). Enhanced Nordic collaboration on MAEs could further strengthen access to innovative therapies across the region.

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