A comparative analysis of the Denmark, Finland, Norway, and Sweden market access pathways for medical devices

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Background

Denmark, Finland, Norway, and Sweden are known for their high-quality healthcare systems. While pharmaceutical evaluation and reimbursement processes are well-established and relatively aligned across the region, the approach to medical devices is less developed and varies significantly. Differences in assessment procedures and reimbursement requirements create a more complex landscape for medical device access in these countries.

Objective

This study aims to compare the market access processes for new medical devices across Denmark, Finland, Norway, and Sweden, focusing on the requirements for reimbursement.

Methods

A desk-based research approach was employed to analyze publicly available information from government websites, health technology assessment (HTA) agency reports, and industry publications.

Conclusions

Denmark, Finland, Norway, and Sweden exhibit diverse market access processes for medical devices. While Sweden and Norway maintain structured HTA frameworks, Denmark and Finland do not require HTAs. The assessment of HTA-approved products highlights the impact of these processes on market entry and patient access.

References

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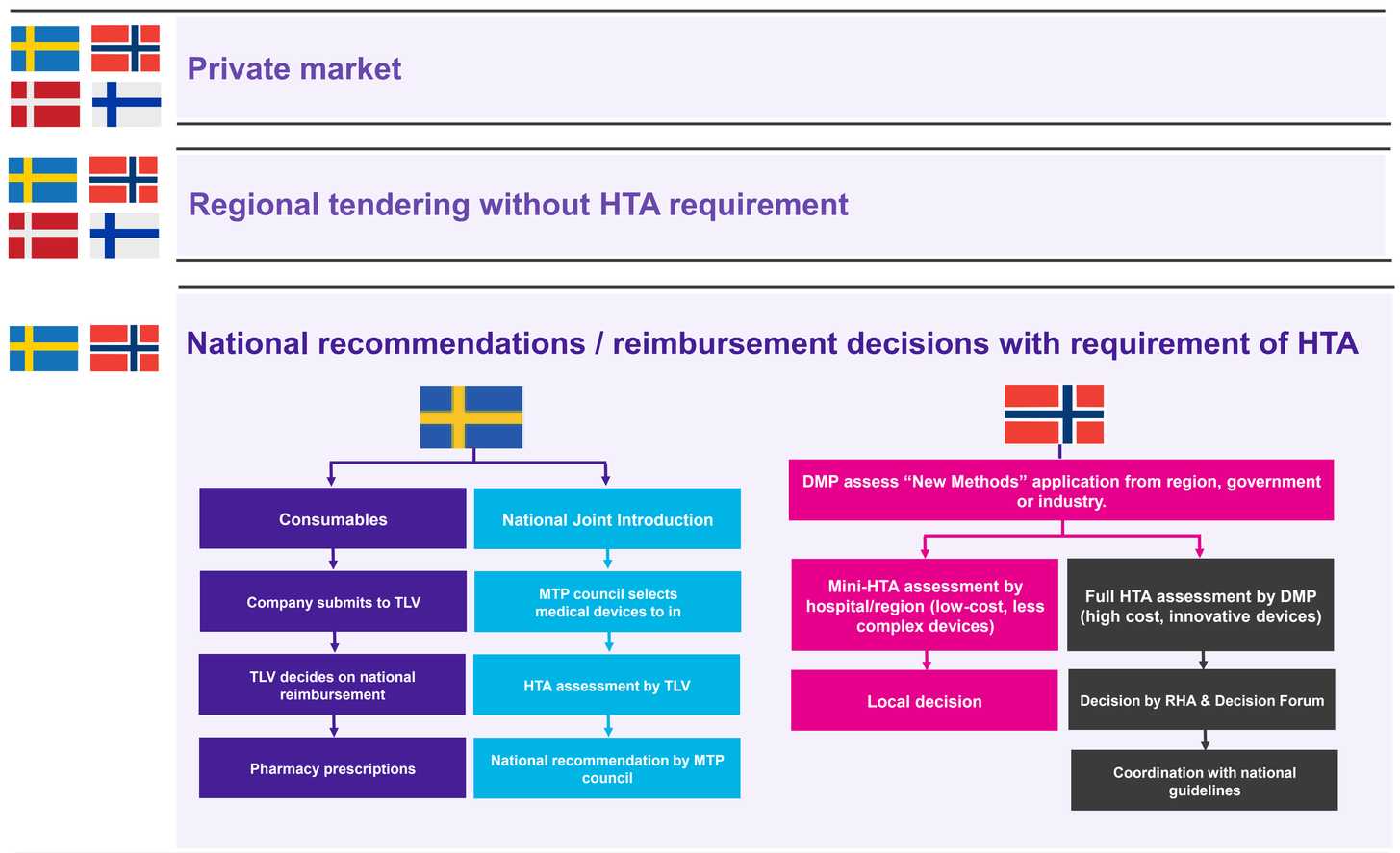
Results

Key identified country findings:

- In Denmark, Finland, Norway, and Sweden, market access for medical devices is possible through private channels and regional tendering. However, only Sweden and Norway have established national processes that include requirements for HTAs. These national pathways, however, apply only to a selected subset of medical devices—typically those meeting specific criteria or chosen for evaluation.
- Sweden: For consumable medical devices, national reimbursement applications, including HTAs, can be submitted to the Dental and Pharmaceutical Benefits Agency (TLV) if being used for stoma care, administration of medication, or self-monitoring of medication. HTAs and national recommendations for selected medical devices can also be provided through the National Joint Introduction process, managed by the Medical Technology Product Council (MTP Council). The MTP Council is a decision-making group composed of representatives from the healthcare regions. Medtech companies cannot apply directly to this process. Instead, product selection is determined by the MTP Council, which evaluates and decides which technologies to include. Only a limited number of products are selected each year, and a total of 5 national recommendations were published in 2024.[1]
- Norway: New Methods (Nye Metoder) oversees national HTAs, while regional health authorities conduct “mini-HTAs.” HTA requests and decisions are published, but few devices have been assessed. New recommendations and criteria for which products must undergo national assessment are currently under development.[2]
- Finland: HTA assessments are not required. The Finnish Medicines Agency (Fimea) manages device registration in the Centralized Medical Device Operator and Device Register (CERE), mandatory for market entry.[3]
- Denmark: As of 2025, HTAs are no longer required for company-submitted medical devices, following the termination of the previous process established by the Danish Health Technology Council for new medical devices.[4]

Figure 1. Denmark, Finland, Norway, and Sweden market access pathways for medical devices



DMP – Directorate for Medical Products; HTA – health technology assessment; MTP – Medical Technology Product; RHA – Regional Health Authorities; DMP - Direktoratet for medisinske produkter; TLV – Dental and Pharmaceutical Benefits Agency.
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