JNHB and introduction of new medicinal products in the Nordic countries

The Joint Nordic HTA-Bodies (JNHB) conducts health technology assessments (HTA) for medicinal products. The joint HTA reports ensure consistent, evidence-based support for national decision-making across the Nordics.

Each of the Nordic countries has established a structured framework for pricing and decision-making when introducing new medicinal products. The frameworks include HTA, price negotiations and recommendations for use or decisions on reimbursement (Box 1 at the end of this paper provides a definition of HTA). In Figure 1 an overview of the HTA-bodies involved in JNHB, and organizations responsible for negotiation and decision-making in the Nordic countries is outlined. JNHB is involved in the HTA step, which is highlighted in grey. Negotiations and decisions on reimbursement/recommendation are outside the remit of JNHB.

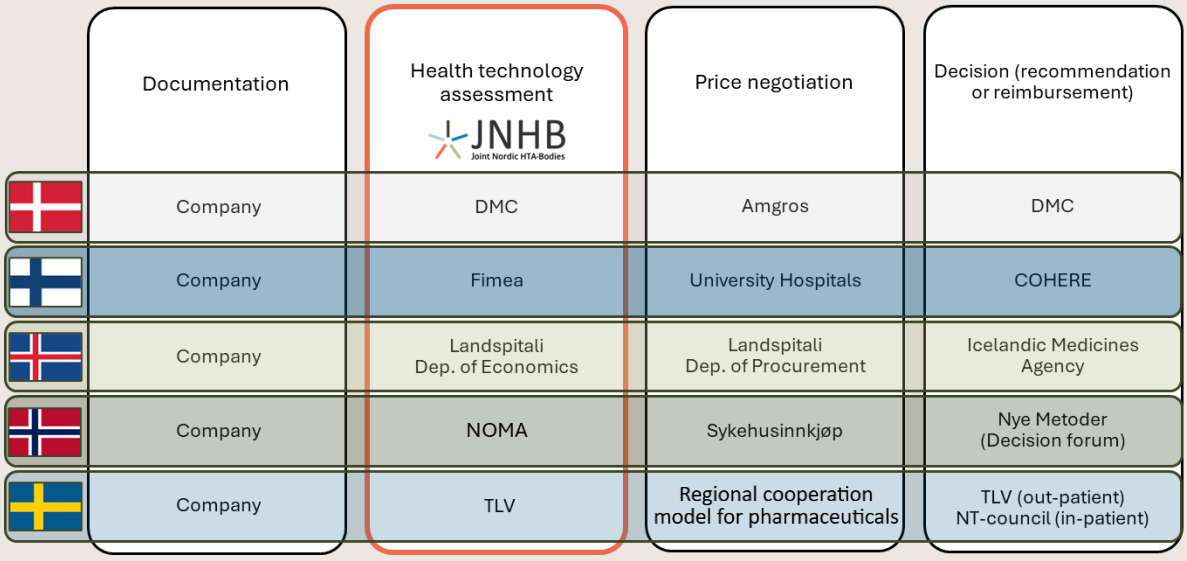

***Figure 1**. An overview of the organizations involved in HTA, negotiations and decision-making in the Nordic countries. In Denmark, Finland and Norway, out-patient pharmaceuticals have separate processes that are not included in the figure.*

To have an HTA through JNHB the health technology developer (HTD) needs to provide a dossier containing the necessary clinical and health economic documentation. During the assessment, the HTA-bodies collect expert opinions on matters such as disease background, patient population(s)and current treatments practices, as well as on the relevance of clinical studies and assumptions in the health economic modelling. Although the Nordic systems for introducing new medicinal products differ, there are fundamental similarities in the HTA processes and methodologies, providing a solid foundation for joint assessments.

Publicly available prices are used in JNHB assessments, as negotiated prices often are confidential at the request of HTD. Consequently, sharing confidential pricing information is not necessary within the JNHB collaboration. The HTA reports may be used for negotiations on national or Nordic level. Finally, the HTA report together with the negotiated price informs national decisions on recommendations or reimbursement for the medicinal product. All these decisions are made at national level.

Similar HTA Methodology across Nordic countries

The Nordic countries follow well-established HTA methods, using cost-utility analyses to estimate incremental costs, incremental quality-adjusted life years (QALYs), and incremental cost-effectiveness ratio (ICER).

JNHB has mapped the current national HTA methodologies for assessing new medicinal products in the Nordic countries. No important differences in the preferred national methods for assessing relative clinical effectiveness and safety were identified during the mapping. In the health economic modelling, the countries show strong similarities in pivotal elements, such as assessing the model structure and input, while relying on clinical data and expert input to address the uncertainty in the model outcomes. There are a few parameters where country-specific input is needed, for example prices for medication that usually differ between countries. The JNHB dossier template gives specific guidance to what should be included in a joint Nordic assessment.

The JNHB report and national appendices

In the joint JNHB report, the results of the health economic analyses will be reported with the settings of the country responsible for conducting the health economic part of the assessment. Results based on country-specific settings for the other Nordic countries will be included in national appendices. A national appendix may include a summary in the national language, budget impact analysis, expected sales and severity calculations.

BOX 1. HTA is defined by the EU HTA Regulation as:

- A **systematic, multidisciplinary scientific process** that integrates medical, statistical, and health economic expertise.
- A process that uses **explicit methods** to evaluate the value of a health technology based on the **best available evidence**.
- A **scientific and independent process**, where assessments are conducted separately from companies and negotiators. Instead, HTA bodies consult clinical experts for input on disease context, patient groups, treatment practices, study relevance, and economic modelling assumptions.
- A process that involves **close coordination** between HTA bodies, negotiators, and companies throughout the assessment.