

# JNHB – Nordic HTA collaboration

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## How we started

- First discussions on collaboration between Fimea and NoMA 2015. TLV joined later.
  - Official start in Stockholm 2018: FINOSE
  - Memorandum of Understanding
- ⇒ Bottom up initiative, starting from the HTA-bodies and not from the political end

## From FINOSE to Joint Nordic HTA-bodies JNHB

Since April 2024 all Nordic countries are included

- The Danish Medicines Council (DMC)
- The Finnish Medicines Agency (Fimea)
- Landspítali - The National University Hospital of Iceland
- The Norwegian Medical Products Agency (DMP)
- The Swedish Dental and Pharmaceutical Benefits Agency (TLV)

## From FINOSE to Joint Nordic HTA-bodies

During 2023 -2024 intensive work with processes and guidelines

- JNHB Process guideline (March 2025)
- JNHB Submission Dossier Template
- JNHB – NED collaboration
- Website: [jnhtabodies.org](http://jnhtabodies.org)

## Other important documents

- Report template
- Waiver of confidentiality
- Memorandum of understanding

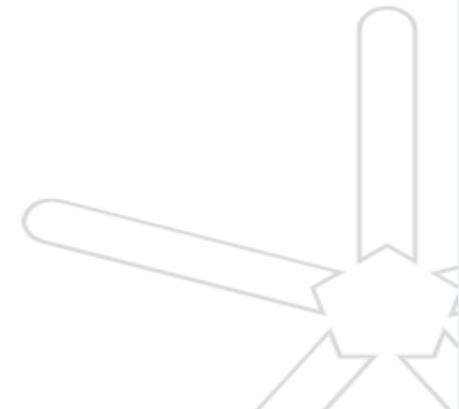
Relaunch in spring 2024

# Welcome to the Nordic collaboration JNHB

The Nordic collaboration JNHB offers efficient and transparent joint health technology assessments of medicinal products in the five Nordic countries.

[Read more](#)

<https://jnhtabodies.org/>



## NEWS

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**June 27 2025**

- Assessment time

[Read more](#)

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**June 19 2025**

- JNHB meeting in Copenhagen

[Read more](#)

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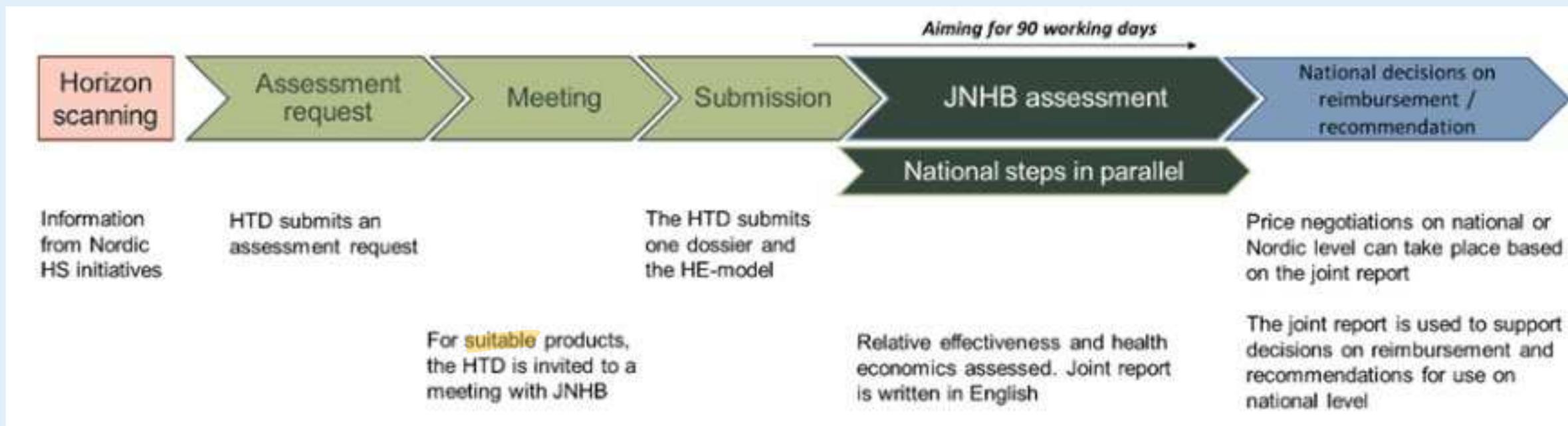
**April 10 2025**

- JNHB Updates Process Guideline and Dossier Template after involvement of Nordic Pharmaceutical Associations

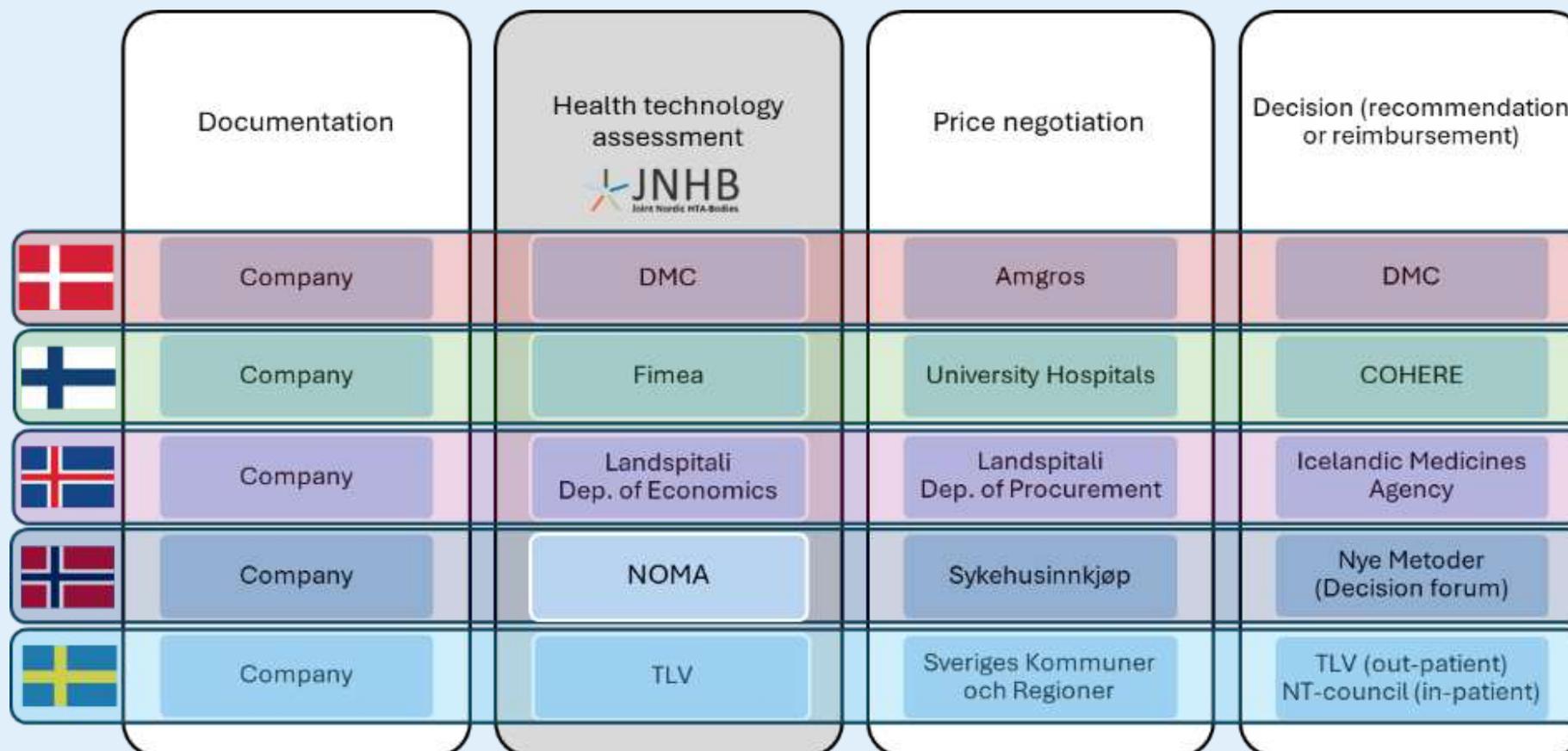
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## Processes and guidelines

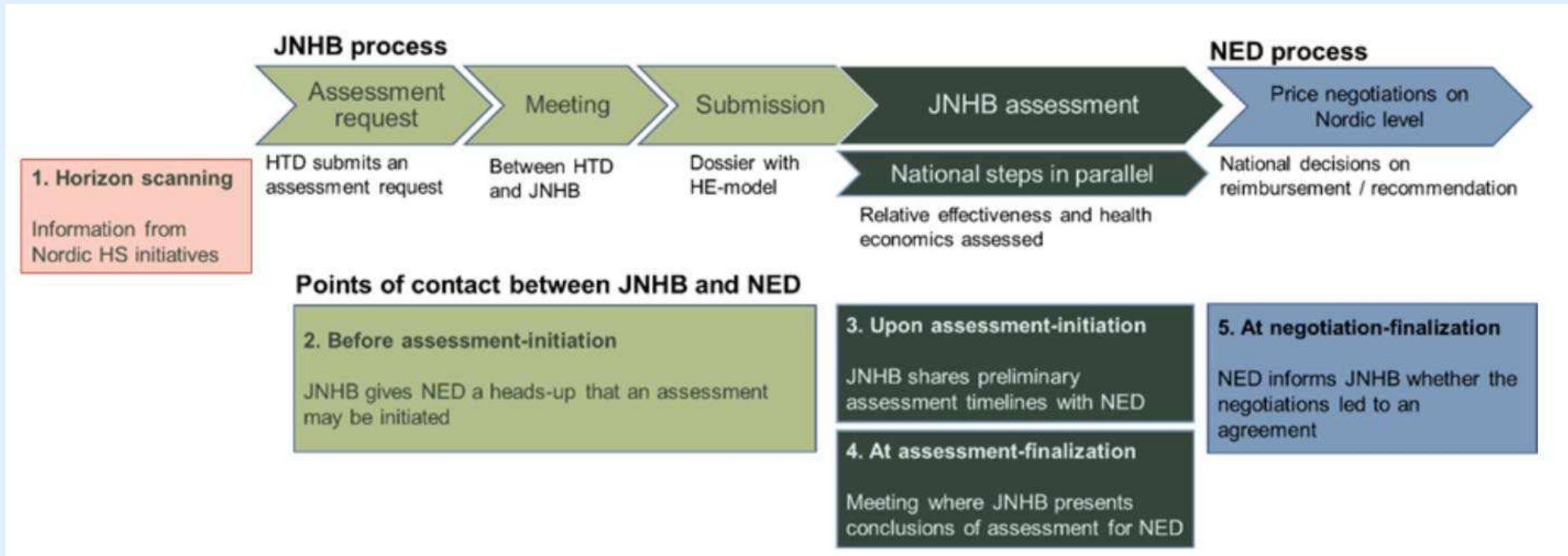


## Processes and guidelines



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

# JNHB – NED collaboration



# The assessments

## **Tofersen (Qalsody) - January 2025**

### [Assessment report - Tofersen](#)

Tofersen (Qalsody) for the treatment of adults with amyotrophic lateral sclerosis (ALS), associated with a mutation in the superoxide dismutase 1 (SOD1) gene.

Assessment time: 68 days

## **Omaveloxolone (Skyclarys) - December 2024**

### [Assessment report - Omaveloxolone](#)

Assessed indication: Omaveloxolone (Skyclarys) for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

Assessment time: 82 days

## **Ivosidenib (Tibsovo) - December 2024**

### [Assessment report - Ivosidenib](#)

Assessed indication: Ivosidenib (Tibsovo) in combination with azacitidine is indicated for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy.

Assessment time: 86 days

## **Ivosidenib (Tibsovo) - December 2024**

### [Assessment report - Ivosidenib](#)

Assessed indication: Ivosidenib (Tibsovo) is indicated for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who were previously treated by at least one prior line of systemic therapy.

Assessment time: 92 days

## **Voxzogo - September 2023**

### [Assessment report - Voxzogo](#)

Assessed indication: Voxzogo is indicated for the treatment of achondroplasia in patients 2 years of age and older whose epiphyses are not closed. The diagnosis of achondroplasia should be confirmed by appropriate genetic testing.

## **Libmeldy - February 2022**

### [Assessment report - Libmeldy](#)

Assessed indication: Libmeldy is indicated for the treatment of metachromatic leukodystrophy (MLD) characterized by biallelic mutations in the arylsulfatase A (ARSA) gene leading to a reduction of the ARSA enzymatic activity:

- in children with late infantile or early juvenile forms, without clinical manifestations of the disease,
  - in children with the early juvenile form, with early clinical manifestations of the disease, who still have the ability to walk independently and before the onset of cognitive decline
- The FINOSE assessment report for Libmeldy was used for joint Nordic negotiations between the HTD and the New Expensive Drugs, NED group in Nordic Pharmaceutical Forum.

## **Zynteglo - June 2020**

### [Assessment report - Zynteglo](#)

Assessed indication: Zynteglo for the treatment of patients 12 years and older with transfusion-dependent  $\beta$ -thalassaemia (TDT) who do not have a  $\beta^0/\beta^0$  genotype, for whom haematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available

## **Xtandi - June 2019**

### [Assessment report - Xtandi](#)

Assessed indication: Enzalutamide for the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer.

## **Tecentriq - June 2019**

### [Assessment report - Tecentriq](#)

Full indication in combination with bevacizumab, paclitaxel and carboplatin  
Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC). In patients with EGFR mutant or ALK-positive NSCLC, Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies.

Assessed subgroups:

- Patients with EGFR mutant or ALK-positive NSCLC after failure of appropriate targeted therapies
- Patients with liver metastasis

# How to apply on JNHB assessment?

## How to contact us?

1. Email to [contact@jnhtabodies.org](mailto:contact@jnhtabodies.org)
2. Contact someone from JNHB agencies
3. Wait for our email

## When to contact us?

- As early as possible
- When PICO is finalized for JCA (~d 120)

**Thank you!**

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[www.fimea.fi](http://www.fimea.fi)