

Collaboration between the Joint Nordic HTA-Bodies and New Expensive Drugs

To strengthen the cooperation between the Nordic countries, the Joint Nordic HTA-Bodies (JNHB) has entered a collaboration with the New Expensive Drugs (NED) section of Nordic Pharmaceutical Forum. The collaboration aims to support joint Nordic negotiations for products assessed through JNHB.

The possibility of joint HTA and negotiations is offered as a voluntary route for suitable products and aims at equal patient access in the Nordic countries. The main steps of the process are outlined below.

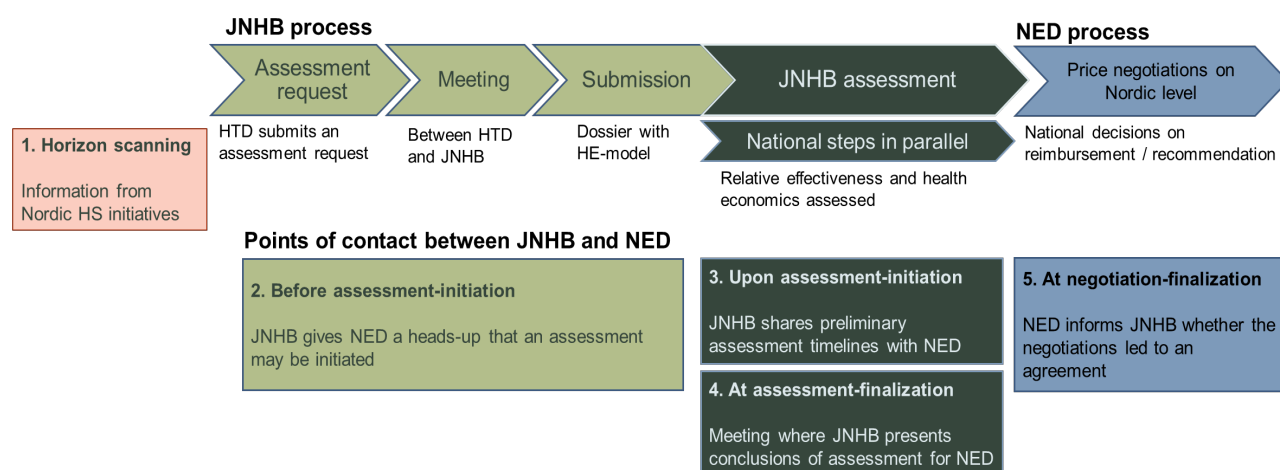


Figure 1. An overview of contact points between Joint Nordic HTA-bodies (JNHB)¹ and New Expensive Drugs (NED)² throughout the health technology assessment (HTA) and negotiation processes.

¹Joint Nordic HTA-bodies (JNHB) is an HTA-collaboration between The Danish Medicines Council (DMC), The Finnish Medicines Agency (Fimea), Landspítali -The National University Hospital of Iceland (Landspítali), The Norwegian Medicines Agency (NOMA) and The Swedish Dental and Pharmaceutical Benefits Agency (TLV).

² NED is a working group in the Nordic Pharmaceutical Forum. The group consists of the price negotiation authorities, Amgros I/S in Denmark, Sykehusinnkjøp HF, divisjon legemidler (LIS) in Norway, Landspítali National University Hospital of Iceland, and the New Therapies council (NT-council) in Sweden.

Horizon Scanning

JNHB and NED collaborate with the Nordic Horizon Scanning initiatives and receive information about which new medicinal products, and new indications for already approved products are on the way to the market. The information also includes facts about the products characteristics that facilitates when identifying products relevant for Nordic collaboration.

Before assessment-initiation

Aim of contact

- For JNHB to give NED a heads-up that a new JNHB assessment may be initiated and that the company is interested in a joint Nordic negotiation.
- To give NED a possibility to consider whether the suggested product is of interest for joint price negotiations.

Process

When a company is considering joint Nordic HTA and negotiations, the JNHB team sends an e-mail to inform NED. At this stage, the company may not have signed the [Waiver of Confidentiality](#), so only public information can be shared. If NED decides that the product is not suitable for joint Nordic negotiations, NED will inform JNHB about this. If this is the case, the collaboration between JNHB and NED for the specific product will cease.

Upon assessment-initiation

Aim of contact

- For JNHB to inform NED that a JNHB assessment has been initiated, and whether the company is interested in joint Nordic price negotiations.
- If yes, the information should include an overview of the preliminary assessment timelines, so the negotiators can start to plan the negotiation process.
- To share contact information for relevant representatives from JNHB and NED in the upcoming process in the event there is a decision on joint negotiations.
- To ensure common grounds for the collaboration between JNHB and NED are established.

Process

Initiation of a JNHB assessment requires that the company sign the JNHB [Waiver of Confidentiality](#). When the Waiver has been signed, the JNHB team can share information about the assessment according to the terms specified in the Waiver of Confidentiality.

If the company is interested in a joint Nordic negotiation for their product, JNHB will inform NED about the PICO and preliminary timelines for the HTA process. Each negotiation authority will decide individually and by applying the selection criteria for joint Nordic negotiation if the

product is suitable for this process³. Additionally, JNHB and NED provide contact details for relevant contact persons from JNHB and NED in the upcoming process.

It is not compulsory for a product assessed through JNHB to go through a joint Nordic price negotiation. Initiation of a joint Nordic price negotiation is a mutual decision between the company and NED. In addition, there is not a requirement for an HTA through JNHB and a joint Nordic report for a product to be suitable for a joint Nordic negotiation.

The steps below will only take place if there is mutual interest, or a decision is made, between the company and NED to enter a joint Nordic price negotiation. The finalized JNHB report can be used to facilitate the negotiations, although the HTA agencies will not participate in the negotiations.

At assessment-finalization

Aim

- For JNHB to present the key points from the assessment report.
- To give the NED negotiation team a possibility to ask questions about the assessment and conclusions.
- To provide an opportunity to address any concerns/issues regarding the assessment and the joint work.

Process

JNHB sends a meeting invitation to the NED negotiation team approximately three weeks prior to the release of the final assessment report. The meeting will be held as soon as the JNHB assessment is finalized and JNHB will share the finalized report with NED prior to the meeting. The finalized JNHB report will be published on the national HTA-bodies' websites.

At negotiation-finalization

Aim

- For NED to inform JNHB whether the negotiation has reached an agreement.

Process

The NED negotiation team informs the JNHB team whether NED and the company agreed on a common price. The information does not include the result from the negotiation. Each country will enter into a national agreement with the company based on the results of the negotiation.

³ [statement-faelles-nordiske-forhandlinger-eng- final.pdf \(amgros.dk\)](#)