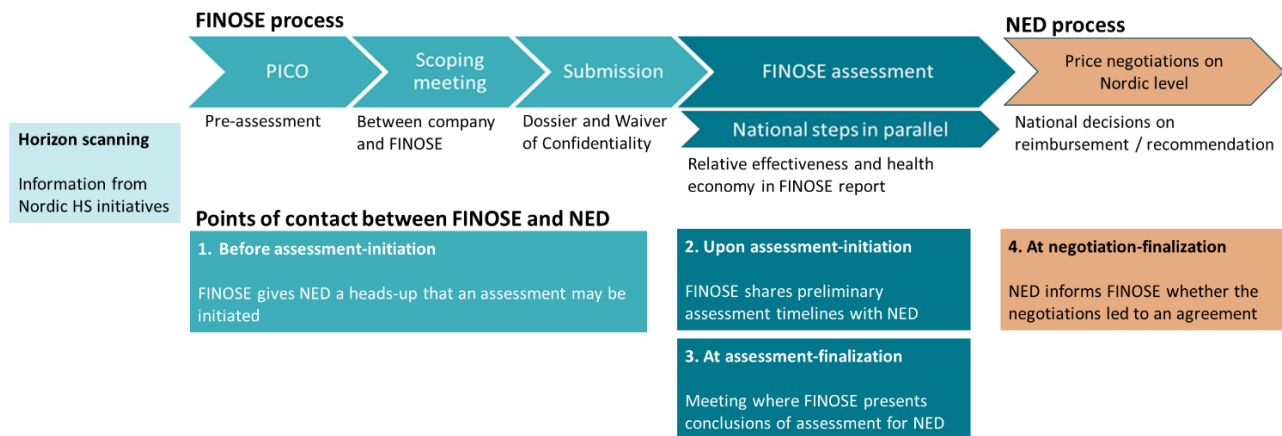


Description of the collaboration between FINOSE and New Expensive Drugs (NED) in the process for new drugs going through FINOSE HTA and joint Nordic negotiations



Points of contact between FINOSE¹ and New Expensive Drugs (NED)² throughout the health technology assessment (HTA) and negotiation processes.

0. Horizon Scanning

FINOSE and NED receive information from the Nordic Horizon Scanning initiatives. Information is about which new medicines and new indications for already approved medicines are on the way to the market, as well as information on a medicine's characteristics. The Nordic Horizon Scanning initiative facilitates identifying products interesting for Nordic collaboration.

1. By e-mail – before a FINOSE assessment is initiated.

1.1. Aim

- For FINOSE to give NED a heads-up that a new FINOSE 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.

1.2. Process

When a company is considering joint Nordic HTA and negotiations, the FINOSE 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

¹ FINOSE is a collaboration for joint Nordic HTA between the Danish Medicines Council (DMC), the Finnish Medicines Agency (Fimea), 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.

will inform FINOSE about this. If this is the case, the collaboration between FINOSE and NED for the specific product will cease.

2. By e-mail – When a FINOSE assessment has been initiated.

2.1. Aim

- For FINOSE to inform NED that a FINOSE assessment has been initiated, and whether the company is interested in joint Nordic price negotiations.
- If yes, the e-mail 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 FINOSE and NED in the upcoming process in the event there is a decision on joint negotiations.
- To ensure common ground for the collaboration between FINOSE and NED is established.

2.2. Process

Initiation of a FINOSE assessment requires that the company sign the FINOSE [Waiver of Confidentiality](#). When the Waiver has been signed, the FINOSE 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, FINOSE 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, FINOSE and NED provide contact details for relevant contact persons from FINOSE and NED in the upcoming process.

It is not compulsory for a product assessed through FINOSE 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 FINOSE and a joint Nordic report for a product to be suitable for a joint Nordic negotiation.

Steps 3 and 4 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 FINOSE report can be used to facilitate the negotiations, although the HTA agencies will not participate in the negotiations.

3. Meeting – When the FINOSE assessment is finalized.

3.1. Aim

- For FINOSE 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.

3.2. Process

FINOSE 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 FINOSE assessment is

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

finalized and FINOSE will share the finalized report with NED prior to the meeting. The finalized FINOSE report will be published on the national FINOSE agencies' websites.

4. By e-mail – when the joint negotiation has been finalized.

4.1. Aim

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

4.2. Process

The NED negotiation team informs the FINOSE 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.