



FINOSE – PROCESS FOR JOINT ASSESSMENT

1 The FINOSE collaboration

The FINOSE is a Nordic collaboration of Finland, Norway and Sweden in HTA (Health Technology Assessment). The collaborating agencies are Sweden's Dental and Pharmaceutical Benefits Agency (TLV), the Norwegian Medicines Agency (NoMA) and the Finnish Medicines Agency (Fimea). FINOSE is now accepting applications for joint assessment.

2 Objectives of the assessment process

The FINOSE collaboration aims at:

- Supporting timely and equal access to medical technologies
- Gaining additional knowledge about the products
- Increased efficiency in production of assessment reports
- Less divergence in HTA methodologies and evidence requirements
- Reduced complexity in industry submissions

Consequently, the collaboration is expected to result in reduced workload and time to market.

The collaboration seeks synergies by enabling communication between the agencies during the normal HTA processes in participating agencies. There is no intention to build an additional process for FINOSE assessments. Rather, the FINOSE assessment would ideally add only two new features to the current national processes:

- 1) The company should submit simultaneously to Fimea, NoMA and TLV
- 2) The company should sign a waiver to allow communication on confidential material submitted within the FINOSE assessment between the agencies

FINOSE collaboration is not aiming for joint decision making.

3 Selection of the assessment topics

The FINOSE collaboration focuses on new products that are coming to market after marketing authorisation. The assessment is initiated in such a manner that its outcomes are available as soon as possible after the marketing authorisation has been granted.

The actual FINOSE assessment process requires the company's consent for data sharing. For this reason, the selection of potential topics is based on companies' expression of interest. The decision to launch a FINOSE assessment is made based on common interests of Fimea, NoMA and TLV, taking account of national measures already taken on the topic in question.

All kinds of pharmaceuticals can be submitted to FINOSE. Nevertheless, it should be noted that in case of an out-patient product in Finland, the FINOSE assessment cannot replace the normal process for pricing and reimbursement. For confirmation of reimbursement and a reasonable wholesale price of an out-patient product in Finland, the company must submit an application to the Pharmaceutical Pricing Board as usual.

4 Assessment process

A flowchart of the assessment process is presented in Figure 1 below.

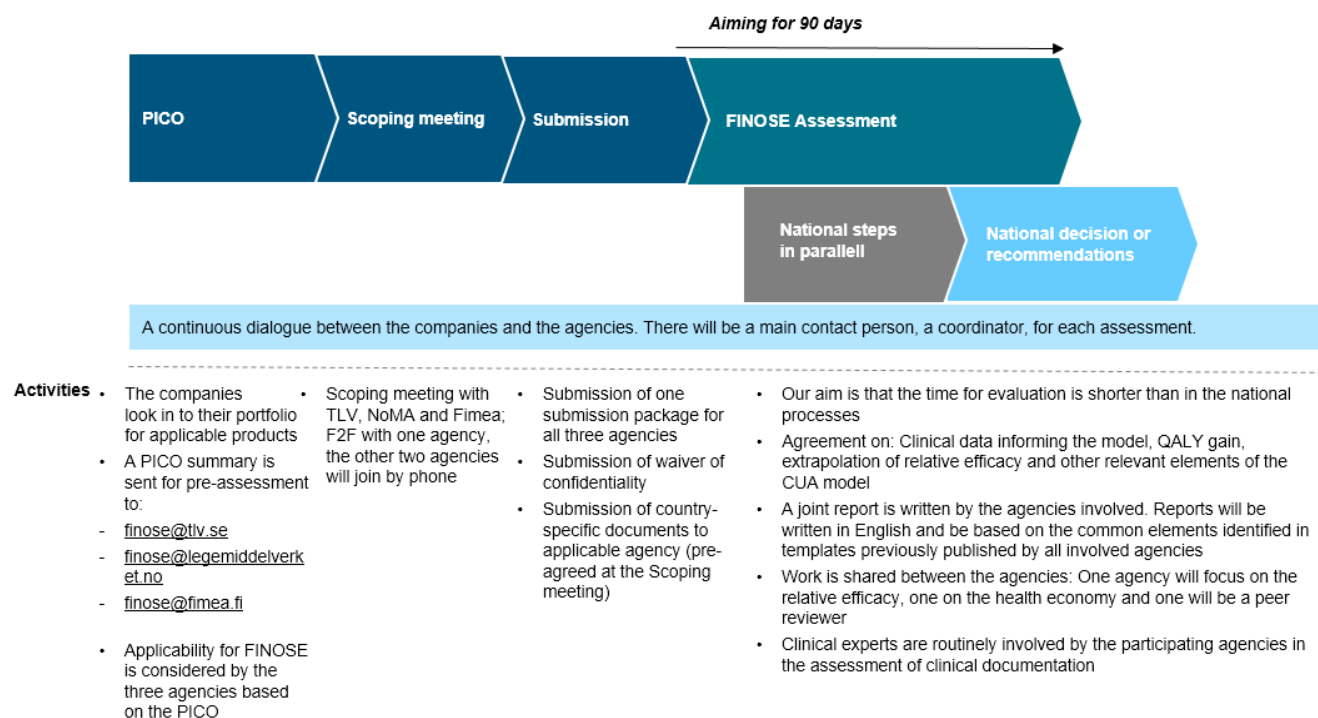


Figure 1. Assessment process in FINOSE collaboration

Companies are invited to look into their portfolios to identify topics that are expected to receive a CHMP positive opinion in the following months. The companies are encouraged to be in contact with Fimea, NoMA or TLV at this point to prepare for immediate initiation of the assessment after CHMP positive opinion.

When the assessment starts, a scoping meeting is agreed upon with the company to discuss the scheduling and content of the assessment, and to discuss on process details.

The company makes identical submissions to Fimea, NoMA and TLV to start the joint part of the work. The agencies produce a draft joint report written in English. To allow joint work with confidential material, the company signs a waiver of confidentiality.

Before the joint report becomes public, the company has the possibility to note whether the draft joint report contains confidential data.

The aim is to finalise the FINOSE joint report in 90 days, which is shorter than the current national processes for assessment. The joint report will be complemented with local details and used to inform national decision makers. The national parts of an assessment (such as budget impact analysis) will occur at the same time as the FINOSE assessment if the national documents are submitted

simultaneously with the FINOSE submission. The aim is that the final national report is published in close relation to the FINOSE report.

5 Submission template

Either NoMA's or TLV's submission template can be used to submit material in the FINOSE collaboration. The material submitted to the FINOSE team should be the same as it would be for a national process. However, any information that is not intended to be shared between the FINOSE agencies should be excluded from the FINOSE submission and submitted separately to each agency.

For example, it is possible to submit a health economic model without national costs (e.g. national pricing) to FINOSE. This model will be assessed within FINOSE. In this case, a health economic model with national costs would be submitted separately to each agency in order to present national ICERs in the national reports.

6 Clinical Experts

For the assessment, clinical experts are recruited to inform the agencies on clinical practices. Eligibility of the clinical experts is reviewed by all participating agencies according to local requirements and procedures. An eligible clinical expert must fulfil the requirements of all participating agencies.

7 Working with confidential data in the FINOSE collaboration

In addition to publicly available material, the assessment is based on a company's submission. The company is instructed to make identical submissions to Fimea, NoMA and TLV containing the information and data that are intended to be shared among the agencies. These identical sets of information, sent by the company to Fimea, NoMA and TLV with the intention to serve as a basis for the joint report, are called the common submission.

The foundation of working with confidential data in the FINOSE collaboration is a waiver signed by the company. The waiver allows the participating agencies to discuss on the common submission covered by the waiver and to produce a joint report based on confidential data. A sample waiver is included in this document as annex 2.

The company may also have data that are intended to be used only locally in one of the agencies and not to be shared among the agencies, e.g. data related to local pricing. In this case, the company should not include these data in the common submission but submit these local data separately, in a separate submission to the agency in question, clearly indicating that these data are not intended for sharing among the agencies.

The agencies will provide the company with a draft assessment report insofar as unpublished material submitted by the company was utilised in its preparation. The company has two weeks to mark on the draft any previously unpublished information the company considers confidential or declare that the draft does not contain any confidential information. In the published version of the assessment report, confidential information will be concealed. The company's view on confidentiality is taken into consideration. Nevertheless, it should be noted that Fimea, NoMA and TLV work under national legislation of publicity, which determines the publicity of information submitted to the agencies.

To avoid delays in the process, the clinical experts recruited for the assessment may receive the draft report prior to the checking of the confidential material.

ANNEX 1. Content of the joint the assessment report

An assessment report is divided into the sections described below.

1 SCOPE OF THE ASSESSMENT

P	Population, patients
I	Intervention
C	Comparison, comparators
O	Outcomes
(T)	Time
(S)	Setting

2 DESCRIPTION OF THE INTERVENTION TO BE ASSESSED AND ITS COMPARATORS

This section answers the following questions:

- 2.1 What is the medicinal product to be assessed and for what purposes is it used?
- 2.2 How is the medicinal product to be assessed used?
- 2.3 What are the currently available treatment options?

3 CLINICAL EFFECTIVENESS AND SAFETY

This section answers the following questions:

- 3.1 What are the published clinical studies of the medicinal product being assessed?
- 3.2 What are the ongoing and unpublished clinical studies of the medicinal product being assessed?
- 3.3 What is the effect of the medicinal product being assessed on overall survival compared to its comparators?
- 3.4 What is the effect of the medicinal product being assessed on clinical endpoints compared to its comparators?
- 3.5 What is the effect of the medicinal product being assessed on the patient-reported outcomes compared to its comparators? (for example, the quality of life)
- 3.6 What is the effect of the medicinal product being assessed on surrogate outcomes compared to its comparators?
- 3.7 Is the effect of the intervention consistent between different patient groups (subgroups)?

- 3.8 How safe is the treatment compared to treatment options?
- 3.9 What type of uncertainty is potentially associated with the clinical effectiveness and safety?

4 COST-EFFECTIVENESS (only applicable parts will be jointly assessed)

The section answers the following questions:

- 4.1 What are the major determinants of expected benefits and costs associated with the medicinal product being assessed and its comparators?
- 4.2 What type of uncertainty (methodological, structural and parameter) is associated with the cost-effectiveness?
- 4.3 Is the cost-effectiveness of the intervention likely to be different between patient groups?

5 OTHER FACTORS (when necessary)

This section answers the following questions where necessary:

- 5.1 Are there any ethical, organisational, social or legal aspects specific to the intervention that should be taken into consideration in assessment?
- 5.2 Is the intervention associated with any specific patient perspectives that should be taken into consideration in assessment?

This joint report will be complemented with local data and analysis. This may include national budget impact analysis cost-effectiveness results based on national price, etc.

ANNEX 2. Waiver of confidentiality.**Waiver of Confidentiality**

On behalf of [Company] I confirm that [Company] agrees to waive the confidentiality restrictions which govern

- The Dental and Pharmaceutical Benefits Agency (TLV) under The Public Access to Information and Secrecy Act (Swedish Code of Statutes – SFS 2009:400)
- the Finnish Medicines Agency (Fimea) under the Act on the Openness of Government Activities (621/1999)
- and the Norwegian Medicines Agency (NoMA) under the Freedom of information Act of 19 May 2006 No. 16

regarding information in case number:

Agency	Case number
TLV	
Fimea	
NoMA	

This waiver is granted only with respect to disclosures

- 1) to the following organizations in relation to the joint assessments between
 - The Dental and Pharmaceutical Benefits Agency (TLV)
 - The Finnish Medicines Agency (Fimea)
 - The Norwegian Benefits Agency (NoMA)
- 2) of material submitted by [Company] for the joint assessment.

On behalf of [Company] I confirm that submissions to TLV, Fimea and NoMA for joint assessment are identical. All information intended to be used in the national process only, -will be submitted separately, indicating clearly that the information disclosed is not covered by this waiver.

Agreeing to waive confidentiality restrictions is voluntary and is not a requirement in the processing of [Company]'s application to TLV, for the rapid assessment of new hospital-only medicinal products at Fimea or a single technology assessment at NoMA, but is necessary to enable a joint discussion about case number (as specified above) between TLV, Fimea and NoMA.

The parties will treat information in an application and assessment according to applicable national or EU law, e.g. for Finland; Act on the Openness of Government Activities (621/1999), for Norway; Freedom of information Act of 19 May 2006 No. 16 relating to the right of access to documents held by public authorities and public undertakings' and for Sweden; The Public Access to Information and Secrecy Act (2009/400), that will have precedence over any other agreement.

This waiver does not apply to information obtained in the course of processing any other case either now or in the future. This waiver can be withdrawn, and such a withdrawal shall be made in writing.

Date:

Signature (clearly print name after signature)

Company

Address

Registration number