**List of documents and information required to be included in the company dossier for joint HTA through FINOSE.**

The listed documents and information below are required to be included in the dossier for the dossier to be regarded as complete.

In addition to items listed below, the person representing the company is required to have a power of attorney, informing that he/she is authorised to represent the company in this matter.

Once the dossier is complete and the submitted power of attorney has been approved the processing and assessment is initiated.

* Approval for market authorisation
* Nordic Article Number\*
* Summary of product characteristics, SmPC
* Summary of the scientific assessment of the medicinal product or protocol from the approving (regulatory) authority
* Pricing information for Denmark, Finland, Norway, and Sweden. If there is confidential pricing information that is not intended to be shared between the countries, a public list price should be used in the economic modelling. The national price information is then submitted separately to each agency and will be used for the national decision makers
* A health economic analysis of the drug's cost-effectiveness
* The studies that form the basis of the health economic analysis
* Information on the patient group(s) for which the medicine is intended
* Information on which drugs are already reimbursed within the current indication areas
* Information on the estimated number of patients in Denmark, Finland, Norway and Sweden who may be eligible for treatment
* Information on estimated average treatment cost per day
* Information on estimated average treatment time
* Information(s) about the most relevant treatment option(s) in Denmark, Finland, Norway and Sweden
* Brief description of all relevant clinical studies and their results as well as references to reported studies
* Information on whether an application has been submitted to the regulatory authority for a new or changed indication for the medicinal product
* We prefer to have the same submission as far as possible. However, if there is country specific information that the company does not wish to share with all three agencies, it is possible to submit this information separately to the concerned agency.

\*Medicines marketed in Denmark, Finland, Norway and Sweden must have a Nordic Article Number, which must be stated on the packaging. Nordic item numbers are administered by Lääketietokeskus OY in Finland.

Further information about the submission process can be found at NoMA:s web page [Submission guideline.pdf](https://www.legemiddelverket.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/submission-guidelines-nov-23.pdf)

The documentation should be submitted in the following format:

* Main document (dossier) as a Word file
* Attachments to the dossier as PDF or Word file
* Health Economic model as an Excel file
	+ Reference list as a compressed EndNote library (.enlx), alternatively .txt file.
	+ Any full-text PDF files should be included in the compressed library or sent as separate attachments.
* All published articles cited to in the dossier (and in the appendices) must be attached as a pdf.
* If "data on file" is used as documentation in the assessment, the relevant part of the documentation must be sent in a separately marked "data on file".

In all models delivered (e.g. in spreadsheets), the sources for input data in the model must also be stated in the attached spreadsheet.

All relevant variables and parameters in the model must be changeable for the FINOSE assessment team.