JNHB
Joint Nordic HTA-Bodies

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JNHB – Joint Nordic HTA-Bodies
www.jnhtabodies.org

Joint Nordic HTA-Bodies Process Guideline

Steps and Responsibilities

Version 1 June 2024

Version log

Version	Description of key changes	Valid from*
1.0	New document.	2024-06-03

*The document and its updates must be adapted by DMC, Fimea, Landspitali, NOMA and TLV in consensus to be valid.

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1. List of Abbreviations

Abbreviation	Meaning
DMC	Danish Medicines Council
Fimea	Finnish Medicines Agency
HE	Health Economics
HTA	Health Technology Assessment
HTD	Health Technology Developer
JCA	Joint Clinical Assessment
JNHB	Joint Nordic HTA bodies
NOMA	The Norwegian Medicines Agency
PICO	Population, Intervention, Comparator, Outcome
TLV	Swedish Dental and Pharmaceutical Benefits Agency

2. Aim of JNHB process guideline

The aim of this guideline is to describe the Joint Nordic HTA bodies (JNHB) process, from initial contact between the health technology developer, HTD and JNHB, up to publication of the finalized JNHB assessment report. The process guideline is a non-binding support for both HTA bodies and HTDs engaging with JNHB.

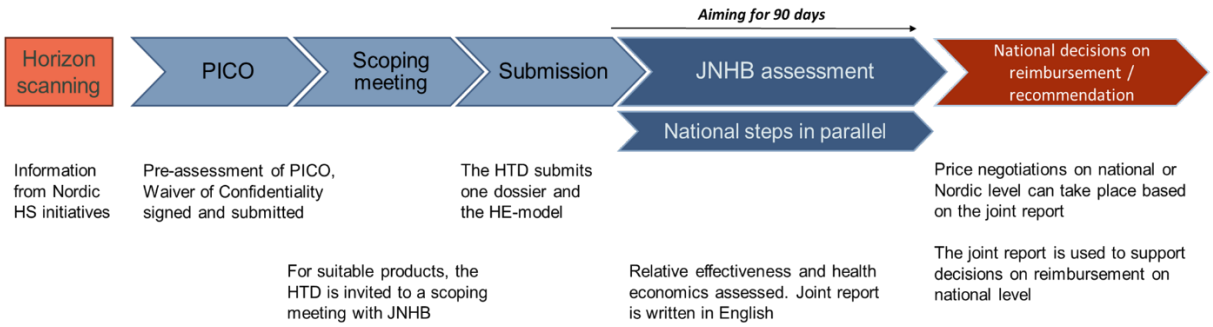
3. Initial contact between HTD and JNHB

The JNHB process can be initiated through the following pathways:

- JNHB can contact HTDs directly regarding products, identified through JNHB's horizon scanning procedure, likely to be suitable for joint assessment.
- The HTD can contact JNHB regarding products in their pipeline that they consider relevant for joint assessment.
- Suggestions for products for joint assessment can also be put forward by the Danish Medicines Council, the NT-council in Sweden and Nye Metoder Bestillerforum in Norway.

After initial contact, the JNHB team can arrange a meeting with the HTD to address general questions regarding the JNHB process, timelines and required documentation. The main steps of the JNHB process are outlined in figure 1, and details of each step are described below.

Figure 1. Outline of the main steps in the JNHB process



4. PICO proposal and pre-assessment

PICO proposal

Responsible	The HTD is responsible for submitting a PICO proposal and the signed Waiver of Confidentiality. The JNHB coordinator is responsible for contact with the HTD and for sharing information within JNHB.
Timeframe	It is suitable for the HTD to send the PICO proposal 2-3 months before dossier submission, to allow planning of the assessment, and enable the assessment within the given timeframe.

The HTD should send a signed Waiver of Confidentiality and PICO proposal by email to contact@jnhtabodies.org. It is usually suitable to send a PICO proposal a few months before the anticipated submission date. However, the timeframe is flexible and should be decided on jointly between the HTD and JNHB.

The PICO proposals should have a Nordic perspective and include information on:

- Population anticipated in each of the Nordic countries, and if relevant sub-populations.
- Intervention
- Comparator anticipated based on treatment practices in each of the Nordic countries.
- Outcomes
- Reference to relevant treatment guidelines for each of the Nordic countries.
- Reference to clinical expert opinions when relevant.
- Reflection on relevant differences between the treatment landscapes in the Nordic countries.
- Type of health economic analysis anticipated.
- Expected timeline for application.

Pre-assessment of PICO proposal

Responsible	JNHB coordinator together with assessors at individual HTA bodies. The JNHB coordinator informs the HTD about the outcome of the pre-assessment
Participants	If required, experts may be consulted for the pre-assessment.
Timeframe	The pre-assessment is conducted within approximately four weeks after receiving the PICO proposal from the HTD.

The JNHB conduct a pre-assessment of the PICO proposal to determine whether the product is suitable for a joint JNHB assessment. This includes considering any national aspects that may need to be addressed and ensuring that the current treatment practices are sufficiently

comparable in the Nordic countries. If the HTA bodies find that any clarifications are needed to proceed with the pre-assessment, the JNHB coordinator sends a request for clarification to the HTD by e-mail.

If the pre-assessment concludes that the product is suitable for a joint JNHB assessment, JNHB informs the HTD, and a scoping meeting is planned. Products prioritized for JNHB assessment are listed here www.jnhtabodies.org.

If the pre-assessment concludes that the treatment practice differs too much between the Nordic countries, or any other reason for making a joint JNHB assessment unsuitable, JNHB informs the HTD and recommends the HTD to proceed using national pathways.

5. Scoping meeting

Responsible	The JNHB coordinator sends the meeting invitation and is responsible for the meeting agenda.
Participants	HTD, JNHB team together with involved colleagues at the individual HTA bodies.
Timeframe	The scoping meeting is held approximately four weeks after the receival of the PICO proposal from the HTD.

The pre-assessment and the information shared at the scoping meeting is non-binding for all participating parties.

At the scoping meeting the following topics may be discussed/addressed:

- The PICO proposal and the products suitability for JNHB
- The submission procedure
- Dossier-contents and HE model as outlined in JNHB submission dossier template. procedure and timelines
- Expectations, for instance the assessment team will likely send questions that the HTD needs to answer in a timely manner to not delay the process.
- Contact person/coordinator for the assessment, if determined at this stage
- Questions from the HTD
- Questions from JNHB and assessors for the specific product / therapeutic area

After the scoping meeting, the HTD and JNHB agree on whether to initiate a JNHB assessment process, and if doing so, the approximate submission date of the dossier. If the submission date is changed, JNHB should be informed, to allow planning of the work and assessment timeframes.

6. Roles and responsibilities

A JNHB assessment is a collaboration between the involved HTA bodies. This means that the involved HTA bodies have agreed on the conclusions presented in the joint assessment report, regardless of whether participating as assessor, co-assessor or reviewer.

Appointment of Assessor, Co-assessor, and Reviewers

Responsible	Decision on which HTA bodies are appointment as assessor, co-assessor and reviewers is a joint decision between the HTA bodies.
Timeframe	The HTD will be informed about the roles of each HTA body prior to initiation of the assessment.

For each JNHB assessment an assessor, a co-assessor, and reviewers are appointed. The roles assessor, co-assessor and reviewer refers to the appointed HTA bodies, not to specific individuals. The appointments are influenced by available resources, expertise in a specific area or field of interest.

The assessor is responsible for coordinating the assessment. An assessment coordinator is selected from the assessor-HTA body and is the person responsible for coordinating the assessment process, ensuring that the timelines agreed on during the start-up meeting (section 8) are kept. The assessment coordinator is also responsible for ensuring that information is conveyed to everyone in the assessment team, including the reviewers and for the contact with the HTD.

The HTA-bodies acting as assessor and co-assessor are responsible for writing the assessment report. Each HTA body participating in a joint assessment appoint reviewers from their organization. The reviewers take active part in the assessment, by reading and commenting on the draft reports during the predefined review periods (section 8). The reviewers may interact with clinical experts during the assessment and give input to the assessment.

Observers

If the assessment of a specific product is outside the remit of one HTA body, or for other reasons not relevant, this HTA body can be an observer during the assessment. This for instance the case for outpatient drugs, that are not assesses by Fimea. The observer has a less active role but may read and comment the draft assessment reports on a voluntary basis.

7. Submission of dossier

Responsible	The HTD is responsible for submitting a dossier containing the documents specified in the JNHB submission dossier template.

	The HTD is responsible to adhere to the agreed submission timelines and to inform the JNHB team about deviations to the submission timelines. The JNHB contact person at TLV is responsible for sharing the submitted dossier with the assessment team.

The HTD submits their dossier with the required documents and health economic model. The information and documentation that is formally required for a JNHB submission to be considered as complete is found in the list of required documents in the JNHB submission dossier template (link to the pdf-version of JNHB submission dossier template). We recommend using the JNHB submission dossier template for the submission.

For practical reasons, JNHB submissions are sent to TLV and should be submitted according to TLVs national procedure.

- For out-patient medicinal products TLVs national procedure should be used, Apply for reimbursement - Tandvårds- och läkemedelsförmånsverket TLV.
- For hospital medicinal products the submission is sent by e-mail to registrator@tlv.se.

If the HTD wishes to submit something that should not be shared between the HTA bodies, such as confidential price information, this information should be sent to the concerned country be e-mail, as descried in the Waiver of Confidentiality.

8. Administrative check of dossier completeness and Start-up meeting

Administrative check of dossier completeness

Responsible	Each HTA body is responsible for performing a dossier completeness-check according to the JNHB list of required documents, and informing the assessment coordinator if the dossier is complete of if additional information or documentation. The assessment coordinator informs the HTD about the result of the completeness check and askes the HTD to submit any missing information or documentation.
Participants	Each HTA body decides who is responsible for the completeness check within their organisation.
Timeframe	The completeness check and communication to the HTD should be conducted within 10 working days from receiving the dossier.

Each HTA body ensures that all required documents and the health economic model, specified in the JNHB checklist for required documents are included in the submission, and that the relevant country-specific information is provided.

The administrative completeness check is conducted to ensure that the required documentation is included in the submission. However, additional information or clarifications may still be requested once the work is initiated and the submitted documentation assessed.

Start-up meeting

Responsible	The assessment coordinator invites the assessment team and other involved colleagues to a start-up meeting.
Participants	Assessment coordinator, assessment team. Other involved colleagues and/or managers at the individual HTA bodies may be invited as needed.
Timeframe	The start-up meeting should take place approximately two weeks after receiving the HTDs dossier.

The term assessment team refers to the persons from each HTA body in JNHB responsible for conducting the assessment, either by writing or reviewing. A start-up meeting is held approximately two to three weeks after receiving the HTDs dossier. The aim of the meeting is to plan the assessment and agree on roles, responsibilities, and timelines. An agreement on whether the dossier is complete should be reached at the start-up meeting.

After the Start-up meeting, the assessment coordinator informs the HTD whether submission is complete or if additional documentation is required. The assessment coordinator should specify what is missing and the time frame for the HTD to provide the missing documentation.

9. Steps in the JNHB assessment process

Timelines for the assessment

The assessment start-date is the date when the submission is agreed on by the assessment team to be complete. The main steps of the assessment process are outlined in figure 2 and the timelines agreed on at the Start-up meeting are followed throughout the procedure.

The assessment coordinator informs the HTD about the overarching timelines for the assessment, according to figure 2. Throughout the assessment, the assessment coordinator informs the HTD about assessments progress at the main assessment steps and any deviations from the initially communicated assessment timeline.

Figure 2. Main steps of a JNHB assessment.

JNHB assessment steps							
Preparation 1st draft	Review 1	Preparation 2nd draft	Review 2	Preparation final draft	Company review*	Preparation final report	Sign off and publication

*Company review includes factual error check and indication of information considered by HTD to be confidential.

Preparation of first draft

Responsible	The assessment team is responsible for preparing the draft report.
Timeframe	According to the timelines agreed on at the Start-up meeting.

In the first draft of the assessment report, the main questions of the evaluation should be identified and addressed, and the main uncertainties are and their impact on the results reported. In addition, the most relevant drivers in the HE-model and the major conclusions required for the report should be drafted. Clinical experts may be consulted during the preparation of the first draft.

The first draft should include:

- A short description of the disease.
- A description of the main clinical studies.
- An outline of the PICO.
- An outline of the relative efficacy estimate.
- A description of the health economic model submitted by the HTD.
- A summary of the main uncertainties and the main drivers of the model.
- An assessment of the overall suitability of the model, the chosen health states etc.
- A suggestion for a JNHB base case and scenario and / or sensitivity analyses.
- A suggestion on what to include in the core report.
- If national appendices are anticipated a suggestion for what they should cover.

Review 1

Responsible	The assessment coordinator distributes the first draft of the assessment report to the reviewers. The reviewers are responsible for conducting the review and to send their comments to the assessment coordinator within the given timeframe. The assessment coordinator informs the HTD that the first review period is initiated.
Timeframe	According to the timelines outlined in table 2.

The aim of the first review period is to discuss and address the main questions of the assessment. The reviewers should read the full report and consider whether they agree with the conclusions proposed. The reviewers should also identify the need for any national requirements during the first review period. Clinical experts may be consulted during the preparation of the second draft.

Preparation of second draft

Responsible	The assessment team is responsible for preparing the draft report.
Timeframe	According to the timelines outlined in table 2.

The second draft should be as close to a finalized report as possible.

The second draft should include:

- A description of all clinical data, relevant uncertainties and how they are addressed.
- The finalized JNHB base case with relevant scenario and sensitivity analysis.
- Country-specific analysis included in national appendices should be drafted.

Review 2

Responsible	The assessment coordinator is responsible to distribute the second draft of the assessment report to the reviewers. The reviewers are responsible for conducting the review and to send their comments to the assessment coordinator within the given timeframe. The assessment coordinator informs the HTD that the second review period is initiated.
Timeframe	According to the timelines outlined in table 2.

The aim of the second review period is to evaluate if the questions identified during the first review round have been adequately addressed or whether additional adjustments are required. The reviewers should read the full report and consider whether they agree with the conclusions proposed.

Preparation of final draft

Responsible	The assessment team is responsible for preparing the draft report.
Timeframe	According to the timelines outlined in table 2.

After the second review round the assessment team prepares the final draft. The assessor has the main responsibility for correcting spelling, grammar, and layout.

Factual error and confidentiality check

Responsible	The assessment coordinator is responsible for sending the final draft to the HTD. The HTD is responsible for sending their comments to the assessment coordinator within the given timeframe.
Timeframe	According to the timelines outlined in table 2. The HTD is asked to provide any comments within one week.

The final draft is shared with the HTD approximately two weeks before finalization of the report and the HTD is asked to check for any factual errors. If the HTD wishes anything to be redacted prior to publication, this should be marked in the report and a motivation to why the information is considered confidential should be included. However, the final decision on what information is redacted before publication is made by the HTA bodies, based on national legislations on publicly available documents. The HTD may submit written comments to the report, maximum two pages in length.

Finalization and publication of the joint report

Responsible	The assessment team is responsible for finalizing the report. The assessment coordinator is responsible for distributing the finalized report for formal approval at each JNHB HTA body.
Timeframe	According to the timelines outlined in table 2.

If the HTD identifies factual errors in the assessment report, these are corrected by the assessment team. When the assessment report is finalized the assessment coordinator ensures that the finalized joint report is distributed to the assessment team, reviewers and observers, for formal approval by the JNHB HTA bodies. After formal approval from the JNHB HTA bodies, the finalized report can be signed of nationally and each HTA body publishes the report according to their national procedures.

The HTD can leave a written response of maximum two pages to the report if they wish. If a written response is provided, it can be shared with decision makers in each country. The written response can be published in conjunction to the JNHB report, for those HTA bodies that have this a part of their national procedure.

Finalization of national appendices

The HTA bodies should aim to finalize the national appendices at the same time as the joint JNHB report is finalized. In some countries the national appendices will be published immediately based on public prices, while in other countries they are published when the decisions are made.

Negotiations, procurement and decisions on reimbursement/recommendation depend on country-specific arrangements that are outside the remit of the JNHB process. Information on how JNHB collaborates with the negotiation function in the Nordic Pharmaceutical Forum can be found at the JNHB webpage.

10. References

Link to JNHB webpage – www.jnhtabodies.org

- Link to Waiver of Confidentiality
- Link to submission dossier template
- Link to Q&As

Link to national HTA bodies (in alphabetical order after name in English, to match the format of this document):

- Danish Medicines Council (DMC) – mediniraadet.dk Medicinrådet - uafhængige anbefalinger til regionerne (medicinraadet.dk)
- Finnish Medicines Agency (Fimea) - fimea.fi Etusivu - Fimea.fi - Fimea
- Landspitali – Landspitali - The National University Hospital of Iceland - Landspítali
- Norwegian Medicines Agency (NOMA) – dmp.no Forside - Direktoratet for medisinske produkter (dmp.no)
- Swedish Dental and Pharmaceutical Benefits Agency (TLV) – tlv.se Tandvårds- Läkemedelförmånsverket - Tandvårds- och läkemedelsförmånsverket TLV

Link to Nordic Pharmaceutical Forum - Nordic Pharmaceutical Forum

Link to HTA regulation Regulation - 2021/2282 - EN - EUR-Lex (europa.eu)