Help section

Frequently asked questions

PROCESS

Q: How are medicinal products prioritized for JNHB assessment?

A: JNHB will prioritize hospital products that are utilized in a comparable fashion across the national healthcare systems within the Nordic countries.

Q: Can we meet the JNHB team before the assessment?

A: Yes, a meeting is held typically 2-4 months prior to the start of an assessment. The aim of the meeting is to explain the JNHB assessment process and allow the Health Technology Developer (HTD) to present their product. This meeting also serves to discuss the assessment PICO and the timelines for the process.

Q: Why is the HTD asked to sign the JNHB Waiver of Confidentiality?

A: The HTD's submission often contains confidential information, which cannot be shared within the collaboration without the HTD's permission. By signing the JNHB Waiver of Confidentiality the HTD allows the HTA bodies to share and discuss the submission during the joint assessment and to produce a joint assessment report based on both non-confidential and confidential information.

Q: When should the HTD sign the Waiver of Confidentiality?

A: The waiver should preferably be signed when the HTD submits the request for assessment. Signing the waiver does not initiate the assessment process, but it enables discussions regarding the process. Signing early enhances predictability for the HTD during the process. A signed waiver is required to initiate a joint assessment; thus, the waiver should be signed when the dossier is submitted to JNHB at the latest.

Q: What happens after the JNHB assessment?

- **A: Denmark**: Once the JNHB assessment is completed, the JNHB report, including the national appendices is shared with Amgros for price negotiations. The Danish Medicines Council base their national decision (recommendation) on both the assessment and the negotiated price.
- **Finland:** In case the assessment concerns hospital only medicinal product, it is introduced and delivered to the Council of choices in Healthcare, which gives a recommendation on use. The University hospitals are then responsible for the procurement of the product. The pharmaceutical pricing board that makes decisions on reimbursement of outpatient pharmaceuticals is not part of the JNHB collaboration.

Thus, in terms of outpatient medicines, a separate national application for reimbursement to pharmaceutical pricing board is required.

- **Iceland**: Once the JNHB assessment is completed, the JNHB report, including the national appendices is shared with the Procurement Department at Landspítali for use in price negotiations. The report is also shared with the Medicines Committee, which uses it to make recommendations to the Icelandic Medicines Agency regarding implementation decisions.

- **Norway**: Once the JNHB assessment is completed, the report, including the national appendices is shared with "Sykehusinnkjøp HF" who is responsible for the price negotiation. The price negotiation will follow usual national procedures. The report alongside with the price note will be presented for the Nye Metoder Beslutningsforum who will make the final national recommendation.

- **Sweden**: For out-patient products, TLV´s Pharmaceutical Benefits Board makes the decision on reimbursement. The board will base their decision on the JNHB assessment report. The decision process - Tandvårds- och läkemedelsförmånsverket TLV For in-patient products, the NT council uses the JNHB assessment report when issuing recommendations to the Swedish regions for how a product should be used. Recommendations - Janusinfo.se

Q: What are joint Nordic negotiations?

A: The negotiation bodies from each country are responsible for conducting price negotiations according to national procedures. For suitable products, the negotiation bodies and the HTD may choose to commence joint negotiations following the completion of the JNHB assessment. Further information about joint Nordic negotiations can be found at Collaboration with Nordic Pharmaceutical Forum

Q: When are the national appendices finalized?

A: The national appendices are prepared in parallel with the JNHB assessment. Each country aims at finalising the national appendices at the same time as the JNHB assessment. The national appendices usually include summary in national language, conversion to national currency and analysis with national model settings.

Q: Can we see the draft report before the assessment is finalized?

A: Yes, 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.

Q: How do we know how the assessment is proceeding?

A: The assessment coordinator keeps the HTD informed during the assessment process and questions can always be sent to the assessment coordinator during an on-going assessment.

Q: Who do we contact if we have a question?

A: Please use the mailbox: contact@jnhtabodies.org. During assessment you should contact the assigned assessment coordinator.

Q: How is the assessment organized?

A: 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 HTA body appointed as the assessor is responsible for coordinating the assessment. A person from the assessor HTA body will act as assessment coordinator, facilitating the communication within the assessment team and being the point of contact for the HTD. The assessor and co-assessor are responsible for conducting the assessment and writing of the assessment report. They may divide the tasks between them as they prefer, typically one HTA body takes responsibility for the clinical part and one for the health economic part.

Q: **What is the reviewer's role?**

A: The reviewers read and comment on the draft report during the predefined review periods and may give input during the assessment. All participating HTA bodies will take active part in the review process to ensure it reflects the clinical practice in their country and that the assessment fulfils the national requirements for decision making.

Q: **What is the role of an observing HTA body?**

A: 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 have an observer role during the assessment. The observer does not take active part in the assessment but can read and comment the joint report.

In Finland this is the case for outpatient drugs, since they are not assessed by Fimea. Hence, Fimea will have an observer role if JNHB assess products that are outpatient products in Finland. In Sweden TLV may have an observer role in cases where the NT council has not requested an assessment of an in-patient product being assessed through JNHB.

In cases where one HTA body / country is observer, the HTD is not required to submit a dossier that covers that country's national aspects.

Q: Can the HTD determine which country is responsible for carrying out specific parts of the assessment?

A: No. The assessment process is always a collaboration between the HTA bodies and therefore, the appointment of assessors and co-assessors is not expected to affect the outcome. The appointments are influenced by available resources, expertise in a specific area or field of interest. The HTD cannot choose to exclude a HTA body from the assessment.

Q: **How does JNHB interact with clinical experts during an assessment?**

A: All HTA bodies consult clinical experts during assessment, and this is an important part of current national assessment processes.

The clinical input is mainly in relation to (but not limited to), information of disease background, course of disease, patient population(s), current treatments practices, relevance of clinical studies, relevance of endpoints and assumptions in the health economic modelling.

In JNHB assessments, the HTA bodies have the responsibility of interacting with clinical experts to the extent needed to ensure that the assessment reflects national clinical practice and requirements.

Q: **How do you interact with patients during an assessment?**

All HTA bodies have the responsibility to obtain input from patients/patient representatives according to their national processes. Below are links and/or descriptions of how patient involvement is conducted in the respective countries.

- **A: Denmark**
  HTA: 1-2 patients/representatives are members of the expert committees that are consulted during the assessment Inddragelse af patienter i fagudvalg (medicinraadet.dk) Further information for the patient/representatives can be found here Patientrepræsentant i fagudvalg (medicinraadet.dk)
  Decision: DMC council makes recommendations. Two patient representatives are members of the council

- **Finland**
  HTA (in-patient medicine): FIMEA writes a HTA report, publishes it and opens a 2 week period for public feedback. Patient organizations are welcomed to comment. The comments received are published on FIMEA's website along with the HTA report and forwarded also to the COHERE.
  Decision (in-patient medicine): COHERE issues a recommendation on use based on FIMEA's assessment. A draft of the recommendation is published for public consultation for at least 3 weeks. There are no patient members on COHERE.

- **Iceland**

Iceland has not yet implemented a formal process for HTA. Patient organizations are not currently represented on the Medicine Committee.

- **Norway**
  HTA: DMP Brukerinnspill når vi vurderer nytte og kostnad ved nye legemidler og medisinsk utstyr – Direktoratet for medisinske produkter (dmp.no)
  Decision: Nye Metoder Brukermedvirkning – Nye metoder

- **Sweden**
  HTA (in-patient and out-patient medicines): TLV
  Decision: (out-patient medicines): TLV decides on price and remibursment Patientsamverkan - TLV
  Decison: (in-patient medicines): The NT council issues recomendations for use to the Swedish regions Patientsamverkan – Janusinfo.se

METHODS

Q: What should the submission dossier contain?

A: The submission should contain a clinical part and a cost-effectiveness part, supporting the clinical evidence and the health economic model. We have developed a dossier submission template to help you with the content of the dossier and a guidance on how to include country-specific variables.

Q: Is there a template for the dossier submission?

A: Yes, there is a JNHB submission dossier template that we recommend the HTD to use.

Q: Should we always submit a health economic model?

A: Yes, please include a model for the assessment.

Q: Should we submit a health economic model for each country?

A: No, please submit a single health economic model that has sufficient flexibility, enabling the assessment team to adjust the input parameters and variables for all countries (as outlined in the submission dossier template).

Q: Are there country specific requirements for the health economic model?

A: Yes, there are country-specific requirements. Guidance can be found in the submission dossier template.

Q: What currency is reported in a JNHB report?

A: The currency of the HTA body performing the health economic modelling will be in the JNHB report.

Q: What is the purpose of the national appendices?

A: The national appendices serve to report the results in the national currency, along with model settings pertinent to that specific country. Any specific national descriptions and calculations related to disease severity will also be included in the national appendix as well as a summary in national language.