MEMORANDUM OF UNDERSTANDING

Joint Nordic HTA-bodies

This Memorandum of Understanding is entered into by and between:

1. **DIREKTORATET FOR MEDISINSKE PRODUKTER (NOMA)**
2. **LANDSPÍTALI (LANDSPITALI- UNIVERSITY HOSPITAL OF ICELAND)**
3. **LÄÄKEALAN TURVALLISUUS- JA KEHITTÄMISKESKUS (FIMEA),**
4. **MEDICINRÅDET (DMC)**
5. **TANDVÅRDS- OCH LÄKEMEDELSFÖRMÅNSVERKET (TLV)**

individually referred to as a "Party" or collectively as the "Parties",

considering

- The Nordic Council report "Det framtida nordiska hälsosamarbetet".
- The Mandate for the Nordic Council Working Group on Exchange of Experience in the Medicinal Area.
- The European Union Pharmaceutical Strategy for Europe of 25 November 2020.
- The Regulation (EU) 2021/2282 on health technology assessment (HTAR), including the procedural rules defined in the implementing acts as referred to in the same regulation.
- The new Directive of The European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.
- The new Regulation (EU) laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.
- The Memorandum of Understanding between Fimea, NOMA and TLV from 2017, and its updated versions, including DMC from 2023 and including Landspitali from 2024.

THE PARTIES AGREE AS FOLLOWS:

1. Aims of the Collaboration

This agreement aims at exploring ways of collaborating between the Parties in the Joint Nordic HTA-bodies, (JNHB), notably on the assessment of designated pharmaceutical technologies. The collaboration endeavours to support timely and equal access to medical technologies in the Nordic countries. Through the collaboration the Parties aim at gaining additional knowledge about the products, increasing quality of the assessment/s, as well as gaining insights in best practice and developing assessment capacity. There is also a potential for increased effectiveness through the production of joint assessment reports, in a longer perspective. Also, joint assessment should have the potential to decrease the administrative burden on participating health technology developers (HTDs).

2. Scope of the Collaboration

The collaboration will primarily, but not by definition exclusively, consist of information sharing between the Parties and jointly produced health technology assessment reports on both relative effectiveness and applicable parts of a health economic analysis. The assessments may later be the basis for national decisions corresponding to each Party´s remit. The activities in the collaboration arise from the premise that collaborative research and information sharing will be used to inform, but not mandate, the content of national decisions.

A more detailed description of the methods and procedures used in joint assessments is provided in separate documents on the JNHB web site. The descriptions of methods and procedures are kept up to date to reflect current practices in the JNHB collaboration.

3. Legal Basis

The collaboration will operate according to applicable national and EU law.

4. Selection of Products

Products for the assessments will be jointly chosen by the Parties based on the products suitability for a collaborative approach. The products must have suitable comparators for the health technology assessment (HTA) to be useful for all Parties involved in the assessment. HTDs are encouraged to submit their products for a joint assessment.

5. Expected Outcomes

The intention of joint assessments is to find a common view on methodological choices and interpretation of evidence. This goal is supported by general discussions and agreement on methods used for assessments.

The final wording of the joint reports will be agreed by the Parties.

6. Roles

For each assessment, an assessor and co-assessor is appointed among the collaborating Parties. The assessor is responsible for coordinating the assessment process and is the point of contact for the HTD.

The assessor and co-assessor are responsible for writing the assessment report. Each Party participating in a joint assessment appoints reviewers within their organization, that read and comment on the draft report and may give input during the assessment. A Party may also choose not to have any role in a specific assessment, for example if a specific product is outside the Party´s remit.

7. Rights and Obligations of the Collaborating Parties

Each Party shall actively participate in the activities of the collaboration and undertake all reasonable endeavours to perform and fulfil promptly, actively and on time, all its agreed upon obligations.

Parties are to inform the other Parties of relevant communications they receive from third Parties in relation to the activities of the collaboration.

8. Stakeholder Involvement

The activities of the collaboration are to comprise stakeholder involvement to the extent that the Parties would normally involve stakeholders in their national assessment processes. Involvement of clinical experts, patients and their representatives, as well as other relevant stakeholders should be considered.

9. Acting on the Behalf of the Collaboration

Each Party shall inform the other Parties of any occasion of their representatives acting on behalf of the collaboration (e.g. when giving presentations, writing communication) for prior decision, coordination, and documentation purposes.

In cases when a Party is invited to participate in projects or other activities "on behalf of the collaboration" its role and responsibility as a "representative" would be limited to

- Informing the other Parties of such involvements
- Providing relevant information to the other Parties on the developments in the new project
- Providing information about the developments within the collaboration

Parties cannot express a view or take a position "on behalf of the collaboration" unless a clear consent of the Parties is sought and received in advance.

10. Right to Use Material from Joint Evaluations

Each Party can individually use and adapt texts and conclusions from the joint assessment reports. Joint assessment reports can be used by external Parties with the expressed consent of the collaborating Parties and the HTD whose product has been assessed.

11. Right to Disagree with the Joint Conclusions

Each Party can express a different opinion to that of the other Parties. Moreover, the Parties are not bound to follow the conclusions in the joint assessment report, or to use the joint assessment report as a basis for decision making in the respective organisations.

12. Confidentiality

The Parties shall treat information in a submission and assessment according to applicable national or EU law, e.g. for Denmark: The Public Administration Act (433 2014-04-22) and the Public Access to Information Act (145 2020-02-24), for Finland: Act on the Openness of Government Activities (621/1999); for Iceland: The Information Act No. 140/2012; 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.

For the purposes of the assessment, an HTD participating with a product can allow for openness of information between the Parties relating to their application/s by agreeing to waive the confidentiality. The confidentiality can either be waived entirely or for specific parts of the application. This should be done in writing.

13. Intellectual Property Rights

The Parties acknowledge that nothing in this Memorandum of Understanding will affect ownership of any intellectual property rights.

14. Obligations to Avoid a Conflict of Interest

The Parties will take all measures to prevent any situation where the impartial and objective implementation of the collaboration is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('conflict of interests'). They are to formally notify to the other Parties without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Parties national procedures for assessing and handling conflict of interest will be applied for assessors, clinical and patient experts, and other relevant stakeholders.

15. Processing of Personal Data by the Parties

The Parties will process personal data in compliance with applicable EU and national law on data protection (including authorisations or notification requirements). The Parties may grant their personnel access only to data that is strictly necessary for implementing, managing, and monitoring the collaboration.

16. Duration

This Memorandum of Understanding will become effective when signed by all Parties. The collaboration under this Memorandum of Understanding will continue until 30 June 2031, with a possibility for extension if agreed by the Parties. The Parties will assess the collaboration at an appropriate time with regards to the outcomes of the collaboration as well as the further developments in the collaboration on HTA in the European Union.

17. Other

A Party may at any time withdraw from the collaboration and terminate its involvement in the activities set out in this Memorandum of Understanding and Non-Disclosure Agreement. Such termination shall be done in writing to all other Parties.

This Memorandum of Understanding is not intended to create a legally binding agreement between the Parties and shall not be construed as such. It is a statement of mutual understanding and cooperation between the Parties and does not create any legal rights or obligations.

Each Party shall cover its own costs related to the collaboration.

IN WITNESS WHEREOF, the Parties hereto have caused this Memorandum of Understanding and Non-Disclosure Agreement to be executed as of the date stated below.

FOR

DIREKTORATET FOR MEDISINSKE PRODUKTER (NOMA), based in Oslo – Norway

Electronic signature below

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Trygve Ottersen, Director General

LANDSPÍTALI (LANDSPITALI- UNIVERSITY HOSPITAL OF ICELAND), based in Reykjavik – Iceland

Electronic signature below

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Runólfur Pálsson, Director

LÄÄKEALAN TURVALLISUUS- JA KEHITTÄMISKESKUS (Fimea), registered in Kuopio – Finland

Electronic signature below

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Eija Pelkonen, Director General

MEDICINRÅDET (DMC), based in Copenhagen – Denmark

Electronic signature below

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Søren Gaard, Director

TANDVÅRDS- OCH LÄKEMEDELSFÖRMÅNSVERKET (TLV), based in Stockholm – Sweden

Electronic signature below

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Magnus Thyberg, Director General

Runolfur Palsson - Runolfur@landspitali.is - 130.208.204.26
Company - Yritys - Företag - Selskap - Virksomhed: Landspitali University Hospital
7c5b9528-4964-4fd8-a947-220e67ea987d - 2026-05-29 14:41:14 UTC +03:00

Trygve Ottersen - Trygve.Ottersen@dmp.no - 212.31.109.146
Company - Yritys - Företag - Selskap - Virksomhed: Norwegian Medical Products Agency
9c47fb41-1008-407c-ac3a-533fdfdc94dc - 2026-05-29 15:22:14 UTC +03:00

Eija Pelkonen - Eija.Pelkonen@fimea.fi - 147.161.187.28
Company - Yritys - Företag - Selskap - Virksomhed: Fimea
4a86d21d-9e6b-49b3-8ed1-01315995f527 - 2026-05-29 16:10:53 UTC +03:00

Magnus Thyberg - Magnus.Thyberg@TLV.se - 212.31.109.146
Company - Yritys - Företag - Selskap - Virksomhed: TLV
d210ad07-5a38-490f-8f6a-6840fc661d3c - 2026-05-29 16:32:11 UTC +03:00

Søren Gaard - soega@medicinraadet.dk - 2.106.81.202
Company - Yritys - Företag - Selskap - Virksomhed: Medicinrådet
c4d9cbbb-30e6-44b6-835f-6c55433160d0 - 2026-06-01 09:52:59 UTC +03:00
Authority to sign - Asemavaltuutus - Ställningsfullmakt - Autoritet til å signere - Myndighed til at underskrive