April 2024

JNHB
Joint Nordic HTA-Bodies

MEMORANDUM OF UNDERSTANDING

Joint Nordic HTA-bodies

This Memorandum of Understanding is entered into by and between:

1. **DIREKTORATET FOR MEDISINSKE PRODUKTER (DMP),**
2. **LANDSPÍTALI (LANDSPITALI - THE NATIONAL 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 Pricing and Reimbursement of Pharmaceutical Products,
- The European Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States of the 17 June 2016,
- European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(lNl)),
- The European Union Pharmaceutical Strategy for Europe of 25 November 2020,
- The Regulation (EU) 2021/2282 on health technology assessment (HTAR)
- The Memorandum of Understanding between Fimea, NoMA and TLV, 2017, and its updated versions from 2020 and 2023.

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.

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.

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 2026, 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 proposed continued collaboration on HTA in the European Union post 2024.

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

Audun Hågå, Director General

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

Signature

Runólfur Pálsson, Director

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

Electronic signature below

Eija Pelkonen, Director General

Electronic signature below

Piia Vuorela, Director

MEDICINRÅDET (DMC), based in Copenhagen – Denmark

Electronic signature below

Søren Gaard, Director

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

Electronic signature below

Agneta Karlsson, Director General