# MEMORANDUM OF UNDERSTANDING

**THIS AGREEMENT** is entered into on this [date] by and between:

1. **LÄÄKEALAN TURVALLISUUS-JA KEHITTÄMISKESKUS (FIMEA),**
2. **STATENS LEGEMIDDELVERK (NOMA),**
3. **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(INI))
- The European Union Joint Action "EUnetHTA" and especially its Consortium Agreement.

**THE PARTIES AGREE AS FOLLOWS:**

## 1. AIMS OF THE COLLABORATION

This agreement aims at exploring ways of collaborating between the Parties, notably on the assessment of designated pharmaceutical technologies. The collaboration endeavours to support timely and equal access to medical technologies. 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 staff 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 regulatory burden on participating companies.

## 2. SCOPE OF THE COLLABORATION

The collaboration will primarily, but not by definition exclusively, consist of several pilot projects where the scope could be either information sharing between the authorities or a jointly produced HTA assessment report on both relative efficacy and applicable parts of a health economic analysis. The

assessment can take the form of a joint report for each product assessed that may later be the basis for national decisions corresponding to each agency'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.

As there will be no standard procedure initially, the technical details of each pilot collaboration are agreed on a case-by-case basis. Based on the experiences gained, a standard operating procedure for the collaboration may later be developed.

## 3. LEGAL BASIS

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

## 4. SELECTION OF PRODUCTS

Products for the pilot assessments will be jointly chosen by the Parties based on the products suitability for a collaborative approach. If the scope is a jointly produced assessment report, the products must have suitable comparators for the HTA assessment to be useful for all parties involved in the assessment. Also, products will be chosen to complement the EUnetHTA Joint Action, avoiding duplication or competition between the initiatives. Companies are encouraged to submit their products for a joint assessment, but their participation is not compulsory. The consent of a company to submit its product to a joint assessment should be done in writing to the coordinator and copies shared with all three parties.

## 5. EXPECTED OUTCOMES

For each pilot, a joint assessment report could be edited comprising the conclusions including a health economic assessment. Joint assessment reports are intended to be used by the parties in a way that avoids duplication of assessment work. Furthermore, the pilot team from the three Parties are to document their reflections on the collaboration in the pilot and lessons learned.

## 6. ROLES

For each pilot assessment, there will be a ***coordinator*** chosen from one of the Parties. The coordinator will be responsible for communication with the involved company and possible other external communication about the pilot. The communication should be agreed with the other parties. Each Party is responsible for communication on its pricing and reimbursement decisions.

There will also be a ***main author*** responsible for editing the assessment report, coordinating the work of the Parties and acting as project leader. The main author is responsible for the organisation of activities and management of their respective pilot, including providing information to the other Parties on the carrying out of the pilot, implementation updates and results. The main author can be the same party, or party representative, as the coordinator.

One or several of the other Parties participate as **co-authors**, responsible for separate parts or participating in a joint assessment and editing with the main author.

For each assessment, a ***reviewer*** from one or several of the Parties will be assigned. The reviewer should not be a member of the author group.

One of the Parties may also choose not to have any role in a specific assessment.

## 7. RIGHTS AND OBLIGATIONS OF COLLABORATING PARTIES

Each Party is to 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

· Promptly notify the coordinator and the main author of any significant problem and delay likely to affect the progress of the collaboration, and

· 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 is to comprise stakeholder collaboration to the extent that the Parties would normally involve stakeholders in their national assessment work. Stakeholders such as patients' and their representatives, health care provider and active clinicians should be considered.

## 9. ACTING ON BEHALF OF THE COLLABORATION

Each Party will 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 various projects or other activities "on behalf of the collaboration" its role and responsibility as "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 can not express a view and take positions on issues "on behalf of the collaboration" unless a clear consent of the Parties is sought and received in advance.

## 10. RIGHT TO USE THE 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 company 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, either motivated in writing in the joint conclusions or orally. 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 will treat information in an application and assessment according to applicable national or EU law, e.g. for Finland: Act on the Openness of Government Activities (621/1999), 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 The Public Access to Information and Secrecy Act (2009/400), that will have precedence over any other agreement.

A company participating in an assessment with a product can allow for openness of information relating to their application/s between the parties, for the purpose of the assessment 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 MoU will affect ownership of any intellectual property rights.

## 14. OBLIGATION TO AVOID A CONFLICT OF INTERESTS

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 under the collaboration 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

The collaboration will in a first stage continue until 30 June 2020. The collaboration is in this way parallel in time to the European Union Joint Action EUnetHTA JA 3. The parties will assess the collaboration in a mid-term review in January 2019 and will also, at the end of the period, assess the outcomes of the collaboration as well as the further developments in the proposed continued collaboration on HTA in the European Union post 2020.

## 17. OTHER

A Party may at any time withdraw from the collaboration and terminate its involvement in the activities set out in this MoU & NDA. Such termination shall be done in writing to all other Parties.

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 above.

FOR

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

Signature

Sinikka Rajaniemi

Sinikka Rajaniemi

Director General

Place and date

Helsinki 12.9.2017

Pertti Happonen

Director

Place and date

Kuopio 11.9.2017

STATENS LEGEMIDDELVERK, based in Oslo – Norway

Signature

Audun Hågå

Director General

Place and date

Oslo 180917

TANDVÅRDS- OCH LÄKEMEDELSFÖRMÅNSVERKET, based in Stockholm – Sweden

Signature

Sofia Wallström

Director General

Place and date

Stockholm, 2017-09-22