Statens legemiddelverk
Norwegian Medicines Agency

fimea

TLV

Joint health economic assessments in FINOSE

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INFARMED Conference 28-29th of November 2018

Agenda

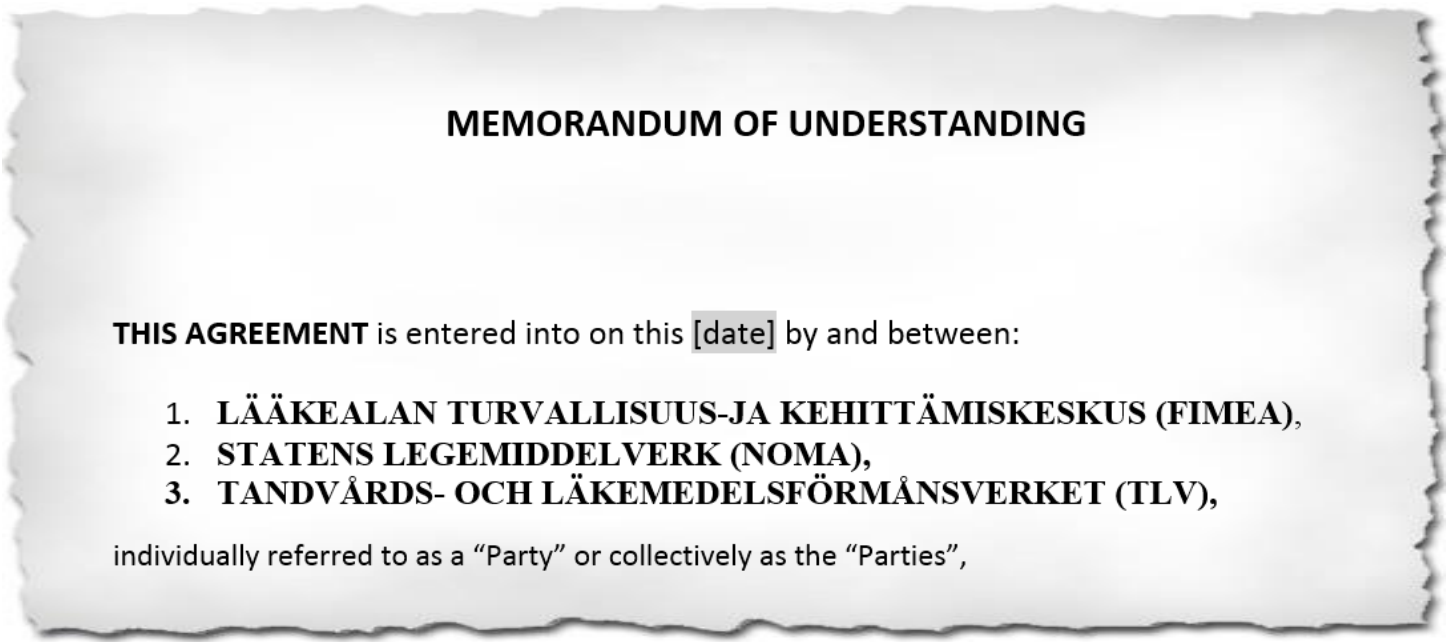
- Background
- Aim of the collaboration
- Practicalities
- Current situation
- Results of the collaboration

Background

- Bottom up initiative from FI, NO, SE authorities
- Co-operate on
  - Assessment of both relative efficacy
  - Applicable parts of a health economic analysis
- Launched in March 2018
- Pilot until 2020

FINOSE's formal starting point is a MoU

- Why us 3? – Common approach
- Not straight forward for FINOSE either!
- Solution:



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",

The FINOSE collaboration aims at

- Supporting timely and equal access to medical technologies
- Gaining additional knowledge about the products
- Increased efficiency in production of assessment reports
- Less divergence in HTA methodologies and evidence requirements
- Reduced complexity in industry submissions

→ Reduced workload and time to market

Practicalities: How does it work?

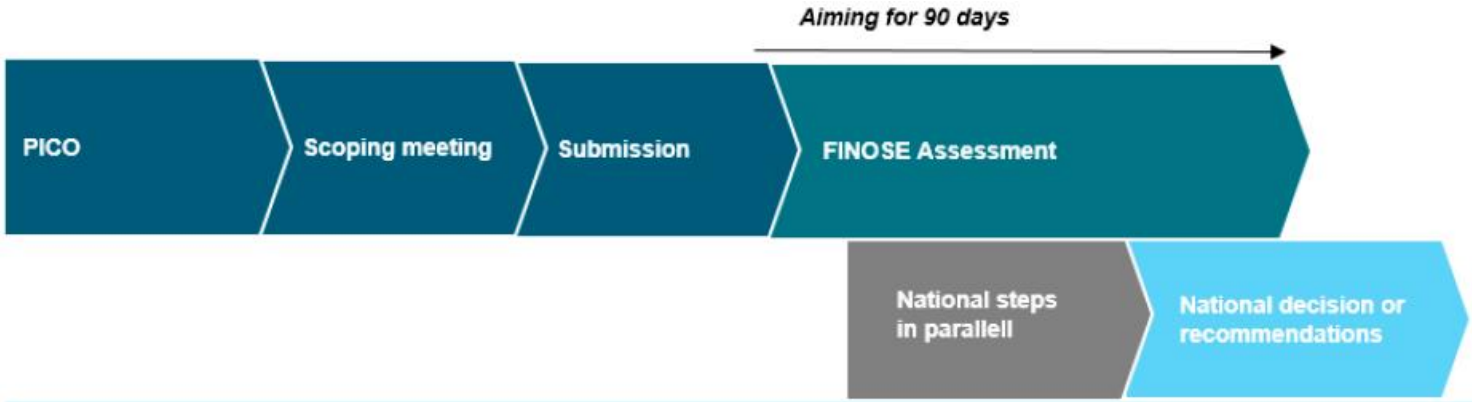
- Projects where the scope will be jointly produced health technology assessment reports on both relative efficacy and applicable parts of a health economic analysis.
- Based on the collaborative assessment, each partner will individually make a national decision, in accordance with their national regulations.
- In practice, participating in the collaboration normally means simultaneous submissions to Fimea, NoMA and TLV, and signing a waiver on data sharing.
- In case of an ongoing European level (EUnetHTA) assessment, we are interested in exploring the possibilities for building the economic evaluation on the results of the EUnetHTA assessment.

Practicalities: What do companies need to do?

If a company is interested → Contact one of the participating authorities → Arrange a meeting to see if the product is appropriate for the FINOSE → To aid evaluation fill in a PICO before the meeting

PICO	
Population	---
Intervention	---
Comparison	---
Outcomes	---
In-/outpatient drug	

Practicalities: FINOSE process



A continuous dialogue between the companies and the agencies. There will be a main contact person, a coordinator, for each assessment.

Activities

- The companies look in to their portfolio for applicable products
- A PICO summary is sent for pre-assessment to:
  - finose@tlv.se
  - finose@legemiddelverket.no
  - finose@fimea.fi
- Applicability for FINOSE is considered by the three agencies based on the PICO

- Scoping meeting with TLV, NoMA and Fimea; F2F with one agency, the other two agencies will join by phone

- Submission of one submission package for all three agencies
- Submission of waiver of confidentiality
- Submission of country-specific documents to applicable agency (pre-agreed at the Scoping meeting)

- Our aim is that the time for evaluation is shorter than in the national processes
- Agreement on: Clinical data informing the model, QALY gain, extrapolation of relative efficacy and other relevant elements of the CUA model
- A joint report is written by the agencies involved. Reports will be written in English and be based on the common elements identified in templates previously published by all involved agencies
- Work is shared between the agencies: One agency will focus on the relative efficacy, one on the health economy and one will be a peer reviewer
- Clinical experts are routinely involved by the participating agencies in the assessment of clinical documentation

Current situation

- We are reaching out to companies with new, soon to be authorized pharmaceutical products to contact us and to discuss their possible participation in the FINOSE-collaboration
- We want to contribute to a system that is beneficial both for the collaborating authorities and the pharmaceutical company
- We see a future for joint development of HTA in a rapidly progressing pharmaceutical environment
- We have dialogues with interested companies

Results of the collaboration

- Dialogues with stakeholders
  - Decision makers
  - Pharmaceutical industry
- Methodology workshops
  - →Assessment of histology independent indications
  - →Assessment of myeloma combinations
- Awaiting two FINOSE applications before Christmas

Thank you!