Joint health economic assessments in FINOSE

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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-JÄ KEHITTÄMISKESKUS (FIMEA),
2. STATENS LEGEMIDDELVERK (NOMA),
3. TANDVÅRDS- OCH LÄKEMEDELSFÖRMÄNSVERKET (TLV),

individually referred to as a “Party” or collectively as the “Parties”,

TLV
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

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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@legemiddelverktet.no
  - finose@timea.fi
- 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!