PNS24: NORDIC COLLABORATIONS ON PROCUREMENT AND HEALTH TECHNOLOGY ASSESSMENT: CONCEPTS, COMPONENTS, AND OUTLOOK

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OVERVIEW

To improve efficiency in **health technology assessments**, **Finland, Norway, and Sweden** have started a **collaboration**

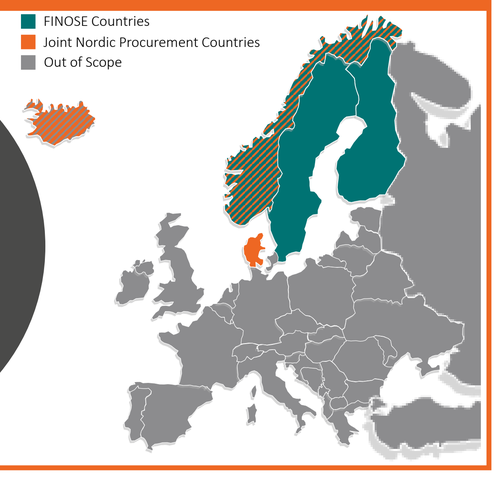
2 **joint assessments** have been conducted so far, with **divergent local follow-up**

Aiming to acheive **lower prices** and greater security of supply, **Denmark, Norway and Iceland** have started plans to **jointly procure medcines**

This involves **cross-border tenders** on price, to leverage economies of scale with suppliers

Both schemes are in the **pilot phase**, with tenders only on older, generic medicines, but expansion to novel drugs is anticipated

How the two schemes will **work together** in practice in the future is **uncertain**, though **refinements** are **required** both in **collaboration** and **local** practice



BACKGROUND & FRAMEWORKS

FINOSE: Nordic Collaboration in Health Technology Assessment

- In 2017, Sweden's Dental and Pharmaceutical Benefits Agency (TLV), the Norwegian Medicines Agency (NoMA), and the Finnish Medicines Agency (Fimea) outlined a plan to explore ways for collaborating on health technology assessment (HTA) to reduce time to patient access for medicines[1]
- The FINOSE collaboration aims to increase efficiency in HTA assessments by sharing the work between agencies and having cross-border agreement on relative effectiveness and aspects of health economics:[2]
  - Clinical data informing the model and extrapolation of relative efficacy
  - Health-related quality of life and QALY gain
  - Other relevant elements of the economic model (e.g. healthcare resource use)
- Individual agencies are still responsible for transferring the findings of the regional FINOSE assessments to nationally relevant results to inform local decision-making
- Manufacturers are required to submit a PICO summary to all three agencies and have a joint scoping meeting, which will also be used to determine the country-specific documentation required
- Manufacturers then submit a single dossier to all agencies, as well as country-specific material to the relevant agency

Joint Nordic Procurement

- The joint procurement programme aims to ensure better security of medicines supply and to optimise pricing opportunities by increasing the bargaining power with economies of scale[3]
- Core countries are Denmark and Norway, with Iceland involved in some tenders, and Sweden currently sitting as an observer
- The procurement procedure is largely aligned with current tendering processes in Denmark and Norway, with the opportunities for multiple winners and rankings, and prices remaining confidential even in the cross-border agreements
- Although price is tendered jointly in Euros, countries still have individual (though non-binding) volume quotas, and price is converted to the local currency on an annual basis for local procurement[4]
- The pilot phase is targeting older, generic drugs with a limited number of suppliers that are at risk of a de facto monopoly

Figure 1. Proposed market access pathway. Regulatory approval is required before procurement but not necessarily before HTA

COLLABORATION IN PRACTICE

- Thus far, FINOSE has published two joint assessment reports:
  - Atezolizumab for metastatic non-squamous non-small cell lung cancer[5]
  - Enzalutamide for high-risk non-metastatic castration-resistant prostate cancer[6]
- TLV has developed national reports for both drugs,[7,8] NoMA has reported on enzalutamide,[9] and Fimea on atezolizumab[10]

Drug	FINOSE	TLV	NoMA	Fimea
Atezolizumab	▪ Subgroup with liver metastases uncertain and not considered ▪ Multiple base cases presented for EGFR/ALK mutations subgroup	▪ Consistent with FINOSE for population, survival & QALYs ▪ Extended analyses with inclusion of local cost data		▪ Focussed mostly on subgroup with liver metastases due to local relevance ▪ Limitations highlighted agree with FINOSE's
Enzalutamide	▪ Concluded that OS gains are uncertain and approach used by manufacturer not valid	▪ Accepted FINOSE conclusions, suggests different approach ▪ Swedish costing shown	▪ Requested simple Markov cost analysis model as OS benefit not determined	

- With regards to joint tendering, Norway will use the Danish system for procurement[11]
  - In Denmark, hospitals and pharmacies buy from the framework
  - Given the challenges on the Norwegian frameworks, the regions in Norway will sign the contracts and the hospitals are committed to buy from the winner of the tender

IMPLICATIONS FOR MANUFACTURERS

- FINOSE process has not yet eased the submission burden for manufacturers
  - National assessment steps are still required and approaches between markets are not yet align
  - Though the overall time for processing submissions is generally thought to be reduced
- The examples of FINOSE assessments so far have shown that country-specific requirements are divergent on economic analyses, though comparable on relevant effectiveness
  - In practice, this is not substantially different for manufacturers than the current process
- There are both risks and benefits to reimbursement decisions and recommendations from different markets if strategy is unified, particularly NoMA adopting the cost per QALY framework for all submissions
- The balance of Nordic collaboration with domestic sovereignty, with separate HTA processes in Denmark and Norway, but the desire to jointly tender on expensive novel medicines in the future[11]
- Joint procurement can provide some financial stability to manufacturers with regards to exported revenues, with prices being fixed in Euros
  - Additionally, security against weaknesses in the exchange rate of local currencies is provided by the minimum price being the lowest of the conversion or an existing price set locally[4]

OUTLOOK FOR THE FUTURE

- As of October 2019, only TLV has published local reports finalising the assessment process for both assessments conducted as part of the FINOSE collaboration
  - On both published FINOSE reports, TLV has acted as an author and provided the health economists working on the appraisals
- This suggests either capacity issues in NoMA and Fimea in localising the findings, or a that the transition from regional to local HTA is not as simple
- HTA agencies need to align their appraisal frameworks to improve the efficiency of the collaborative HTA, allowing manufacturers to submit a single cross-border model/report
  - TLV appraises most drugs on a cost per QALY basis
  - NoMA aims for cost-effectiveness assessment but often cost-comparisons are conducted
  - Fimea is a relative newcomer to the HTA game publishing a limited number of reports
- FINOSE agencies are keen to explore options for outcomes-based contracting and integrate real-world evidence into appraisals
  - Extensive registry data is available in the Nordics, but cross-border data sharing poses challenges
  - Constructing sound reimbursement models and integrating these into HTA appraisals will require support across the board
- Joint Nordic Procurement aims to include novel and high cost pharmaceuticals in the future, however if both schemes are continued it is uncertain how they will align
  - Either a course change from Danish authorities into a cost-effectiveness appraisal process,
  - NoMA maintains its current track of keeping the relative effectiveness and costing assessment separate to inform local recommendations
  - Or mutation HTA recognition between the markets

References

1. Memorandum of Understanding. 2017. Available from: https://www.tlv.se/download/18.500ea4181641067957aeb14/1529322046499/memorandum_of_understanding_finose.pdf
2. FINOSE. Process for Joint Assessment. 2018. Available from: https://www.tlv.se/download/18.500ea4181641067957aeb13/1529322046472/finose_process.pdf
3. Amgros. Joint Nordic Procurement (Denmark, Norway and Iceland): Information and Dialogue Meeting. Presented September 28, 2018 at Amgros, Denmark.
4. Amgros. Joint Nordic Framework Agreement. Available from: https://sykehusinnkjop.no/joint-nordic-procurement
5. FINOSE. FINOSE Joint Assessment Report: Tecentriq (atezolizumab). 2019. Available from: https://www.tlv.se/download/18.799b0a9f16b9029968838c8/1561553375250/bes_190617_tecentriq_eng.pdf
6. FINOSE. FINOSE Joint Assessment Report: Xtandi (enzalutamide). 2019. Available from: https://www.tlv.se/download/18.44daa2b916b2b015a09a7409/1560430441257/finose_assessment_xtandi.pdf
7. TLV. Underlag för beslut i regionerna: Tecentriq (atezolizumab). 2019. Available from: https://www.tlv.se/download/18.799b0a9f16b9029968836a4/1561552998161/bes190617_tecentriq.pdf
8. TLV. Underlag för beslut om subvention: Xtandi (enzalutamide). 2019. Available from: https://www.tlv.se/download/18.3764f3f416b52b886f79440c/1560850880951/underlag_beslut_xtandi.pdf
9. NoMA. Single Technology Assessment: Enzalutadmide (Xtandi). 2019. Available from: https://legemiddelverket.no/Documents/Offentlig%20finansiering%20og%20pris/Metodevurderinger/X/Xtandi_prostatakreft_2019.pdf
10. Fimea. Atetsolitsubabi: FINOSE-raportin kansallinen versio. 2019. Available from: https://www.fimea.fi/documents/160140/5743446/Atetsolitsumabi_lyhennelma.pdf
11. Information meeting for potential suppliers – Joint Nordic Tender. 2018. Available from: http://amgros.dk/media/46326/summary-information-meeting-for-potential-suppliers-on-september-28th-2018.pdf

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