MedTech Passport to HTAs

MT44

Submission Process and Requirements of Nordic Health Technology Assessment Organisations for Medical Technologies: Results of an Online Survey

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BACKGROUND

- Health technology assessments (HTAs) of pharmaceuticals have been performed for some time. In recent years, HTA organisations have also started to assess medical technologies (MTs) to a greater extent.[1] As a result, MT companies may be required to provide different types of evidence such as health economic models that were previously not required.
- However, the assessment of MTs by HTA organisations is still developing, with no current consensus on process and methods.[2] Therefore, HTA process and methods for MTs and the types of evidence considered can vary globally and within countries.
- The 4 Nordic countries—Denmark, Finland, Norway, and Sweden—are often grouped for market access efficiency. In order to strategically plan for these submissions, the first step is to understand the different processes and requirements and their implications.

OBJECTIVE

- To identify HTA processes and requirements for MTs globally.
  - More specifically, we sought to assess the different MT processes and requirements in Nordic countries and the implications for MT companies.

METHODS

- We developed an online survey requesting information on the selection process, general submission process, and types of evidence considered part of the clinical and economic assessment of MTs.
- The survey was sent to 55 organisations worldwide in spring 2023.
- 11 HTA organisations in the Nordics were identified as potentially relevant based on our experience and a literature search.
- Table 1 presents the different organisations by country, Denmark (n = 3), Finland (n = 2), Norway (n = 3) and Sweden (n = 3).
- Quantitative and qualitative data were obtained and collated in Excel.

RESULTS

- From the 11 Nordic HTAs contacted, 5 responded (45.5% response rate) with at least 1 response from each country.
- Key differences in submission processes and requirements across organisations from different countries (Table 2, Table 3) included the following:
  - **Selection process:** Some countries use an external referral process, and some use internal referral plus company request.
  - **Organisations conducting clinical and economic SLRs:** Sweden is the only country that does not perform a SLR.
- Process and requirement variations should also be considered within countries depending on the different processes and requirements between organisations.
  - There are some important differences to consider when comparing replies from the 2 organisations in Denmark: e.g., submission of confidential data, earliest possible time of assessment, type of data accepted, type of economic analysis considered, and the perspective of an analysis. Therefore, results described by country should be interpreted with caution and seen as representing the responding organisation within that country.

CONCLUSIONS

- The selection process carries important implications for market access strategy. All organisations have internal and external selection/referral processes (apart from digital devices in Finland).
- Unlike pharmaceutical evaluation, MT evaluation cannot always be influenced by the MT company. Because assessments can be initiated by the organisations, by third-party payers, or even by competitors, MT companies need evidence-generating strategies fit for clinical and health economic evaluations ready for assessment.
- Many similarities between organisations can provide efficiencies. For instance, economic analysis requirements are similar enough that the same core model can be adapted to different organisations, similar to pharmaceutical evaluation.
- However, it is important that MT companies are aware of specific differences that will impact evidence-generation needs and submission planning.

Table 1. HTA Organisations Contacted in the Nordics

Denmark	Finland	Norway	Sweden
• **DEFACTUM** • **The Danish Health Technology Council (DHTC)** • Danish Medicines Agency (DMA)	• **Health technology assessor: Finnish Coordinating Center for Health Technology Assessment (FinCCHTA)** • Pharmaceuticals Pricing Board (PPB/HiLA)	• **Nye Metoder** • Norwegian Institute of Public Health (NIPH) • The Norwegian Medicines Agency (NoMA)	• **The Dental and Pharmaceutical Benefits Agency (TLV)** • Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) • Swedish Medical Products Agency (LV)

Note: Responding HTA organizations are presented in black. Non-responding HTA organizations are presented in grey.

Table 2. Differences in the HTA Submission Processes Between the 5 Organisations (4 Countries)

Parameter	Denmark	Finland	Norway	Sweden
Organisation	DEFACTUM and DHTC	FinCCHTA	Nye Metoder	TLV
SELECTION PROCESS				
Review request method	External referral process (e.g., by local government)[a]	Digital devices are requested directly by a MT company	Internal selection process, external referral process (e.g., by local government), and requested directly by a MT company	External referral process (e.g., by local government)
GENERAL SUBMISSION PROCESS				
Type of process	Dedicated and specifically designed for MT	General, covering all products/ medicines; a different, dedicated process for digital technology	Dedicated and specifically designed for MT	Dedicated and specifically designed for MT
Can MT companies submit evidence as part of HTA process?	Yes	Yes	Yes	Yes
Submission template for dossier?	Yes	No	Yes	No
Submission of confidential data allowed?	No[a] Yes[b]	Yes	Currently under evaluation	Yes
Earliest possible time for assessment	Before regulatory approval[a] After regulatory approval[b]	After regulatory approval	After regulatory approval	Not answered
Timeline from start to recommendation	> 9 to ≤ 12 months[a] > 6 to ≤ 9 months[b]	> 3 to ≤ 6 months	Depends on HTA type	> 3 to ≤ 6 months
Types of evidence considered	Clinical (safety and efficacy), Economic, Healthcare staff opinion			
	• Patient opinion • Research based knowledge on patient and organisational issues[a]	• For digital technologies data security and protection, usability	• Patient opinion • Ethics and legal	• Patient opinion

[a] DEFACTUM only. [b] DHTC only.

Table 3. Differences in the Clinical and Economic Evidence Considered Between the 5 HTA Organisations (4 Countries)

Parameter	Denmark	Finland	Norway	Sweden
Organisation	DEFACTUM and DHTC	FinCCHTA	Nye Metoder	TLV
CLINICAL EVIDENCE				
Type of data accepted	• RCT, RWE, Registry • Qualitative data concerning organisational and patient issues[a] • Only published/peer-reviewed registry data[b]	RCT, RWE, Registry	RCT, RWE, Registry	RCT, RWE, Registry
Does the organization conduct clinical SLRs?	Yes	Yes	Yes	No
ECONOMIC EVIDENCE				
Type of analysis considered	CUA, CEA • CBA[a] • CMA • Price comparison analysis[a] • BIA	CUA, CEA • CBA • Price comparison analysis	CUA, CEA • CMA • BIA	CUA, CEA • CBA • CMA • Price comparison analysis
Perspective of analysis	• Societal • Healthcare system[a] • Specific institution[a] • Limited societal	• Societal • Healthcare system • Individual patient	• Healthcare system	• Societal
Discount rate (effect and cost)	3.5%[b]	0%, 3%	4%	3%
Possible outcomes of the assessment	• Conclusion/recommendation about the technology that is not mandatory	• Conclusion/recommendation about the technology that is not mandatory	• Advice/information only • Conclusion/recommendation about the technology that is mandatory	• Based on the evaluation by TLV, MTP-rådet[c] may issue a national recommendation
Economical SLR is conducted and covers:	• Utility • HCRU/cost • Economic evaluations	• HCRU/cost • Economic evaluations	• Utility • HCRU/cost • Economic evaluations	• Economic SLR is not conducted

BIA = budget-impact analysis; CBA = cost-benefit analysis; CEA = cost-effectiveness analysis; CMA = cost-minimisation analysis; CUA = cost-utility analysis; HCRU = healthcare resource utilisation; N/A = not applicable; RCT = randomised controlled trial; RWE = real-world evidence; SLR = systematic literature review.

[a] DEFACTUM only.
[b] DHTC only.
[c] The Medical Technology Product Council.

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