

What Evidence Should Medical Technology Companies Expect HTA Bodies to Review?



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BACKGROUND

- Health technology assessments (HTAs) of pharmaceuticals have been performed for some time, but in recent years, HTA authorities have also started to include the assessment of medical technologies (MTs).¹
- However, the assessment of MTs by HTA organisations is still developing, with no current consensus as to process and methods.²
- Publicly available information on the type of evidence considered in HTAs of MTs—including devices (invasive and non-invasive), diagnostics, and digital health technologies—is difficult to find.
- HTA requirements for MTs can vary among authorities globally. They can also vary within an authority.
- The type of evidence considered within the HTA process and used for assessment can also vary by and within country for MTs.

OBJECTIVE

- To identify HTA processes and requirements for MTs globally.
 - More specifically, we sought to determine the types of evidence HTA bodies consider in the assessment of different types of MTs.

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. Specifically, the survey asked:
 - What types of evidence are considered part of the HTA process for MTs?
 - Clinical (e.g., safety and efficacy)
 - Economic (e.g., cost/resource use)
 - Health and care staff opinion
 - Patient opinion
 - Other (free text)
 - Can a medical technology company submit evidence as part of the HTA process (yes/no)?
 - Does your organisation have a specific evidence submission template for companies to complete (yes/no)?
- Quantitative and qualitative data were obtained and collated in Excel.

Figure 1. 12 HTA Bodies Across the World That Assess MTs Responded



Table 1. Type of Evidence Considered by HTA Organisation

Country	Organisation		Clinical Data	Economic Data	Healthcare Professional Opinion	Patient Opinion
Canada	Canadian Agency for Drugs and Technologies in Health	CADTH	✓	✓	✓	✓
Denmark	DEFACTUM	DEFACTUM	✓	✓	✓	✓
Denmark	The Danish Health Technology Council	DHTC	✓	✓	✓	✓
Finland	Health technology assessor: Finnish Coordinating Center for Health Technology Assessment	FinCCHTA	✓	✓	✓	✗
Germany	Federal Joint Committee	G-BA	✓	✗	✗	✓
Japan	National Institute of Public Health	NIPH	✓	✓	✗	✗
Norway	Nye Metoder	Nye Metoder	✓	✓	✓	✓
Spain	Agency for Health Quality and Assessment of Catalonia	AQuAS	✓	✓	✗	✗
Sweden	Dental and Pharmaceutical Benefits Agency	TLV	✓	✓	✓	✓
Tunisia	National Authority for Evaluation and Accreditation in Health	INEAS	✓	✓	✓	✓
UK	National Institute for Health and Care Excellence	NICE	✓	✓	✓	✓
US	Agency for Healthcare Research and Quality	AHRQ	✓	✗	✗	✗

✓ = Yes; ✗ = No

RESULTS

- Of the 55 HTAs contacted, 17 responded (30.9%). The completion rate was 27.3%.
- Of the 17 responders, 12 confirmed that they assessed MTs, 3 stated they did not assess MTs, and 2 declined to participate.
- These 12 represented HTA organisations from across the globe: Tunisia, Germany, the United Kingdom (UK), Canada, Spain, the United States (US), Finland, Denmark (2 HTA organisations), Sweden, Norway, and Japan (Figure 1). The organisations that responded are presented in Table 1.
- All 12 organisations review clinical efficacy and safety data for MTs.
- All organisations except for G-BA and AHRQ consider economic evidence.
- Most but not all organisations consider opinions of healthcare professionals and/or patients. For example, G-BA considers opinions of patients but not healthcare professionals, and FinCCHTA considers opinions of healthcare professionals but not patients, while NIPH considers neither.
- A few organisations will consider additional aspects such as ethics (CADTH, Nye Metoder) or environmental considerations (CADTH).
- All HTA organisations allow MT companies to submit evidence as part of the HTA process (Table 3). Most have specific templates that are required for submission.
- There is no consensus regarding inclusion of confidential data (i.e., unpublished data).

CONCLUSIONS

- All HTA organisations consider clinical evidence in the assessment of MTs. However, the vast majority also consider economic evidence, highlighting the importance to companies of considering the cost/cost-effectiveness impact of introducing their new MT into the healthcare system.
- HTA organisations are also starting to consider the environmental impact of introducing a new MT into the care pathway.

Table 2. Other Data Considered by HTA Organisation

Organisation	Country	Other Data Considered
CADTH	Canada	Ethical considerations, implementation considerations and feasibility, starting to think about environmental as well
DEFACTUM	Denmark	Research-based knowledge on patient and organisational issues
FinCCHTA	Finland	For digital technologies, data security and protection, usability
Nye Metoder	Norway	Ethics, juridical
AQuAS	Spain	Review on organisational, social, legal, ethical, environmental

Table 3. Submission Information by HTA Organisation

Organisation	Country	Can an MT company submit evidence as part of the HTA process?	Is there an HTA-specific template for evidence submission?	Can confidential data (such as unpublished study results) be considered in the HTA process for MTs?
CADTH	Canada	✓	✗	This has not come up yet for MT (but has for drugs) but would be considered
DEFACTUM	Denmark	✓	✓	✗
DHTC	Denmark	✓	✓	✓
FinCCHTA	Finland	✓	✗	✓
G-BA	Germany	✓	✓	✓
NIPH	Japan	✓	✓	✓
Nye Metoder	Norway	✓	✓	Currently under evaluation
AQuAS	Spain	✓	✓	✗
TLV	Sweden	✓	✗	✓
INEAS	Tunisia	✓	✓	No, only data in the public domain can be considered
NICE	UK	✓	✓	✓
AHRQ	US	✓	✗	✗

✓ = Yes; ✗ = No

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