MedTech Passport to HTAs

MT48

What is the HTA Process for Medical Technologies in Scotland?

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BACKGROUND

- Health technology assessments (HTAs) of pharmaceuticals are the industry standard for evidence-based value assessment. 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 regarding process and methods.[2] Therefore, the HTA process and methods for MTs, and the types of evidence considered, can vary globally and within countries.
- In addition, information on HTA processes and requirements for MTs is not always clearly available. Therefore, it can be difficult for MT companies to work out what is required.
- The website for Scotland's HTA organisation, the Scottish Health Technologies Group (SHTG), provides an evidence standards framework with some information on the process and methods for MT HTA.[3]

OBJECTIVE

- To identify HTA processes and requirements for MTs globally.
  - More specifically, we sought to understand the process and methods for MT HTAs used in Scotland by the SHTG.

METHODS

- We reviewed publicly available information from the SHTG website and supplemented findings with results from an online survey.
- We developed an online survey to request 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 HTA organisations worldwide, including SHTG in Scotland.
- Quantitative and qualitative data were obtained and collated in Excel.

RESULTS

- MTs are considered for assessment by the SHTG, and the website provides a brief overview of the process and methods used for MT HTA within the evidence standards framework. The SHTG does not consider medicines. This is the remit of the Scottish Medicines Consortium (SMC).
- Responses to the online survey revealed the following:
  - The types of MTs the SHTG can consider for HTAs include invasive and noninvasive devices, diagnostics, and digital technology such as apps or software.
  - MTs are internally selected for SHTG for review.
  - For MTs selected for HTA:
    - A general HTA process is used (e.g., the same process used for assessing pharmaceuticals).
    - Clinical efficacy and safety data, economic data, and opinions from health and care staff and patients are considered.
    - MT companies can submit evidence as part of the HTA, including confidential or unpublished data.
    - The SHTG conducts a systematic literature review to identify clinical evidence for the HTA and will consider information from randomised controlled trials, real-world data, and registry data.
    - Economic analyses that can be used in the HTA are cost-utility analysis, cost-effectiveness analysis, budget-impact analysis, cost-benefit analysis, cost-minimisation analysis, and price comparison analysis. A healthcare system perspective is used for economic analyses.
    - After regulatory approval, it usually takes the SHTG > 6 to ≤ 9 months to complete an HTA for an MT.
    - The outcome of the HTA is a recommendation or conclusion made; however, following the recommendation is not mandatory for the healthcare system. Because the SHTG does not deal with pricing negotiations for reimbursement of the technology, local and national procurement teams are involved.

Survey Responses

What types of clinical evidence are considered as part of the health technology assessment (HTA) process for medical technologies?

- ☑ **Randomised control trials (RCT)**
- ☑ **Real-world data (RWD)**
- ☑ **Registry data**

Does your organisation conduct clinical systematic literature reviews (e.g., safety and efficacy) as part of the health technology assessment (HTA) process for medical technologies?

◉ **Yes** ○ **No**

Does your organisation conduct economic systematic literature reviews (e.g., resource use) as part of the health technology assessment (HTA) process for medical technologies?

◉ **Yes** ○ **No**

What topics do the economic systematic literature review (SLR) cover?

- ☑ **Utility**
- ☑ **Health resource use/cost**
- ☑ **Economic evaluations**

Does your organisation consider economic evaluations as part of the health technology assessment (HTA) process?

◉ **Yes** ○ **No**

What kind of economic evaluations does your organisation consider?

- ☑ **Cost-utility analysis (CUA)**
- ☑ **Cost-effectiveness analysis (CEA)**
- ☑ **Budget-impact analysis**
- ☑ **Cost-benefit analysis (CBA)**
- ☑ **Cost-minimisation analysis (CMA)**
- ☑ **Price comparison analysis**

If your organisation considers cost-utility analysis, do you have a willingness to pay (WTP) threshold?

Yes

What is the willingness to pay (WTP) threshold your organisation uses?

Flexible - aligned with SMC in that a cost per quality-adjusted life-year < £30k is the threshold guide. However, the SHTG acknowledge that the MT landscape is very different and therefore do not apply a threshold to all reviews.

Perspectives for economic evaluations

Select all that apply.

- ☐ **Societal**
- ☐ **Individual patient**
- ☑ **Healthcare system**
- ☐ **Target groups of specific services**

Discount rates

3.5% (where applicable, i.e., if the SHTG receives/develops an economic model)

CONCLUSIONS

- A major challenge for MT companies is establishing whether a technology requires or is eligible for HTA in different markets. If eligible, MT companies need to understand which types of clinical, economic, and other types of evidence are considered and what the likely outcome of an HTA will be (e.g., a mandatory recommendation that healthcare services must follow or advice and information that is optional for healthcare services to use or follow).
- In Scotland, although it was clear that MTs are eligible for HTA, information about the process and methods used was not explicit on the SHTG website.
- Our survey results show that the SHTG has a flexible approach to the HTA of MTs by having a general MT HTA process and methods that considers a range of data sources and economic approaches. This suggests that the SHTG can accommodate a diverse range of MTs; however, a dedicated approach may be more suitable for HTA of MTs, as using general processes is typically set up for pharmaceutical technologies.
- Despite the internal referral process, it is not clear how much MT companies can influence the timing of HTA or the approach that the SHTG will take for MTs.
- MT companies should be prepared to contact HTA agencies directly to obtain information about the HTA process and methods to inform market access strategies and HTA submission plans.

REFERENCES

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