MedTech Passport to HTAs

HTA Requirements for Medical Technologies in Canada

MT26

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BACKGROUND

- Health technology assessments (HTA) of pharmaceuticals have been performed for some time. In recent years, HTA organizations 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 organizations is still developing, with no current consensus as to process and methods.[2] Therefore, HTA processes and methods for MT 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 Canada's HTA organization, the Canadian Agency for Drugs and Technologies in Health (CADTH), provides brief information on the process and methods used.

OBJECTIVE

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

METHODS

- We reviewed publicly available information from the CADTH 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 organizations worldwide, including CADTH in Canada, in spring 2023.
- Quantitative and qualitative data were obtained and collated in Excel.

RESULTS

- CADTH's website provides some information on the process and methods used for evaluation of MT. CADTH has a Health Technology Expert Review Panel (HTERP) for MT.
- CADTH responses to the online survey revealed the following:
  - The types of MTs that CADTH can consider for HTA include invasive and noninvasive devices, diagnostics, and digital technology, such as apps or software.
  - MTs and pharmaceutical technologies are subject to the same referral and selection process. Both are externally referred (e.g., by local government) to CADTH for review.

For MTs selected for HTA:

- A general HTA process (e.g., the same process used for assessing pharmaceuticals) is used.
- Clinical efficacy and safety data, economic data, and opinions from healthcare professionals and patients are considered.
- Ethical considerations, implementation considerations, feasibility, and environmental considerations are emerging, as well.
- CADTH conducts systematic literature reviews to identify clinical and economic data for the HTA and will consider published randomized controlled trials, real-world data, and registry data. Unpublished data can be considered, although it has not been raised within a specific MT assessment yet.
- MT companies can submit evidence as part of the HTA, but CADTH does not have a specific evidence submission template.
- Economic analyses that can be used in the HTA are cost-utility analysis (CUA), cost-effectiveness analysis, cost-benefit analysis, cost-minimization analysis, price comparison, and budget-impact analysis. A healthcare system perspective is used for economic analyses.
- It usually takes CADTH 9 to 12 months to complete an HTA for MT.
- The outcome of the HTA is advice/information only. No mandatory recommendation or conclusion is made, and CADTH does not deal with pricing negotiations for reimbursement of the technology.

CONCLUSIONS

- A major challenge for MT companies is establishing whether a technology requires or is eligible for HTA in different markets, and if so, which types of clinical, economic, and other evidence are considered and what the likely outcome of 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 Canada, information about the process and methods used was explicit on the CADTH website. Updated information was published in February 2024.
- The wider project of which this is part showed that 42% of HTA organizations that undertake HTA on MTs do not have dedicated MT-HTA processes and methods.
- Our results show that CADTH has a flexible approach to the HTA of MTs by having both general HTA processes and methods but also an expert panel (HTERP) to consult on the reviews. CADTH also considers a range of data sources and economic approaches. This suggests that CADTH's general HTA process in combination with the HTERP can assess a diverse range of MTs.
- However, it is not clear how much MT companies can influence the timing of HTA or the approach that CADTH will take for MTs.
- MT companies should be prepared to contact HTA agencies directly to obtain information about HTA processes and methods to inform market access strategies and HTA submission plans.

Survey Responses

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

- ☑ Randomized control trials (RCT)
- ☑ Real-world data (RWD)
- ☑ Registry data
- ☑ Comparative clinical studies of any design

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

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

No, a WTP threshold is not used

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

Not applicable

Perspectives for economic evaluations
Select all that apply.

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

Discount rates

Outcomes: *5%*

Costs: *5%*

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