MedTech Passport to HTAs

MT13

Digging Into the Medical Technology HTA Process in Tunisia

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BACKGROUND

- Health technology assessment (HTA) of pharmaceuticals has 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 was previously not required.
- However, the assessment of MTs by HTA organisations is still developing, with no current consensus as to process and methods.[2] Therefore, HTA processes 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 Tunisia's HTA organisation, the National Authority for Evaluation and Accreditation in Health (INEAS), provides some information on process and methods used but not in relation to MTs.

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 the INEAS in Tunisia.

METHODS

- We reviewed publicly available information from the INEAS 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 INEAS in Tunisia, in spring 2023.
- Quantitative and qualitative data were obtained and collated in Excel.

RESULTS

- The INEAS website states that MTs are considered, but information on the process and methods used focus on pharmaceutical technologies. Thus, it is unclear whether the process and methods for MTs are the same or different and whether all types of MTs can be considered.
- INEAS responses to the online survey revealed the following:
  - The types of MTs that INEAS can consider for HTA include invasive and non-invasive 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 INEAS for review.
  - For MTs selected for HTA:
    - A general HTA process (e.g., the same process used for assessing pharmaceuticals) or a dedicated HTA process specifically designed for assessing MTs can be used.
    - Clinical efficacy and safety data, economic data, and opinions from healthcare professionals and patients are considered.
    - INEAS conducts systematic literature reviews to identify clinical and economic data for the HTA and will consider published randomised controlled trials (RCT), real-world data (RWD), and registry data. Unpublished data are not considered.
    - MT companies can submit evidence as part of the HTA, and INEAS has a specific evidence submission template for this.
    - Economic analyses that can be used in the HTA are cost-utility analysis (CUA), cost-benefit analysis (CBA), cost-minimisation analysis (CMA), price comparison, and budget-impact analysis. Perspectives used for economic analyses include societal, healthcare system, individual patient, specific institution, or a target group of specific services.
    - If CUA is used, a flexible willingness-to-pay threshold is used, but INEAS does not state what the range of the threshold is.
    - It usually takes INEAS 3 to 6 months to complete an HTA for MT.
    - The outcome of the HTA is advice/information only. No mandatory recommendation or conclusion is made, and INEAS does not deal with pricing negotiations for reimbursement of the technology.

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-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?

Flexible WTP threshold is used

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

Not reported

Perspectives for economic evaluations

Select all that apply.

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

Discount rates

Outcomes: *Not reported*

Costs: *Not reported*

CONCLUSIONS

- A major challenge for MT companies is establishing whether a technology requires or is eligible for HTA in different markets, and if so, what types of clinical, economic, and other types of 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 Tunisia, although it was clear that MTs are eligible for HTA, information about the process and methods used was not explicit on the INEAS website.
- The wider project of which this is part showed that 42% of HTA organisations that undertake HTA on MTs do not have dedicated MT HTA processes and methods.
- Our results show that INEAS has a flexible approach to the HTA of MTs by having both general and dedicated MT HTA processes and methods. INEAS also considers a range of data sources and economic approaches. This suggests that INEAS can accommodate a diverse range of MTs that may not be suitable for HTA using general approaches that may be more suitable for pharmaceutical technologies.
- However, it is not clear how much MT companies can influence the timing of HTA or the approach that INEAS will take for MTs. For example, INEAS may be referred an MT before its evidence package is considered ready for HTA by the company, and it is unclear what influences the decision to use a general or dedicated HTA approach or the approach taken in economic evaluation.
- 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.

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