MedTech Passport to HTAs

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HTA Requirements for Medical Technologies in Spain

Caoimhe Leonard,[1] Preet Bhogal,[1] Ashwathi Puravankara Menon,[2] Caroline Ling,[1] Margaret Mordin[3]

[1] RTI Health Solutions, Manchester, United Kingdom; [2] RTI Health Solutions, Barcelona, Spain; [3] RTI Health Solutions, Research Triangle Park, NC, United States

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.
- The assessment of MTs by HTA organisations is still developing, with no current consensus as to processes and methods.[2] Therefore, HTA processes and methods for MTs, and the types of evidence considered, can vary among authorities globally and within authorities.
- In addition, information on HTA processes and requirements for MTs is not always clearly available. Therefore, it can be difficult for MT companies to determine what is required.
- There are multiple regional and national HTA organisations in Spain, providing brief information on the processes and methods used. However, this information can be difficult to navigate.

OBJECTIVE

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

METHODS

- We reviewed publicly available information from HTA websites in Spain 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.
- Participation in the online survey was requested in spring 2023 from 55 HTA organisations worldwide, including the *Spanish Network of Agencies for HTA and Services of the National Health Service (RedETS, Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud), the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS),* and 3 regional members of *RedETS (Andalusian Health Technology Assessment Body, Agency of Health Quality and Assessment of Catalonia [AQuAS], and Galician Agency for Health Technology Assessment [avalia-t]).*
- Quantitative and qualitative data were obtained and collated in Excel.

RESULTS

- The initial searches revealed a centralised MT HTA process through AEMPS and RedETS, followed by *Comisión de Prestaciones, Aseguramiento y Financiación* for an economic assessment and Consejo Interterritorial del Sistema Nacional de Salud as the key decision-maker for HTA recommendations.
- Limited information on the processes and methods used to review MTs was available on the Spanish HTA organisation websites.
- *AQuAS* was the only organisation to complete the online survey (see figure). Responses to the online survey revealed the following:
  - The type of MTs that *AQuAS* can consider for HTA include invasive and non-invasive devices, diagnostics, and digital technologies (e.g., apps and software).
  - MTs are externally referred (e.g., by local government) to *AQuAS* for review.
  - For MTs selected for HTA:
    - A dedicated HTA process specifically designed for MTs is used. The process differs from the process for assessing pharmaceuticals.
    - Clinical efficacy and safety data, economic data, and reviews on organisational, social, legal, ethical, and environmental evidence are considered.
    - MT companies can submit evidence as part of the HTA, and *AQuAS* has a specific evidence submission template.
    - *AQuAS* will conduct a systematic literature review to identify clinical evidence for the HTA and will consider published information from randomised controlled trials, real-world data, and registry data. Unpublished data will not be considered; only data available in the public domain is allowed.
    - Economic analyses that can be used in the HTA are cost-utility analysis, cost-effectiveness analysis, and budget-impact analysis. A healthcare system and societal perspective is used for economic analyses.
    - If cost-utility analysis is used, a willingness-to-pay threshold is not used.
    - After regulatory approval, it usually takes 9 to 12 months to complete an HTA for MT.
    - The outcome of the HTA is advice/information only. When required, a recommendation or conclusion is made; however, following the recommendation is not mandatory. AQuAS 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-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?

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: *Unknown*

Costs: *Unknown*

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 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 Spain, at a national level, the MT HTA process is centralised through *AEMPS* and *RedETS*. At the regional level, publicly available information about the processes and methods used is limited.
- Our results show that in Catalonia, *AQuAS* has a dedicated HTA process specifically designed for MTs being externally referred to *AQuAS* for review. This differs from the HTA process for pharmaceuticals.
- *AQuAS* considers a range of publically available data sources for clinical evidence that includes randomised controlled trials, real-world evidence, registry data, and various economic evidence sources.
- However, *AQuAS* will only provide advice/information on the HTA outcome, and there is no requirement to follow any recommendation. In addition, the HTA does not include a pricing negotiation for reimbursement; this is undertaken by another organisation.
- 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.

REFERENCES

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CONTACT INFORMATION

Caoimhe Leonard, MSc
Research Associate, Value and Access

RTI Health Solutions
Didsbury, United Kingdom

Phone: +44 (0) 161 447 6037
Email: cleonard@rti.org

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