Evolving HTA and potential EU HTAR ripple effects in the US - Insights from a Stakeholder Survey

HPR4

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Introduction

- The European Union (EU) Health Technology Assessment Regulation (HTAR) applies from January 2025. It encompasses mandatory joint clinical assessments (JCAs), optional joint scientific consultations that can occur either in parallel with or independently of European Medicines Agency (EMA) scientific advice, identification of emerging health technologies as well as voluntary cooperation on certain aspects of HTA for both, medicinal products and medical devices.[1] The scope of our project was medicinal products only.
- The ultimate goal of the HTAR is to contribute to the promotion of innovation, which offers the best outcomes for the EU patients and society as a whole, and it is an important tool for ensuring proper application and use of health technologies.[1]
- Member State HTA bodies will be required to give due consideration to JCA reports.[1] However, the extent of their influence beyond the EU and especially in the US remains uncertain.

Objectives

1. Understand the level of awareness of EU HTA and its implications on Payer and HTA Stakeholders in the US
2. Gauge the level of openness/willingness to leverage outputs from EU HTA for HTA and Payer related decision-making in the US
3. Identify potential challenges/limitations of using EU HTA outputs in the US

Methods

Data collection performed in June-August 2024 (pre-US election)

- Double-blinded, anonymised, online survey administered by the Secretariat of the European Access Academy, EAA[2], with a total of 12 questions, organized into 3 sections.
- Accompanied by an 'EU HTA Factsheet' so that participants who are not aware of/familiar with EU HTA will be able to respond.

Participants selection

- Four target expert groups were selected: Public payer-State, Public payer-Federal, Private payers and Academia
- Contact details of respective Payers/ HTA experts were derived from existing EAA data source and additional desk research
- A total of n=51 payers were approached: n = 9 Public payer-State 15 Public payer-Federal; 21 Private payers; 6 Academia
- Reminder e-mails were shared 2 and 4 weeks apart
- No incentivisation was provided

Results

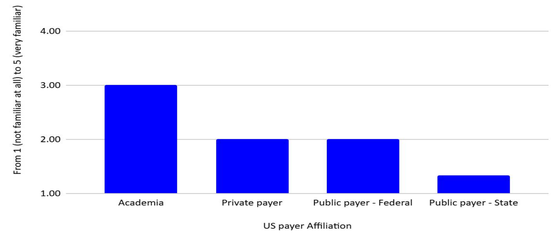
- A total of 11 responses were received, indicating a response rate of 21.6%
- n=2 responses (n=3, n=6) were received after the initial e-mail (reminder 1; reminder 2, respectively)
- Respondents were reflective of all 4 target expert groups: n=3 Public payer-State; 1 Public payer-Federal; 3 Private payers; 4 Academia
- All respondents remained anonymised.

Results (cont'd)

1. Affiliation & Level of awareness of EU HTAR

- Representatives from different US payer types have little or very basic knowledge of the EU HTA Regulation and its objectives/scope (Figure 1).

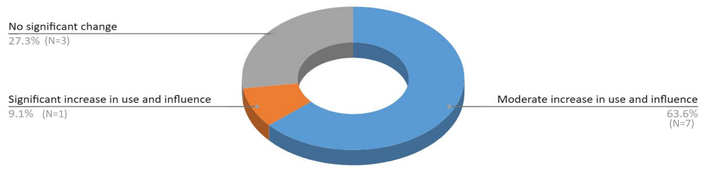
Figure 1. How familiar are you with the EU HTA Regulation and its objectives / scope? (responses by payer type)



2. Evolving role of HTA in the US healthcare system

- Despite the limited knowledge of the EU HTA Regulation, the majority of the respondents indicated either moderate or significant expected increase in the use and influence of HTA principles in the coverage decision-making over the next ten years. 27% of respondents believe that there will not be any significant change (Figure 2).

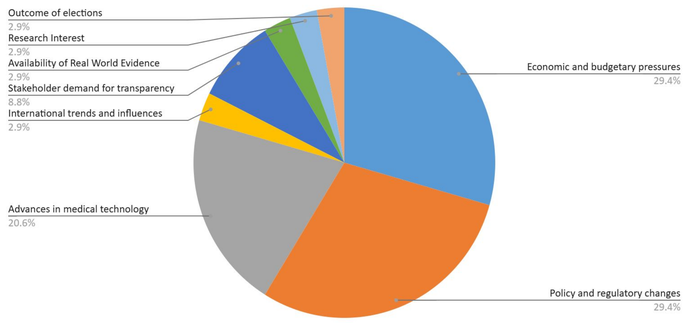
Figure 2. How do you foresee the role of HTA evolving in the US healthcare system and in your coverage decision making over the next ten years?



3. Drivers speaking towards an HTA development in the US

- Advances in medical technology, policy and regulatory changes and budget pressures were highlighted as key drivers for the evolving HTA from a multiple choice question, which, based on another question around the impact of a potential future HTA with free text response, is anticipated to enhance joint decision-making and evidence-based clinical decisions (Figure 3).

Figure 3:Which key drivers, if any, might shape the future of HTA in the US?



Results (cont'd)

4. HTA principles may play a role in informing reimbursement and coverage decisions

- While a mandatory, nationwide HTA process is not widely anticipated, HTA is expected to potentially play a role in informing reimbursement and coverage decisions.
- A cost-effectiveness approach to HTA is perceived as most likely over additional benefit assessment by respondents.

Table 1. Results of the scenario tested for the potential future HTA environment in the US, incl. role of EU-HTA in shaping this development

Likely	Mixed opinion	Unlikely to happen
■ HTA evaluations, although not binding, may be used to inform reimbursement and coverage policies of public and private payers ■ It is expected that any HTA-like solution will originate domestically, given the features of the US healthcare system	■ Enhancement and alignment of current standards and guidelines for HTA methodologies across the US	■ Establishment of a mandatory (binding), nationwide HTA process ■ The US to engage in international collaboration and harmonization efforts to align HTA practices with global standards ■ EU HTAR's affecting coverage and reimbursement in the US

- Forward looking, to the question of how the potentially evolving role of HTA in the US will impact organizations, the responses reflect a variety of perspectives:
  a. **Universities**: See HTA as an evolving and interesting field with research opportunities
  b. **Payers (State and Private)**: Some are aiming for joint decision-making to improve negotiating positions, while others anticipate an increased use of cost-effectiveness models and budget impact models. One payer notes that HTA assessment is already active within their organization and expects growth in related departments and the importance of real-world data.
  c. **Research-focused entities**: Indicate that their research in health economics will be affected by the evolving role of HTA.

Conclusions

- There will not be an immediate effect of EU HTA in the US. However, a trend towards adopting some HTA principles is expected over the next 10 years.
- The drivers speaking towards an HTA development in the US were identified as the following:
  - Advances in medical technology, policy and regulatory changes and budget pressures were highlighted for the evolving HTA
  - Growing need for harmonization, streamlined resources is anticipated to enhance joint and evidence-based decision-making, based on free te.
- Recommendations and solutions put forward from the respondents:
  - HTA principles to have some influence on reimbursement and coverage policies in the future, with cost-effectiveness more likely than additional benefit assessment as a potential HTA framework.
  - Perception of US healthcare's independence and preference for domestic solutions over external influences.
- Limitations identified are: small sample size, sample distribution might not be fully reflective of the US payer and related Academic stakeholders universe and pre-elections.

References

1. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU;
2. European Access Academy. Home Page. Available online: https://www.euaac.org/ (accessed on 19/03/'25)