HPR133

The Global Impact Of EU HTA: Insights from 13 Non-EU Countries

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Introduction

- The European Union (EU) Health Technology Assessment Regulation (HTAR) will apply 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.[1]
- 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]
- EU HTA bodies will be required to give due consideration to JCA reports.[1] However, the extent of their influence beyond the EU remains uncertain.

Objectives

1. Assess the level of awareness of the EU Health Technology Assessment Regulation (HTAR) among non-EU countries.
2. Determine the potential impact of EU HTA on decision-making within and beyond the EU
3. Identify the potential use of EU HTA outputs in non-EU contexts.
4. Gauge the interest and willingness to engage on similar cross-country or pan-region HTA collaboration frameworks.

Methods

Data collection

- Double-blinded, anonymised, online survey administered by the Secretariat of the European Access Academy[2], with a total of 18 questions, organized into 4 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

- Geographic scope: 14 countries with regulatory reliance-on EMA, representing established and nascent HTA systems*.
- Professional background: HTA experts with publicly available contact details.

** Countries with **established HTA**: countries where HTA is fully integrated and supports decision-making with processes and methods varying. Countries with established HTA systems have technical capabilities on HTA in the healthcare systems*
*Countries with **nascent HTA**: countries with an increasing focus on health technology prioritization and decision-making by healthcare systems, but with HTA yet to be fully integrated; countries which have a lower level of capabilities on HTA within the healthcare system, and therefore may refer to other countries while establishing their own processes*

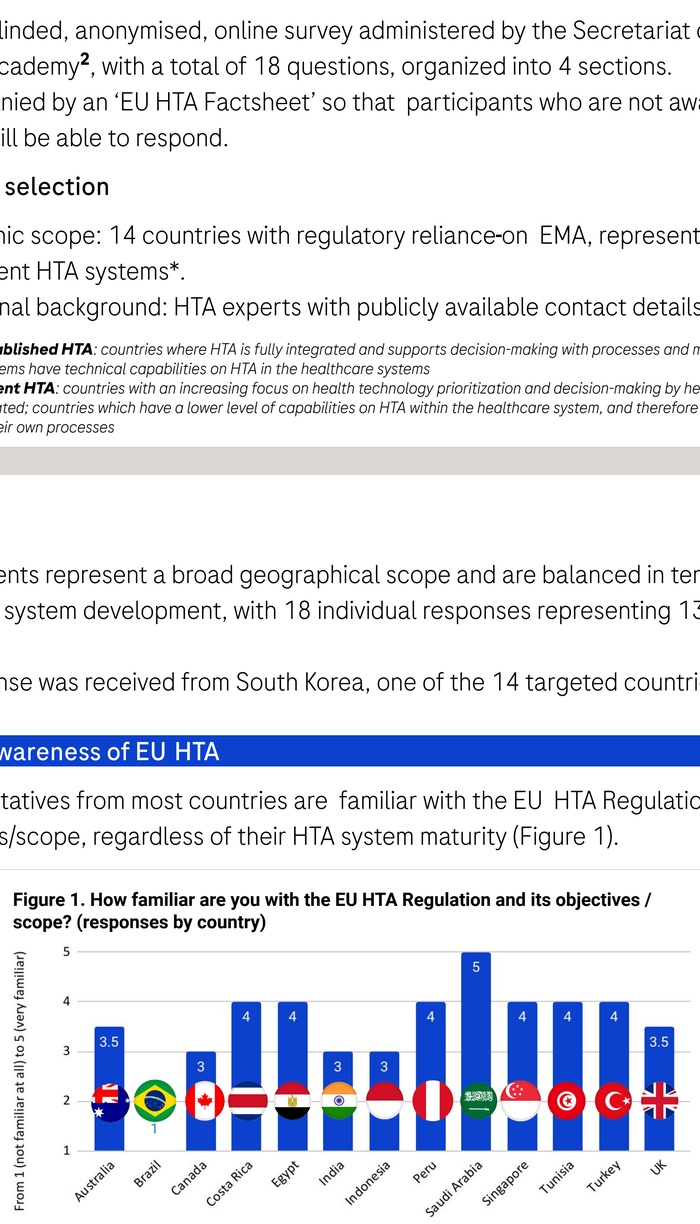
Results

- Respondents represent a broad geographical scope and are balanced in terms of the stage of their HTA system development, with 18 individual responses representing 13 countries (Figure 1).
- No response was received from South Korea, one of the 14 targeted countries.

1. Level of awareness of EU HTA

- Representatives from most countries are familiar with the EU HTA Regulation and its objectives/scope, regardless of their HTA system maturity (Figure 1).

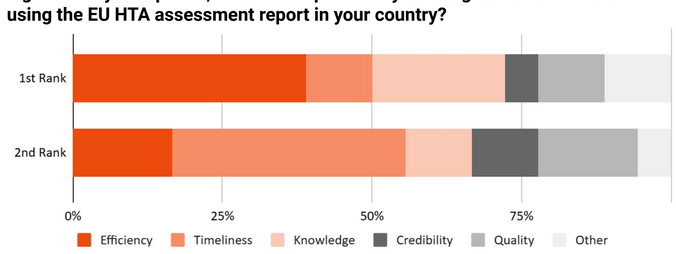
Figure 1. How familiar are you with the EU HTA Regulation and its objectives / scope? (responses by country)



2. Potential Impact of EU HTA within and beyond the EU

- Most of the respondents believe that EU HTA may positively impact patient access within the EU; however, they are more uncertain about its positive impact on patient access in their own countries.
- Efficiency, timeliness and knowledge are seen as the most important benefits of EU HTA across all respondents (Figure 2).

Figure 2. In your opinion, what would potentially be the greatest benefits of using the EU HTA assessment report in your country?



Using the EU HTA assessment report might:

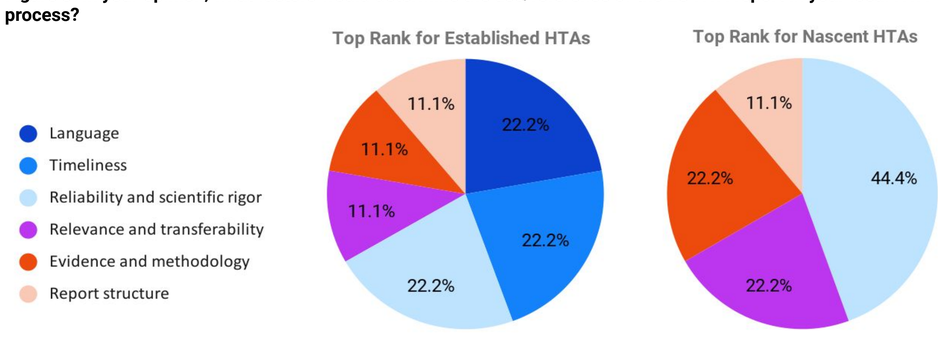
- *save time and / or resources for your HTA agency (**efficiency**)*
- *speed up decision-making and patient access (**timeliness**)*
- *provide valuable expertise or data your HTA agency might lack (**knowledge**)*
- *give your HTA agency additional credibility (**credibility**)*
- *enhance the quality of your HTA agency's work (**quality**)*

Results (cont'd)

3. Potential use of EU HTA JCA reports in non-EU countries

- *Reliability* and *scientific rigor* are the most important factors for countries to use the EU HTA reports (Figure 3).
  - **Established HTA** countries emphasize not only reliability and scientific rigor but also language and timeliness as key factors in deciding whether to use or reference the EU HTA report in their local processes.
  - **Nascent HTA countries**, with less established processes and likely later timing of HTA procedures compared to EU, prioritize scientific rigor and reliability when considering the report.

Figure 3: In your opinion, what factors would determine the use/reference of the EU HTA report in your local HTA process?



4. Interest in creating HTA collaboration frameworks, like EU HTA

- Most countries highly recognize the value of cross-country/joint HTA collaboration frameworks; however some countries, mostly those with established HTA systems, highlight some pitfalls (Table 1).

Table 1. Benefits and pitfalls of cross-country or pan-regional HTA collaboration.

	Countries with Established HTA	Countries with Nascent HTA
Benefits	■ Standardization, consistency, and efficiency ■ Enhanced capacity for conducting evaluations ■ Strengthened horizon scanning capabilities ■ Development of methods and best practices ■ Improved access to strategic information	■ Access to knowledge, expertise and data ■ Cost-sharing and efficiency ■ Harmonization of assessment methods and criteria ■ Global perspective ■ Opportunity to influence international standards and best practices in HTA
Pitfalls	■ May not improve timeliness ■ Economic evaluations may not be applicable across countries ■ Risk of repeating national assessments if clinical and economic evaluations are disconnected ■ Requires sufficient capacity from countries ■ Risk of reduced process agility	■ Variability in standards of care in low- to middle-income countries ■ Requires adequate capacity from all participating nations

- Regardless of the development stage of their HTA systems, there is a general sense that participation in a joint HTA would be at least somewhat feasible. This suggests potential opportunities for future joint HTA collaboration frameworks involving non-EU countries.
- Political resistance, differences among healthcare systems and inadequate resources are highlighted as key challenges for such collaboration models to be established outside the EU.
- Identifying emerging technologies and advancing HTA science are the most common areas of interest for a joint HTA collaboration.

Conclusions

- There is high interest in EU HTA, reflected by the response rate, with many non-EU countries closely monitoring EU HTA developments.
- EU HTA is perceived to have a positive impact on patient access to innovative technologies, particularly within the EU, and to a lesser extent in countries with established HTA systems outside the EU.
- Key benefits identified include efficiency, timeliness, and knowledge sharing, suggesting capacity constraints in countries beyond the EU.
- The reliability, scientific rigor, and methodology of EU HTA reports are critical for their adoption in non-EU countries, especially those with less developed HTA systems.
- Joint HTA collaboration frameworks outside the EU, aligned with EU HTA principles, are seen as feasible despite challenges, offering benefits like horizon scanning and HTA science development.

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 Oct 18, 2024)