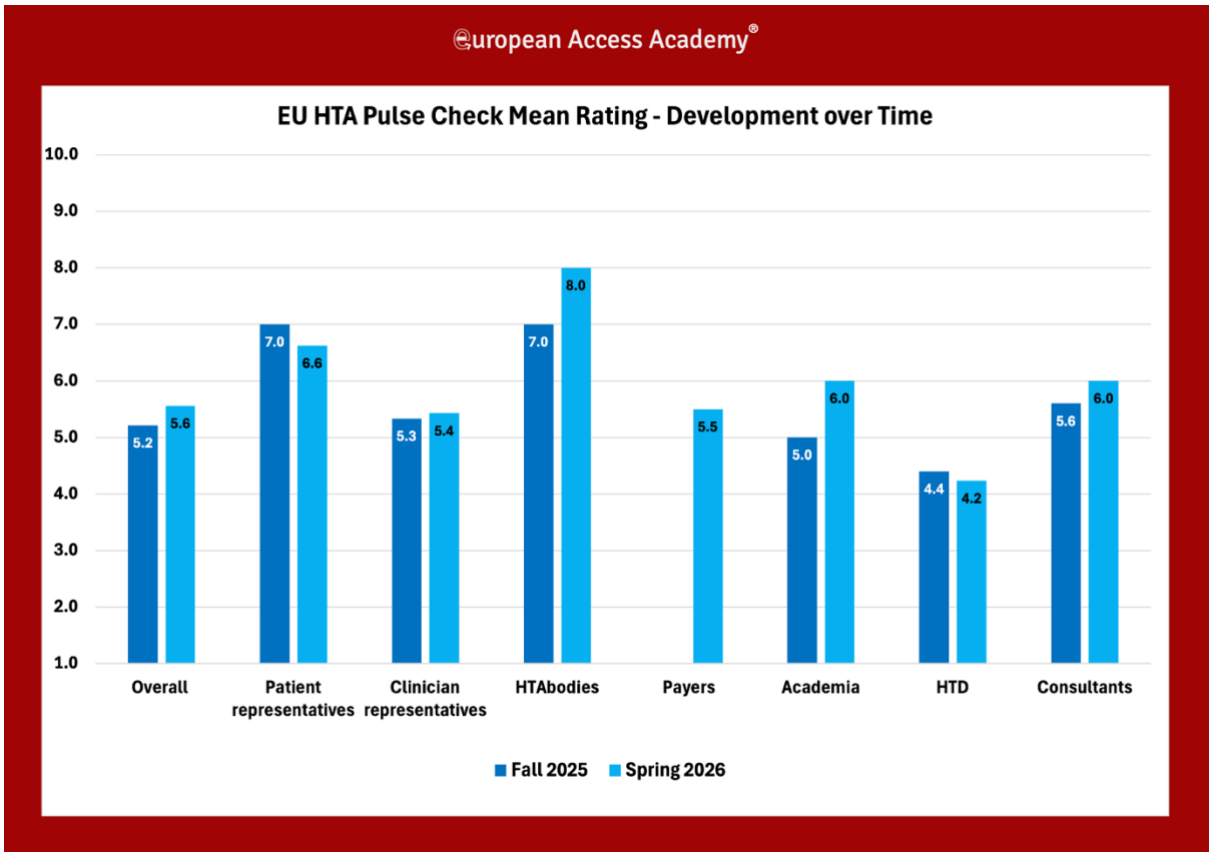
A Pulse Check on EU HTA – Developments from Fall 2025 to Spring 2026

At the European Access Academy Fall Convention at RIZIV/INAMI and Vlerick Business School in Brussels we again asked participating stakeholders about their opinion whether EU HTA is on the "Road to Success" to achieve "best outcomes for patients and society as a whole" as stipulated by Recital 3 of the Regulation.



The average rating on a scale from 1 (not at all on the road to success) to 10 (it is successful already) increased slightly from 5.2 (n=48) at the Fall Convention 2025 to 5.6 (n=52) in Spring '26, confirming that stakeholders still generally consider EU HTA to be on the right path, but that there is opportunity for improvement. Interestingly, the score by HTAbody and academic representatives increased by 1.0 points since Fall '25, while there are only small changes of 0.2-0.4 points difference for other stakeholders. HTDs still consider EU HTA the least on the road to success with a mean rating of 4.2 (compared to 4.4 in Fall). While no payers responded to the initial survey, now the rating for this stakeholder group (5.5) is in line with the overall mean rating.

We received extensive and very thoughtful comments further illustrating the evaluation of the implementation of the EU HTA Regulation – a selection:

We are on the road to success. Improvements are needed
Still a lot of things to be improved, but a lot of things are starting to take place now so we see an improvement. Some countries (east europe) need a little support to start the conversation about it
The ambition is there, the obstacles are high.
Not fit for purpose

JSC Not really in Place; Good: DGSante very supportive
Number of PICO required still an issue
Dossiers are too extensive in order to include all requested data. There is a need to be more pragmatic, as a decions can be made with a 50 page document.
Too early to say but we know already that JSC are in insufficient numbers to make a change and increase quality of the data produced
Too much burden for too little direct benefits.
A bureaucratic exercise with focus on data gathering rather than what actually is needed for real world decision making and to make Europe stroner
No meaningful engagement with HTDs throughout including PICO development which is a critical success factor. Also unclear how JCA output will really be used to drive national decision making and reduce time to access.
We need to ensure that there is pragmatism in the application of this Regulation to ensure it has the desired positive access impact. Currently, the amalgamation of all Member States needs and elevation of these needs to the European level risks creating substantial burden to the developers, with little to no value at the national level. The process needs to ensure that it remains proportional and adopts a streamlined scope with meaningful dialogue with the developers to ensure efficiency and relevance at the national level.
The ideas behind the regulation are good, there needs to be more opportunities for engagement with the HTDs. There is significant planning and resource investment needed for the HTDs, so early engagement (JSCs for all products and a scoping meeting) would help ensure the appropriate evidence is included, and is particularly necessary for small companies. Also, smaller companies may be more insulated from MFN if their manufacturing is in the US, so this engagement is critical to help EU remain a competitive and desirable region for launch.
We need more alignment and guidances , clear templates
Too early to tell but I feel member states will be reluctant at first to adopt decisions from JCAs and will, hopefully not for long, actually replicate work
It is going into the right direction but it is not quite there yet. The positive thing is that it is continuously learning from its experience and updating its practices as they go but it could learn more from other similar processes as well, it does not need to start from zero. For example, it could use EMA's experience with patient and clinician recruitment and engagement. As for providing a JCA that would be used by MS without additional evidence and being the basis for similar added benefit conclusions, this would depend on a lower number of representative PICOs but also on the quality of evidence submitted. Previous analyses (Vreman RA, van Hoof D, Nachtnebel A, et al. The Beneluxa Initiative domain task force health technology assessment: a comparison of member countries' past health technology assessments. International Journal of Technology Assessment in Health Care. 2023;39(1):e44. doi:10.1017/S0266462323000338) show that high quality evidence produce very similar HTA decisions, while uncertainties leave more room for interpretation.

The next data point for the Pulse Check will be generated at the EAA Fall Convention on November 19/20 2026 at INFARMED in Lisbon – we're excited see how perceptions on EU HTA will evolve!