

Implementing Acts: Time to Speed Up!

In December 2021 the European Parliament and the Council of the European Union adopted the European Regulation on Health Technology Assessment, EU HTAR ([EU]2021/2282), which will be applied from January 12, 2025. Article 34 of the EU HTAR provides details on the 'Preparation of Implementing Acts' (IA). Milestones for the IA development are specified in an Implementation Rolling Plan including the adoption of the first IA in Q4 2023 (Joint Clinical Assessment), followed in Q1 2024 by the IA on Conflict of Interest and the IA on Cooperation with the European Medicines Agency. The last IA is to be adopted by the end of Q4, 2024. While the Implementation Rolling Plan suggests that three of the IA are currently in planning, so far, neither has any IA been adopted nor has any IA draft version been circulated for public consultation or any update been shared publicly.

The European Access Academy (EAA) is entirely aware of critical capacity constraints on the side of both, the Commission as well as the EU HTA Coordination group, nevertheless, the timely adoption of the IA is perceived to be a fundamental milestone in the final year of the EU HTA preparatory phase. Considerable efforts are required on the side of all involved stakeholders to ensure readiness for EU HTA. Patient Associations, Medical Societies, Health Technology Developers, Academic Centers, etc. all require sufficient lead time to prepare for their specific contribution into the EU HTA procedures. Hence, timely availability of the IA is critical to guide related workplans.

The EAA faculty is supportive and appreciates all preparatory efforts related to the EU HTAR by the Member States and the Commission but is concerned about the apparent delay of the IA. Furthermore, sufficient time will be required for thorough public consultation of the draft IA in order to gather and implement meaningful feedback – in line with the Commission's 'Better Regulation Guidelines' (SWD[2021] 305 final). Strong societal input of all involved stakeholders will be crucial to ensure that '*HTA is able to contribute to the promotion of innovation, which offers the best outcomes for patients and society as a whole*', as stipulated in the regulation. As a member of the HTA Stakeholder Network and within the remit of this Network, the EAA is committed to support the successful implementation of the EU HTAR and to provide any support possible to advance respective plannings and preparation. Application of the EU HTAR from January 12th, 2025 is the ultimate goal of all stakeholders in the process – so, it's '**Time to Speed Up**'.

The Faculty of the European Access Academy
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