

Two new implementing acts adopted as part of the HTA regulation

25 October 2024

The Heads of Health Technology Assessment Agencies Group (HAG) warmly welcomes the adoption by the European Commission, in October 2024, of two critical implementing regulations concerning the rules for cooperation with the European Medicines Agency (EMA) for joint productions under the Health Technology Assessment (HTA) Regulation, as well as the management of conflicts of interest. These regulations, developed in close collaboration with the Health Technology Assessment Committee, comprising representatives from EU Member States, represent a significant milestone in the full implementation of EU Regulation 2021/2282 on HTA.

The implementing regulation on conflict of interest will play a pivotal role in achieving the overarching objective of ensuring the highest standards of transparency, impartiality, and independence. By doing so, it will foster public trust and reinforce confidence in the outcomes of joint scientific consultation and joint clinical assessment, which are essential for the credibility of the European HTA system.

The implementing regulation on cooperation with EMA is equally crucial, as it will enable effective and seamless communication between the HTA secretariat and the EMA for the planning and forecasting of joint scientific consultations and joint clinical assessments. This regulation will allow the exchange of necessary information to establish the HTA coordination group's annual work program, ensuring that joint work under the HTA Regulation is conducted efficiently and in full respect of confidentiality and data protection requirements.

Together, these two implementing regulations, along with the implementing regulation on joint clinical assessments for medicinal products and the extensive guidance documents published by the HTA Coordination Group during the preparatory phase, lay the foundation for the official launch of joint productions in 2025. These developments represent tangible steps toward the operationalization of a unified European HTA system.

The HAG reaffirms its steadfast commitment to the implementation of the HTA Regulation and will continue to actively engage in this critical process. Our shared vision is to establish a European HTA system that embodies the values of solidarity, inclusiveness, transparency, and impartiality, ultimately benefiting patients and healthcare systems across the EU.