



Consultation response: Health technology assessment – laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medicinal products for human use at Union level

The BioMed Alliance, representing 35 European medical and research societies, welcomes the proposed implementing regulation outlining the procedures for joint scientific consultations on medicinal products for human use at the Union level, as part of Regulation (EU) 2021/2282.

Healthcare professionals and researchers agree that HTA should have a strong scientific basis, and we would like to offer the following remarks and suggestions for consideration:

- **Experts' selection:** Evidence-based, high-quality HTA requires the participation of knowledgeable experts from diverse medical fields and stakeholder organizations. European medical societies can play a crucial role in helping to identify and recruit these experts. Furthermore, referring to "knowledgeable experts," it is important to clarify that expertise alone is not sufficient. EU HTA should prioritise the involvement of the **best available experts**—those with specific, high-level expertise most relevant to the issue at hand—rather than relying on individuals who are generally knowledgeable. This distinction ensures that the HTA process benefits from the most relevant and impactful contributions.
- Medical societies depend on the timely sharing of information and **clear and appropriate timelines for providing feedback**, taking into account the busy schedules of clinical experts.
- **Conflict of Interest:** we emphasise that conflict of interest must be appropriately declared and managed, but that we take a balanced approach taking into account the realities of a sector where high-level experts are often engaged in multiple initiatives involving a wide range of stakeholders, including institutions and industry¹.

¹ See our recent statement on this topic here: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13751-Health-technology-assessment-procedural-rules-for-assessing-and-managing-conflicts-of-interest/F3470374_en