Biomedical Alliance in Europe

24 July 2024

Consultation response: Health technology assessment – cooperation with the European Medicines Agency

The BioMed Alliance welcomes the proposed implementing regulation detailing procedural rules for the cooperation of the Member State Coordination Group on Health Technology Assessment (HTA) and the Commission with the European Medicines Agency.

We support the provisions in the implementing regulation that contribute to an efficient and timely exchange of information, and that enhance alignment between the European Medicines Agency (EMA), the HTA coordination group and the European Commission. Cooperation and coordination with the EMA is essential for the assessment of medicines, but also for medical devices including, but not limited to, through alignment with the Expert Panels on medical devices. The pursuit of synergies could help speed up HTA processes, improve their quality and reduce duplication.

Evidence-based and high quality HTA depends on the involvement of knowledgeable experts from different medical fields and stakeholder organisations. We therefore support the exchange of information related to the identification of patients, clinicians and other individual experts to be involved in Joint Scientific Consultations and Joint Scientific Assessments. European medical societies can be important partners in helping to identify and recruit experts, but they rely on the timely sharing of information and appropriate timelines for providing feedback.

We also reiterate that a balanced conflict of interest policy is necessary to ensure that the required expertise for the clinical assessment of medicines, medical devices and IVDs can be found. The HTA Coordination Group, European Commission and European Medicines Agency must agree on a common policy for assessing and managing conflicts of interest, that is pragmatic, transparent and takes a needs-based approach[1]. We welcome the explicit statement in recital 6 that experts' involvement in EMA evaluations does not preclude their involvement in joint scientific assessments or joint clinical assessments for HTA purposes or vice versa, as long as transparency is ensured.

[1] For more information see our recent consultation response on appropriate conflict of interest policies 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