Biomedical Alliance in Europe

April 2024

BioMed Alliance consultation reply

Implementing Regulation on HTA - joint clinical assessments of medicinal products

The BioMed Alliance, representing 34 European Medical and Research Societies, welcomes the draft implementing regulation on Health Technology Assessment (HTA). Medical societies, and the researchers and clinicians that they represent, agree that the involvement of stakeholders including clinicians is key to achieve a high scientific quality of joint clinical assessment reports. In order to facilitate the process and ensure the right experts are able to provide a meaningful contribution, certain aspects need to be taken into account.

Stakeholder involvement should be standard practice

We welcome the mentioning of stakeholder and clinical expert involvement throughout the proposal, but recommend that this involvement happens in a systematic and consistent way. The wording in several parts of the implementing regulation should be strengthened by changing the word 'may' to 'shall' when referring to the consultation of stakeholders and experts, for instance in article 6.2, article 8, article 9.1, article 10.1 article 14.1, article 15.1.

Medical societies should be seen as key partners in identifying clinical experts

Medical societies represent large numbers of healthcare professionals in different medical fields, and they can be important partners helping to identify clinical experts with relevant and specific expertise. In article 6.2, medical societies should be mentioned as one of the groups to be consulted by the HTA secretariat to compile the list of experts, since not all (European) medical societies are represented in the HTA stakeholder network.

Provide sufficient time to stakeholders and clinical experts to share their input

Timelines for stakeholder and expert involvement should take into account time constraints that stakeholders and clinical experts may have, due to their varying responsibilities in e.g. clinical care, education or research.

Appropriate declaration of interest policies are key, to verify the different factors that could influence the views of experts, but they should not be too rigid.

Conflicts of interest cannot all be eliminated but the risk of bias can be managed, and we therefore believe the text of recital 14 should be amended. We suggest that the words 'free from conflict of interest' are changed into 'while limiting conflict of interest'.

It has been argued that some conflicts of interest in medicine are difficult to recognise and unavoidable and that all sources of possible bias cannot be abolished by disclosure. These may include personal academic interests as well as formal links with industry, so 'competing interests' may be a more helpful and inclusive indicator of potential bias than 'conflicts of interest'. Many scientists and clinicians with the expertise necessary to provide an authoritative

review of a new medicine or medical device, will have worked with manufacturers or may have experience of evaluating competing products. Too rigid application of conflict of interest policies, particularly for some very new or very niche fields (including for orphan diseases or certain paediatric disciplines) could make it very difficult to find the right experts. For more information, see e.g. our reply to a JRC consultation providing recommendations on appropriate conflict of interest policies: https://www.biomedeurope.org/images/pdf/news/Biomed_Alliance_Response_to_JRC_Consultation_10_Sep_2018.pdf .