



Feedback from ESMO on the draft Implementing Act on the Management of Conflicts of Interest

The [European Society for Medical Oncology \(ESMO\)](#), representing more than 35,000 oncology professionals from over 172 countries, welcomes the draft Implementing Act on the management of conflicts of interest in the joint work on Health Technology Assessment (HTA). The HTA Regulation, and the joint processes for assessing new health technologies that will be established under this legislation, hold enormous potential to boost access to new cancer treatments. In anticipation of the entry into application of the HTA Regulation in January 2025, ESMO - as a Society representing oncology professionals and cancer specialists - is committed to make this a reality and contribute to the implementation of the legislation.

A robust management of conflicts of interest within the new HTA framework is important for facilitating the conduct of Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs) for cancer treatments. ESMO considers the draft put forward by the European Commission to be a robust first text, overall striking a right balance between the need for both transparency and expert engagement, and enabling involved healthcare professionals and clinical experts to carry out their work in an impartial and independent manner.

With a view on further improving the draft Implementing Act, we would like to highlight the following points:

- Extreme care should be taken in both the design and implementation of the rules on conflicts of interest to ensure that they do not hinder access to novel cancer treatments for Europe's millions - the annual number of new cancers in Europe is projected to increase to 5.33 million by 2040 ([IARC Cancer Tomorrow](#)) - of patients with cancer;
- Healthcare professionals and clinical experts involved in JCAs and JSCs should be relieved from their obligation to update their declaration of interests (DOI) following the full completion of the joint work in which they have participated;
- As to the format of the DOI set out in Article 3.1, we believe that individual experts involved in JCAs and JSCs should have no obligation to submit their curriculum vitae (CV) in the Europass template. Experts should be provided with the option to submit their own comprehensive CV specifying clearly the person's current or past position relevant for the involvement in the JCA or JSC. Ideally this is to be done through an online form enabling experts to digitally submit the essential information from their CV that is required to be eligible for involvement in the joint processes;
- The process of defining the specific interests and roles that may constitute a conflict of interest, and which could as such limit the involvement of experts in JCAs and JSCs, is volatile by nature and may be subject to rapid changes. The rules and formats set out in the Implementing Act and the accompanying Annexes



should as such be reviewed on an annual basis and modified promptly if the results of these reviews indicate that this is necessary;

- The applicable measures to be taken when a conflict or potential conflict of interest has been determined should take into account the availability of suitable experts needed to conduct the JCA or JSC in an appropriate and robust manner. Here, the specificities of the rare cancers field may be taken into consideration as there tend to be significantly fewer relevant experts available with the requisite practical knowledge. Unjustified exclusion of experts from JCAs and JSCs, as well as low-quality assessments and delays to the joint HTA processes, should be avoided when measures are taken to address conflicts of interest;
- Under Article 10.3, a more precise and clear definition of “gross negligence” should be provided, with clear examples being given as to what would constitute such actions;
- In cases where individual experts are involved in more than one activity, to limit unnecessary administrative burden, experts should be able to access their previously submitted documentation and confirm that it is still up-to-date, rather than re-submitting the entire DOI. This should only be possible if no changes in the declared interests have occurred;
- Where relevant, in cases where they were not the direct recipient, experts should be provided with the option to indicate in a clear manner whether financial interests were paid to their affiliated institution as part of the DOI - bearing in mind the substantial difficulties in capturing and overviewing institutional interests in an adequate and correct manner;
- To reduce bureaucracy, it should be made possible for individual experts to sign their DOI electronically when submitting their documentation online.

ESMO stands ready to collaborate with the EU institutions and all stakeholders on the development of the Implementing Act and offers to mobilise its expert groups and network of medical oncologists to support a successful implementation of the HTA Regulation.