Feedback from ESMO on the draft Implementing Act on Cooperation with the European Medicines Agency under the HTA Regulation

Representing more than 35,000 oncology professionals from over 172 countries, the European Society for Medical Oncology (ESMO) welcomes the draft Implementing Act setting out the procedural rules for cooperation, in the form of exchange of information, with the European Medicines Agency (EMA) in the context of the joint work under the European Union's (EU) Health Technology Assessment (HTA) Regulation.

If implemented in an intelligent manner with the involvement of the healthcare professional community, the Regulation holds enormous potential to improve HTA across the EU and enhance patient access to novel cancer treatments. Close cooperation between the Member State Coordination Group on HTA (HTACG) and the EMA on Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs) is a prerequisite for making this a reality.

ESMO welcomes the consultation on the draft Implementing Act and, with a view on further improving the proposed text, would like to highlight the following:

- The rules on the exchange of information should be aimed at maximising the annual number of JCAs and JSCs for cancer treatments, whilst avoiding delays in the assessments and the implementation of HTAs, especially in situations of unmet need. This while keeping up with the rapid and volatile pace of innovation in the oncology field and facilitating sufficient assessments for all novel cancer treatments;

- The provisions concerning the information exchange related to the planning and forecast of JCAs and JSCs set out in Article 2 should allow for a continuous flow of information, rather than only providing the information once each year;

- Given that engagement with individual experts - including healthcare professionals - is a key condition for conducting the assessments in an appropriate and robust manner, the Implementing Act should allow for the involvement of sufficient qualified experts in both JCAs and JSCs for cancer treatments, especially concerning treatments for rare cancers for which there tend to be significantly fewer relevant experts available.

ESMO stands ready to collaborate with the EU institutions and the HTACG 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.