Feedback from ESMO on the draft Implementing Act on Joint Scientific Consultations on Medicinal Products

The European Society for Medical Oncology (ESMO), representing more than 40,000 oncology professionals from over 177 countries, welcomes the draft Implementing Act laying down the procedural rules for Joint Scientific Consultations (JSCs) on medicinal products.

The Health Technology Assessment (HTA) Regulation, by enabling the conduct of robust clinical assessments for use in HTA, holds enormous potential to improve access to novel cancer treatments benefitting patients. JSCs, by facilitating exchange of information with health technology developers on their development plans, and providing early guidance on the required evidence and data, are to fulfil an essential role in the successful delivery of these assessments.

We consider the draft Implementing Act to be a solid first text that clearly specifies the processes, timelines and key steps to be taken throughout JSCs.

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

- When setting the planned number of JSCs (Article 2), sufficient efforts should be made to maximise the amount of JSCs that are to be conducted to the greatest possible extent. This while keeping up with the rapid and volatile pace of innovation in the oncology field and ultimately improving predictability for all novel cancer treatments. What is more, it will be important not only to have sufficient JSCs but also follow-up advices after a first JSC given the fast progress of innovation in oncology as this makes Joint Clinical Assessments (JCAs) more predictable;

- The Coordination Group should be able to issue additional request periods (Article 2) for the *current* year when this can help achieve the aims of the HTA Regulation;

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- Enabling a robust involvement of oncologists and cancer specialists in the conduct of JSCs for cancer therapies is a key requisite for their successful delivery. Oncology societies, such as ESMO, should as such be consulted by the HTA secretariat when lists of relevant individual experts are compiled that are to be involved in JSCs (Article 5, Paragraph 2). Furthermore, any provisions governing conflicts of interest should take into account the availability of suitable experts needed to conduct JSCs in an appropriate and robust manner.

ESMO stands ready to collaborate with the EU institutions, the Member State Coordination Group on HTA (HTACG), the HTA secretariat, and all stakeholders on the development of the Implementing Act for JSCs on medicinal products and offers to mobilise its expert groups and network of medical oncologists to support a successful implementation of the HTA Regulation.

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