ISPOR
The professional society for health economics and outcomes research

Improving healthcare decisions

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Dear the European Commission:

ISPOR – the professional society for health economics and outcomes research - is pleased to respond on behalf of its membership to your consultation entitled "Implementing Regulation on joint scientific consultations on medicinal products for human use at Union level." We appreciate the opportunity to comment on these draft guidelines.

ISPOR is a scientific and educational society with many of its members engaged in evaluating health technologies, including pharmaceuticals, medical devices, and other interventions. We have a large membership living and working in 100 countries globally; nearly 20% (1 in 5) of our membership resides within the European Union. Members across our organization come from a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government, and health technology assessment bodies. The research and educational offerings presented at our conferences, summits, webinars, and in our journals are relevant to many of the issues and questions raised in this request for information.

The response to this consultation was led by the ISPOR Science and Health Policy Initiatives Office based on conversations we have had with our membership.

ISPOR would be happy to answer any questions about our response, to serve as a partner, or to participate in any follow-up consultations on the relevant program items mentioned within the report.

Sincerely,

Robert Abbott
CEO & Executive Director
ISPOR

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Implementing Regulation on joint scientific consultations on medicinal products for human use at Union level.

We appreciate the European Commission's significant efforts on this guidance, which clarifies the joint scientific consultation (JSC) process. We acknowledge the importance of this guidance to support implementation of Regulation (EU) 2021/2282.

ISPOR supports the draft guidance as is written and have a few comments for consideration.

We have concerns about a potential interpretation of non-committal nature of the word "should" in section 9 on pages 2-3. While recognizing certain legal contexts for the choice of words for the EU regulatory documents addressing healthcare settings and processes, it would be beneficial to ensure a stronger commitment to engaging and involving stakeholders, especially patient representatives, in the EU Health Technology Assessment (HTA) regulation processes.

The document also mentions that priority will be given to stakeholders who span multiple countries, however as we mentioned in our response to the Joint Clinical Assessment procedural document, there is potential to miss smaller, local patient organizations who are just as critical to the patient engagement process as larger organizations (especially for rare diseases). These organizations tend to be disease-specific or local to a country and often have authentic stories of lived patient experience that larger well-known organizations may be missing. There is also a concern that consulting with only the most visible patient organizations will create a divide in the patient engagement world and smaller, local organizations will lose their importance and value.

Finally, we propose that there be an opportunity for further consultations with expert, global, learned societies, including ISPOR, to provide additional insights best practices worldwide and to facilitate connections with similar efforts globally. We welcome the coordination group to continue to participate in our European and global events such as the HTA Roundtables and ISPOR conferences. Given the broad reach of ISPOR's membership, we are eager to assist in bringing together HTA experts and other stakeholders to foster knowledge exchange and collaboration across the global HTA community.

We acknowledge ISPOR staff Laura Pizzi, Mitch Higashi, Julia Chamova, Clarissa Cooblall, and Kelly Lenahan for their help responding to this consultation.