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Rob Abbott
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Lawrenceville, NJ, USA

2 April 2024

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 “Health technology assessment - joint clinical assessments of medicinal products.” 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 110 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 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 Policy Outlook Committee of our most senior advisory body, the Health Science Policy Council. We solicited comments from our Institutional Council, Patient Council, HTA Council, and several European HTA experts. The attached document provides a summary based on their comments. We hope they prove useful.

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

Health technology assessment - joint clinical assessments of medicinal products

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

The guidance focuses on the timelines and processes for JCA. As a scientific society, ISPOR's interests are primarily in the *methods* of JCA (which are separately detailed by the Coordination Group). However, ISPOR is commenting on the process herein since it will impact the quality and amount of evidence available to support assessments.

Accordingly, we appreciate the proposed JCA timeline in the guidance document and recognize that *all* the participants are held to tight turnaround times. We noted that the amount of time that health technology developers (HTDs) have to respond with evidence is particularly short (90 days in most cases but 60 days for certain products). At this stage, the HTD will likely need to conduct a systematic literature review and indirect comparison analysis; elements of these may be anticipated based on regulatory evidence, that is not certain.

We also suggest that HTDs be included in the scoping process because it will allow them to anticipate the PICO's used in the assessment which, in turn, will facilitate compilation of the evidence.

Further, regarding transparency of the scoping exercise, we suggest publishing what each member state proposed since evidence requested by them but not covered by the JCA will likely be requested for decisions at the national level.

ISPOR also has comments relating to Article 6, *Selection of patients, clinical experts, and other relevant experts*. While the HTA secretariat will compile a list of relevant patients and clinical experts, 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). We recognize that the HTA Stakeholder Network has a number of patient organizations involved, however there are many smaller patient organizations who are not represented. 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 fear 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. We suggest that the process include an open call for comments from patient organizations and/or specialized advisory panels of patient representatives that are activated to advise on JCAs for specific disease areas. We also suggest that a standardized template is used to ensure consistency in collecting information from patient groups.

In Article 9, *Assessment scope proposal*, the following sentence says: "At any time during the preparation of the assessment scope proposal, the assessor and/or co-assessor **may** seek, via the HTA secretariat, input on the assessment scope from the patients, clinical experts and/or other relevant experts selected in accordance with Article 6." We suggest changing "may" to "must" because otherwise it seems involvement of these stakeholders is optional.

We acknowledge ISPOR members Lou Garrison, James Ryan, Adrian Griffin, Amanda Cole, and Derick Mitchell for their assistance in assembling these comments, as well as ISPOR staff Laura Pizzi and Kelly Lenahan.