

EUnetHTA WP4 Joint Production

Comments should be submitted no later than March 4th, 2020

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Comment from <i>Insert your name and organisation</i>	Page number <i>Insert 'general' if your comment relates to the whole document</i>	Line/ section number	Comment <i>Please insert each new comment in a new row.</i>
Standing Committee of European Doctors (CPME)	2 and 3	67 and 70	<p>CPME suggests replacing „could provide” with “provide” in two places where discussing the goals for HCP involvement.</p> <p>1. Goals for HCP involvement in REA within JA3 <i>The Task Group agreed that input from HCP could provides important knowledge about the disease (...).</i> <i>In addition, HCP involvement could provides valuable inputs...</i></p>
CPME	3	87-88	<p>In the same paragraph, in the list below, CPME suggests adding one more bullet point at the end to include: “gather information and expertise on the ethical implications”:</p> <ul style="list-style-type: none"> • gather information on clinically relevant outcomes including: <ul style="list-style-type: none"> - possible neglected outcomes

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			<p>- gain further information on importance of outcomes from a health professional's point of view - information and expertise on the ethical implications"</p> <p>We believe HCPs can be the only ones in the process of REA without conflicts of interest.</p>
CPME	3	93-94	<p>CPME suggests not introducing a new term "external healthcare professionals" in the definition of HCP. If the purpose is to exclude specific group of professionals from the specific HTA assessment, CPME suggest the following wording:</p> <p>„2. Definition of HCP (...) Healthcare professionals working for agencies participating in an HTA assessment or at a manufacturer shall not be considered external healthcare professional cannot be part of the HTA assessment"</p>
CPME	3	120-121	<p>Regarding the possible methods for HCP involvement, at the end of the second paragraph, it is stated that an extensive knowledge about HTA or evidence-based medicine is not mandatory for HCP to be involved in REA. Considering the following possibility to provide an HCP with an information flyer developed for patients if needed, CPME is hesitant whether such flyer can serve as substantial information for an HCP on "clinical questions" and whether an HCP in need of such flyer can effectively contribute to REA.</p>
CPME	4	141	<p>CPME suggest adding a one sentence at the end of the paragraph on methods for HCP involvement: "The Q&A approach does not preclude HCP from making spontaneous remarks"</p> <p>"Choice of method for HCP involvement: The choice of method depends on the timelines of the assessment. For assessments with short timelines, the Q&A approach is the preferred method. The Q&A approach does not preclude HCP from making spontaneous remarks"</p>

Please add extra rows as needed.



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CPME	4	188	<p>CPME would like to comment on the text included in Table 1, Participants/(E-)meetings: <i>"HCP will have access to information publicly available, no additional confidential data will be shared."</i></p> <p>CPME believes it should be clearly stated that HCPs need complete information to be able to provide a comprehensive assessment. The current wording could also allow discarding the views of HCPs by arguing that they were not well enough informed while participating in REA.</p> <p>As HCPs should not have any conflict of interest (as would be stated by them in the forms) and are bound by confidentiality rules, CPME is of the opinion that there is no reason to not grant HCPs full information if they are involved in the assessment. CPME suggests suppressing the current restriction in information sharing with HCPs, currently expressed in the whole column under "Participants".</p>

Please add extra rows as needed.