

The authors:  
Krzysztof Landa  
Jacek Siwiec

The co-authors:  
Magdalena Wladysiuk-Blicharz  
Przemyslaw Rys  
Robert Plisko

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## **Mutual Peer Review System (MPRS) in HTA**

### **The initial propositions for quality assurance in economic evaluations**

It is proposed that CEESTAHC will be **managing** mutual peer review with explicit understanding that CEESTAHC takes no ownership of, or responsibility for, the single or consensual views<sup>1</sup> expressed by the reviewers (below also called the “experts”).

It is believed that PRS:

- ◆ would initiate quality assurance in HTA – that would be of great help, especially for the countries introducing HTA to reimbursement policy such as new member states of EU (economic evaluations with biased outcomes and low quality hurt trust of politicians and society to the general idea; that is a serious obstacle to wide use of HTA in decision making);
- ◆ could become a milestone in standardization and harmonization in the field of HTA - obviously variations would be taken into consideration but reaching consensus by reviewers and their close cooperation in groups or committees (being randomly changed) would accelerate this process;
- ◆ could substantially strengthen international cooperation in HTA and the Society itself;
- ◆ could help courts around the world as the reviewers listed on the CEESTAHC website could be selected for court referees – Transparency Directive in EU requires all member states to introduce court jurisdiction over reimbursement decisions; it is probable that courts will require not only national experts but also abroad experts to judge on validity of economic evaluations attached to reimbursement applications; the courts could direct requests to CEESTAHC for help in finding experts;
- ◆ could become one of the major factors in regulation of HTA or economic evaluations “market”.

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<sup>1</sup> Consensual view of 3 reviewers / experts or single view of an expert developed in PRS and presented in writing will be called further on an “**opinion**”.

No.	Question	Answer
a.	What can be reviewed?	Any efficacy & safety analysis of medical technology (reviews, systematic reviews etc.), any cost or economic analysis on hard data or based on modeling.
b.	<b>Who can apply for the peer review?</b>	<b>Only institutional members of CEESTAHC.</b>
c.	<b>Is there a fee to be paid to CEESTAHC?</b>	<b>No, there is not – apart from the fact that an applicant should pay an annual institutional membership fee to CEESTAHC.</b>
d.	What are requirements from applicant?	<p>An applicant will submit 4 full copies of the analysis in English with fulfilled application form directed to CEESTAHC Board. The applicant is responsible for collecting and submission of:</p> <ul style="list-style-type: none"> <li>• full text copies of all primary clinical trials and secondary studies included in the analysis; if requested by the reviewers also full text copies of trials excluded from the analysis and at least a detailed list of trials excluded;</li> <li>• full search strategy or at least key words used in search for clinical trials as well as all investigated data bases with a date of the last search;</li> <li>• primary cost data used for calculations and all assumptions clearly stated;</li> <li>• models in electronic version with open formulas for calculations;</li> <li>• any other data or publications used in the analysis if requested by the reviewers.</li> </ul> <p>If the above cannot be fulfilled by the applicant the reviewers will base their opinions on available material listing the limitations of the given opinions in this respect.</p> <p>Operational language is English.</p>
e.	<b>When does review start and how long does it take?</b>	<p><b>The review begins when the acceptance by the CEESTAHC Board is made, the 3 reviewers randomly selected (they become ad hoc Basic Review Group [RBG]) and the CEESTAHC institutional membership status of the applicant is confirmed.</b></p> <p><b>Any review takes up to 6 weeks.</b></p>

f.	What do 3 single opinions cover?	<p>In mutual peer review single and signed opinions are being given to the applicant.</p> <p>Each opinion covers general and some specific views on validity, complexity, completeness of analysis and its publication in full text. The reviewers are transparently signed under each single opinion. (Their names are not known to the applicant before the review has been ended).</p> <p>The opinions will not be structured, no template will be available at the launch of PRS and no standard procedures for review will be developed by CEESTAHC before the first 90 single opinions are collected.</p>
g.	Who is responsible for the given opinions?	<p>Only and each reviewer is responsible for the given opinion himself.</p>
h.	How can the single opinions be used by the applicant?	<p>The applicant obtains copy rights to the three single opinions given by the 3 reviewers of basic review group. Therefore respecting authorship personal rights of the reviewers the applicant can publish the opinion in any legible way.</p> <p>There may not be CEESTAHC logo or any sentence in the opinion which could lead to a conclusion that CEESTAHC is responsible to any extent for any of given single opinions. There may be stated that CEESTAHC organizes reviewers' work and runs the "mutual PRS" with the link to the specific website of CEESTAHC.</p>
i.	Who can become a reviewer?	<p><b>Any expert delegated by the institutional CEESTAHC member fulfilling the transparent requirements developed by CEESTAHC and the one who is agreed by the CEESTAHC Board of Directors.</b></p> <p><b>Anyone who wants to become a mutual reviewer will need to agree to work on the reviews for free. In return for 3 reviews done by the mutual reviewer (or each of 3 reviews done by 2 or 3 reviewers from the given institution) each institutional CEESTAHC member will get the right for one free of charge application to mutual peer review. In other words for 3 single opinions by the reviewer (or reviewers) from an institutional CEESTAHC member, this institution will be granted the right to have one analysis reviewed free of charge in mutual PRS.</b></p>

j.	Can one appeal against the single opinions given?	<p>Yes. In the first line the applicant applies for the consensual opinion of the 3 reviewers in the Basic Review Group (BRG). This consensual opinion is superior to all the single opinions given. In case the consensual opinion is reached by BRG, the single opinions given formerly may not be published publicly (the applicant agrees on such regulation beforehand).</p> <p>If the applicant is still not satisfied. One can apply to the Appellation Review Committee (ARC) selected and agreed by the CEESTAHC Board. ARC can be asked for its consensual opinion which is a separate one but should not be treated as supreme to the consensual opinion of BRG.</p> <p>Members of ARC are responsible for the opinions given by them and CEESTAHC takes no responsibility for any part or whole of such opinions. Any potential further appellation could be obtained on a legal way.</p>
k.	Who can appeal?	Anyone - any institution, any organization or any person; the applicants to BRG, authors or users of the analysis, producers or the ones who use technologies which the analysis refers to.
l.	What is the appellation process, appellation fee and how long does the appellation take?	<ul style="list-style-type: none"> <li>• The applicant to BRG may submit the fulfilled appellation application form to the CEESTAHC Board. The applicant appellation is free of charge in this case. The consensual opinion of BRG is given up to 4 weeks from the date of appellation form submission.</li> <li>• Any other may submit the fulfilled appellation application form to the CEESTAHC Board as well. The fee of 12.000 euros is charged in this case. Timing and appellation process is decided and organized by the CEESTAHC Board specifically to the case but takes not more than 6 months.</li> </ul>
m.	Are the members of ARC paid for their work and how?	ARCs are organized by CEESTAHC specifically for each possible case. ARC members may be paid for their work and expenses by CEESTAHC on specific to the case basis.
n.	How to apply for review?	The fulfilled application form with the full text copies of analysis and reference materials should be submitted to the CEESTAHC Board of Directors.
o.	Who makes a decision and accepts analysis for review?	The Peer Review Committee of CEESTAHC Board of Directors does.
p.	Who manages review?	The CEESTAHC Secretariat does. BRG and ARC members manage their work individually on their own.
q.	Who selects 3 reviewers and how?	<b>The Peer Review Committee of CEESTAHC Board of Directors selects 3 BRC members randomly from the list of available reviewers from the official list of CEESTAHC mutual PRS reviewers. The selection is secret until the final single opinions are ready.</b>

r.	Will the work of reviewers be assessed, by whom and how? Can a reviewer lose the “CEESTAHC license”?	The Peer Review Committee of CEESTAHC Board of Directors will assess single and consensual opinions of BRGs as well as ARCs members’ performance at least once a year. In case any reviewer is not available for a relatively long time, does not work satisfactory in subjective opinion of the Peer Review Committee or his institution lost CEESTAHC membership, such individual’s name is cancelled from the list of mutual reviewers.
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**LIST OF EXPERTS ON THE WEBSITE - IF REQUIRED**

As mutual reviewers lists agreed by CEESTAHC to participate in MPRS will be transparently placed on the CEESTAHC website when and if at least 3 institutions express their interest in MPRS and join. Anyone is free to contact any of these experts asking for their private opinions. CEESTAHC does not interfere such activities, takes no responsibility of the opinions and charges no fees in this respect.