HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Guidance on the appointment of assessors and co-assessors for Joint Clinical Assessment (JCA) and Joint Scientific Consultation (JSC)

v1.0

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Adopted on 28 November 2024 by the HTACG pursuant to Article 3(7), point (d), of Regulation (EU) 2021/2282 on Health Technology Assessment

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Abbreviation	Definition
EU	European Union
HTA	Health Technology Assessment
HTACG	HTA Coordination Group
HTAR	Health Technology Assessment Regulation (Regulation (EU) 2021/2282)
IVD	*In vitro* diagnostic medical device
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
MD	Medical device
MP	Medicinal product
MS	Member States
RoP	Rules of Procedure
SG	Subgroup

1 Scope and objective

The Member State Coordination Group on Health Technology Assessment (HTA Coordination Group, HTACG) adopted this guidance on the appointment of assessors and co-assessors for joint clinical assessment (JCA) and joint scientific consultation (JSC), including on the scientific expertise required, pursuant to Art. 3(7g)) of the Health Technology Assessment Regulation (Regulation (EU) 2021/2282) ('the HTAR').

The present guidance:

- defines the procedure for the appointment of assessor and co-assessor;
- sets minimum requirements for the appointment of the assessor and co-assessor for JCAs and JSCs for medicinal products (MPs) and medical devices (MDs) and *in vitro* diagnostic medical devices (IVD).

2 Context

The HTACG designates the subgroup for JCA (SG JCA) and the subgroup for JSC (SG JSC) to conduct the joint work on behalf of the HTACG. Activities and tasks are defined in the HTAR, the Implementing Regulations and the Rules of procedure (RoP).

According to Article 9(2) of the RoP: "*the members of the subgroup shall appoint in the subgroup on a permanent basis one representative and one alternate for each member organisation. The appointed representatives and alternates shall have the appropriate HTA expertise."*

According to Article 9(3) of the RoP: "*for the purposes of taking up or assisting in the ongoing or future tasks of assessor or co-assessor for JCA, or for reviewing the draft JCA reports, the members of the SG JCA may appoint in the SG JCA ad hoc representatives who have the appropriate HTA expertise. For the purposes of taking up or assisting in the ongoing or future tasks of assessor or co-assessor for JSC, or for reviewing the draft JSC outcome documents, the members of the subgroup on SG JSC may appoint in the SG JSC up to three ad hoc representatives who have the appropriate HTA expertise."*

3 Procedure for the appointment of assessor and co-assessor

According to Article 8(4) and Article 18(3) of the HTAR *the designated subgroup shall appoint, from among its members, an assessor and a co-assessor from different Member States (MS) to conduct the JCA and JSC, respectively. The appointments shall take into account the scientific expertise necessary for the assessment* (Art. 8(4) of the HTAR) and *for the consultation* (Art. 18(3) of the HTAR).

According to Article 9(3) of the RoP: "*for the purposes of taking up or assisting in the ongoing or future tasks of assessor or co-assessor, the members of the SG may appoint in the SG ad hoc representatives who have the appropriate HTA expertise."*

The assessor and co-assessor are selected among representatives, alternates and ad hoc representatives in the JSC or JCA SG. Their role is to lead on the scientific and technical tasks of the joint work on a specific product and to prepare the JCA reports or JSC outcome documents.

Assessors and co-assessors (irrespective of being representative, alternate or ad hoc representative), as well as additional ad hoc representatives, need to fulfil the minimum expertise set up by this guidance (relevant expertise as defined in section 4).

When applying for the role of assessor or co-assessor, the member of the SG shall provide to the SG and the HTACG secretariat via the IT platform a filled-in **application in the form set out in Appendix I** confirming the compliance with the requirements set out in section 4. This application shall be submitted by the representative, the alternate or the ad hoc representative of the member of the SG.

The appointed assessor and co-assessor will be communicated to the HTACG and the HTA secretariat. Furthermore, the HTA secretariat will be informed about the ad-hoc representatives (if any) in due time by the relevant SG member, ideally prior to the start of the procedure though nomination of ad hoc representatives is also possible during an ongoing procedure.

4 Requirements for the appointment of the assessor, co-assessor and assisting ad hoc representatives

The assessor, co-assessor and assisting ad hoc representatives shall together fulfil the general requirements and the required scientific expertise as defined in this section to ensure the high quality, impartiality and timeliness of the joint work.

4.1 General requirements

The assessor and co-assessor shall be available for the JCA/JSC timeframe.

According to Article 5(2) of the HTAR, *the representatives appointed to the […] subgroups […] shall not have any financial or other interests in the health technology developers' industrial sector which could affect their independence or impartiality.* Details are laid down by the Commission Implementing Regulation (EU) 2024/2745 of 25 October 2024 laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council as regards the management of conflicts of interest in the joint work of the Member State Coordination Group on Health Technology Assessment and its subgroups.

In accordance with Article 8(4) of the HTAR, *if the health technology has been the subject of a JSC in accordance with Articles 16 to 21, the assessor and co-assessor for the JCA shall be different from those appointed pursuant to Article 18(3) for the preparation of the JSC outcome document. According to Article 8(5), notwithstanding Article 8(4), where, in exceptional circumstances, the necessary specific expertise is otherwise not available, the same assessor or co-assessor, or both, involved in the JSC may be appointed to conduct the JCA. Such an appointment shall be justified and subject to approval by the HTACG and shall be documented in the JCA report.* In such exceptional circumstances, the SG together with the SG member will provide a justification and share the case with the HTACG with the request of written approval within 10 days.

4.2 Scientific expertise requirements

The scientific expertise requirements to be fulfilled by the assessor, co-assessor or ad hoc representatives are provided in the Table 1 and in further explanations below.

Table 1: Scientific expertise requirements

#	Scientific expertise requirements	Relevant for MP and/or MD/IVD	Relevant for JCA and/or JSC	Fulfilled by assessor AND co-assessor	Fulfilled within the assessor or co-assessor or (assisting) ad hoc representatives
1	**HTA expertise**	MP and MD/IVD	JCA and JSC	x	
2	**Technical/scientific expertise related to the MPs or MDs under assessment**				
2a	Expertise in the relevant therapeutic area	MP and MD/IVD	JCA and JSC		x
2b	Understanding of the relevant technology	MD/IVD	JCA and JSC		x
3	**Other specific expertise**				
3a	Information specialist	MP and MD/IVD	JCA		x
3b	Statistical expertise	MP and MD/IVD	JCA and JSC		x

Note: 'X' indicates that the requirement is to be fulfilled by the specified roles.

Supplementary remarks:

1) **HTA expertise** may include:
   - **regarding JCA:** experience in the review of dossiers of clinical evidence, or assessment of relative effects and uncertainty, or preparation and provision of HTA reports, which include assessments related to comparative/relative effects and associated uncertainty, at European and/or national level;
   - **regarding JSC:** Experience in review and appraisal of clinical trials, including patient populations, endpoints and study design, assessment of comparative/relative effects and uncertainty. Experience in conducting scientific consultations, drafting and providing scientific HTA advice letters (e.g. written recommendations) at European and/or national level is desirable.

2) **Technical/scientific expertise related to the MPs or MDs/IVDs under assessment** should include expertise in the relevant therapeutic area (oncology or cardiology for example). For MD/IVD, an understanding of the relevant technology is key, which can be demonstrated by previous HTA experience (or other relevant expertise) with related technologies or by familiarising with the relevant literature prior to the JCA/JSC.

3) **Other specific expertise** may include:
    a. regarding **information specialist:** experience in developing search strategies and conducting searches for HTA, systematic reviews or other evidence syntheses;
    b. regarding **statistical expertise**: experience in statistical methods for HTA, which may include the assessment of evidence from clinical trials and epidemiological studies, meta-analyses, comparative effectiveness analyses or other related evidence-syntheses;

Where the HTD applies for a JSC and raises questions in the optional section related to **health economic assessment**, it is preferable to have health economic expertise such as experience in the economic evaluation of health technologies, which may include cost-utility analysis, within the assessor, co-assessor or the assisting ad-hoc representatives. However, this situation shall not prevent assessors, co-assessors or assisting ad-hoc representatives with the relevant HTA expertise but without health economic expertise from being appointed as assessor and/or as co-assessor.

4.3 Additional considerations for the appointment

If several applications, meeting the appointment requirements, are provided for the role of an assessor or co-assessor for the same JCA and JSC, the SG shall make a selection from the applications, and where relevant consider additional criteria listed below, with the aim of building and increasing relevant capacity.

- **HTA and technical/scientific expertise**: when relevant, the representative from a member of the SG having the greater expertise shall be appointed as assessor and a representative from a member of the SG with less expertise as co-assessor;
- **Previous experience in JSC or JCA at EU level**: when relevant, the representative from member of the SG having relevant EU level experience shall be appointed as assessor and a representative from member of the SG without relevant EU level experience as co-assessor;
- **Geographical spread**: there should be geographical diversity in terms of MS taking up assessor and co-assessor roles between the various JSC and JCA.

4.4 Risk mitigation and escalation procedures

The HTA secretariat has the responsibility to initiate yearly (e.g., in Q4 2024, Q4 2025, etc) a survey on how many resources (i.e. how many JSC/JCA) each MS can provide for the role of assessor or co-assessor for JCAs and JSCs.

In cases where no assessor and/or co-assessor can be identified, the HTA secretariat will consult the SG members again, supported by the SG chairs. If this additional contact still does not reveal an assessor or co-assessor candidate, the HTACG shall be informed. This should also be done in case there are applicants, but none meets the minimum requirements.

Appendix 1 – Application form

This application form shall be completed and uploaded to the IT platform by the deadline specified per JCA or JSC. The application form has to be uploaded by representative, alternate or ad-hoc representative.

Application to participate in JCA/JSC MP/MD/IVD; identifier […]

1. Member State:
2. SG member (organisation's and person's names):
3. The applied for role (both options can be chosen):
   - □ Assessor
   - □ Co-assessor
4. Please confirm the compliance with the requirements set out in Section 4.

#	Minimum scientific expertise requirements	Relevant for MP/MD	Relevant for JCA/JSC	Please indicate if the mandatory expertise (item 1) can be fulfilled by the envisaged assessor/co-assessor*, **	Please indicate which other specific expertise (item 2 and 3) can be fulfilled in your organisation*, ***
1	**HTA expertise**	MP and MD/IVD	JCA and JSC	☐	
2	**Technical/scientific expertise related to the MPs or MDs under assessment**				
2a	Expertise in the relevant therapeutic area	MP and MD/IVD	JCA and JSC		☐
2b	Understanding of the relevant technology	MD/IVD	JCA and JSC		☐
3	**Other specific expertise**				
3a	Information specialist	MP and MD/IVD	JCA		☐
3b	Statistical expert	MP and MD/IVD	JCA and JSC		☐

** The assessor and co-assessor are selected among representatives, alternates or ad hoc representatives in the SG JSC or JCA.*

*** Items 1 is mandatory to be fulfilled by both the assessor AND co-assessor*

**** Item 2 and 3 should be covered by either the assessor OR co-assessor or (assisting) ad hoc representative*

5. For JCA: Has the proposed assessor/co-assessor been involved in a JSC for the health technology subject to the JCA?
   - □ Not applicable/No JSC took place
   - □ Yes

□ No

6. For JSC: Have the proposed assessor/co-assessor or assisting ad-hoc representative(s) got expertise in health economics?

□ Yes

□ No