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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA 21

Guidance Document

D5.3.1 - Procedural guidance for appointment of assessors and co-assessors for JCA/CA

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DOCUMENT HISTORY AND CONTRIBUTORS

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Disclaimer

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The work in EUnetHTA 21 is a collaborative effort. While the agencies in the Hands-on Group actively wrote the deliverable, the entire EUnetHTA 21 consortium was involved in its production throughout various stages. This means that the Committee for Scientific Consistency and Quality (CSCQ) reviewed and discussed several drafts of the deliverable prior to validation. Afterwards the Consortium Executive Board (CEB) endorsed the final deliverable prior to publication.

External Stakeholder Contribution

The draft deliverable was reviewed by associated HTA bodies and was open for public consultation between 07-03-2022 till 05-04-2022.

Associated HTA bodies who reviewed	Finnish Medicines Agency, [FIMEA], Finland The Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices [JAZMP], Slovenia Evaluation AND Planning Unit – Directorate of the Canary Islands Health Service, [SESCS], Spain Regione Emilia-Romagna, [RER], Italy Directorate for Pharmaceutical Affairs, Malta The Norwegian Institute of Public Health, [NIPH], Norway
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LIST OF ABBREVIATIONS

CA	Collaborative Assessment
CEB	Consortium Executive Board
COI	Conflict of Interest
CSCQ	Committee for Scientific Consistency and Quality
DOI	Declaration of Interest
ECA	EUnetHTA 21 Confidentiality Agreement
EUnetHTA	European Network of Health Technology Assessment
HaDEA	European Health and Digital Executive Agency
HTA	Health Technology Assessment
HTAb	HTA bodies
HTAR	Health Technology Assessment Regulation
JA3	Joint Action 3
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
OT	Other Technologies
PT	Pharmaceutical Technologies
SOP	Standard Operating Procedure

1 GENERAL PRINCIPLES AND PURPOSE

On 17 September 2021, the European Health and Digital Executive Agency (HaDEA) signed the Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA with the aim of supporting EU cooperation on Health Technology Assessment (HTA) beyond May 2021, when the EU–co-funded EUnetHTA Joint Action 3 (JA3) ended.

The EUnetHTA 21 consortium consists of 13 European national HTA bodies (HTAb) and its work will build on the achievements and lessons learned from the EUnetHTA Joint Actions and focus on supporting a future EU HTA system under the HTA Regulation (HTAR). The main objectives of this Service Contract are to further advance the development of HTA methodology and to continue the European collaboration on HTA in EUnetHTA, producing a specified number of Joint Clinical Assessments (JCAs)/Collaborative Assessments (CAs) and Joint Scientific Consultations (JSCs).

1.1 General principles

During JA3, criteria were developed for the selection of assessment teams. These criteria described the competencies that should be covered within an assessment team and were used when prioritisation was needed between partners. These criteria, as well as details on the experience and challenges in establishing assessment teams during JA3, are available on the EUnetHTA website under the report entitled "Recommendations for production process of Relative Effectiveness Assessments after Joint Action 3" and the corresponding Project Plan for Deliverable 5.3.

In accordance with the Regulation of the EU Parliament and of the Council on HTA and amending Directive 2011/24/EU (HTAR) adopted on 13 December of 2021, the future Member State Coordination Group on Health Technology Assessment (Coordination Group) should develop and shall adopt guidance on the appointment of assessors and co-assessors for JCAs and JSCs, including on the scientific expertise required to implement the joint work set out in the Regulation (Rec. 48; Art. 3(7g)). The designated subgroup shall appoint, from among its members, an assessor and a co-assessor from different Member States to conduct the JCA. It is important to clarify that the assessor and co-assessor refer to institutions in the subgroup, however the criteria for appointing assessors and co-assessors should cover both institutions and their appointed representatives to carry out the joint work. The appointments shall take into account the scientific expertise necessary for the assessment.

In accordance with Article 8(4) of the HTAR, if the health technology has been the subject of a JSC, the assessor and co-assessor shall be different from those appointed for the preparation of the JSC outcome document. Notwithstanding, 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 Coordination Group and shall be documented in the JCA report (Art. 8(5)).

Owing to all of the above, it is important to revise the procedural guidances for the appointment of an assessor and co-assessor.

1.2 Purpose and Scope

During EUnetHTA JA3, two Standard Operating Procedures (SOPs) entitled *Call for Collaboration and Formation of Assessment Team* were developed to formalise the process of composing assessment teams for Pharmaceutical Technologies (PT) and Others Technologies (OT). As part of these SOPs, criteria for selection of assessment team members were also outlined.

The present Guidance Document aims to fine-tune the list to set minimum selection criteria for the appointment of assessors and co-assessors of JCAs/CAs for pharmaceuticals and medical devices. These criteria will be applicable under the EUnetHTA 21 service contract only; however, they could also be valid for HTAR after further adaptations.

2 ACTORS AND THEIR SCOPE

2.1 EUnetHTA 21 actors

Table 2.1 presents definitions for the main EUnetHTA 21 actors for appointment of assessors and co-assessors for JCAs/CAs.

Table 2-1: Definitions.

Assessment team (JCA/CA)	An assessment team includes an institution for the role of assessor and another institution for the role of co-assessor. Both assessor and co-assessor can consist of multiple individuals from the respective institution.
CEB	The Consortium Executive Board (CEB) is the principal decision-making body of the EUnetHTA 21 consortium. The CEB comprises representatives of each of the 13 consortium member organisations.
Coordination Group	The Coordination Group is defined as in Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on Health Technology Assessment and amending Directive 2011/24/EU (Art. 3).
CSCQ	The EUnetHTA 21 Committee for Scientific Consistency and Quality (CSCQ) is in charge of the process that ensures the scientific consistency and quality of activities and deliverables covered by the EUnetHTA 21 service contract. The CSCQ is composed of representatives of all member organisations of the EUnetHTA 21 consortium and can convene in three different configurations (CSCQ JCA, CSCQ JSC and CSCQ Transversal).
CSCQ JCA	The CSCQ JCA is responsible for the validation of JCA deliverables, i.e., methodological guidelines, procedural guidelines, templates and JCA/CA reports.
EUnetHTA 21 Secretariat	The EUnetHTA 21 Secretariat consists of the ZIN Secretariat as consortium lead, the ZIN JCA Secretariat and the G-BA JSC Secretariat.
JCA/CA Assessor JCA/CA Co-assessor	The HTAb participating in JCA/CA production through their representatives are responsible for undertaking a single (or set of) task(s) and for the quality and timing of the task(s). During JA3, assessors and co-assessors were called authors and co-authors, respectively.
JCA/CA Project Manager(s)	A person or a team at the JCA Secretariat responsible for coordinating JCAs or CAs.
Joint work	Jointly produced clinical assessments, scientific consultations or other joint work that require management of conflict of interest.
Subgroup (of the Coordination Group)	Subgroups of the Coordination Group are composed of HTA authorities and bodies that provide adequate technical expertise for carrying out JCAs and JSCs. The members of the subgroup shall appoint their representatives, who shall have the appropriate HTA expertise, in the subgroups on an ad hoc or permanent basis.

An assessment team consists of two different roles: a JCA/CA assessor and a JCA/CA co-assessor. The terms “assessor” and “co-assessor” refer to national or regional authorities which shall appoint their representatives in the CSCQ JCA group. They could be supported in their work by additional members from their organisation.

The criteria for the composition of assessment teams listed in Table 2.2 were developed to ensure the high quality, impartiality and timeliness of assessments. They are applicable to EUnetHTA 21 consortium members for selection of an assessor and a co-assessor for a JCA/CA.

Table 2-2: Selection criteria for the appointment of an assessor and a co-assessor.

#	Criteria for the appointment of an assessor and a co-assessor	Individual level	Institutional level	Assessment team level
1.	Availability during suggested timelines.		X	
2.	No Conflict of Interest (COI) for participating persons identified as a result of evaluation by the COI Committee (following the *Procedure Guidance for handling Declaration of Interest (DOI)* and *EUnetHTA 21 Confidentiality Agreement (ECA)* forms).	X		
3.	The assessor and co-assessor should come from different member states and be members of the CSCQ JCA (or JCA subgroup in the future HTAR).		X	
4.	Scientific expertise required to implement the joint work, acquired via previous EU and/or national HTA experience, should be available within the assessment team. (see below)			X
5.	One member of the assessment team must have scientific expertise in information retrieval and one member in statistical analyses (see Table 2.3).			X
6.	The assessor and co-assessor shall be different from those participating in the work of the respective JSC (HTAR, art. 8(4)) (unless there are exceptional circumstances; see below).		X	

In order to define the main set of requirements for an assessor and a co-assessor in the current guidance, some criteria must be met at an individual level (criterion 2), whereas others are expected to be met at an institutional level (criteria 1, 3 and 6) or assessment team level (criteria 4 and 5), as shown in Table 2-2.

The following requirements related with scientific expertise shall be taken into consideration on the appointment of the assessment team:

- **Scientific competence** including clinical, epidemiological, methodological expertise;
- **HTA experience** including experience in the review of dossiers, preparation and provision of HTA assessment reports at European and/or national level;

In accordance with the HTAR, external experts with relevant in-depth specialised expertise shall provide input to JCAs to ensure that the joint work is of the highest scientific quality and reflects the state of the art. Such experts should include clinical experts in the therapeutic area concerned, patients affected by the disease, and other relevant experts on, for example, the type of health technology concerned or issues related to clinical study design. External experts should be selected for their subject matter expertise and act in an individual capacity rather than representing any particular organisation, institution or Member State. The independence and impartiality of clinical experts involved should be ensured and conflicts of interest should be avoided in order to preserve the scientific integrity of the JCAs. More details can be found in the guidance document D7.2.1 *"Guidance for the interaction with patient representatives, health care professionals (HCP) and other experts".*

As a minimum requirement for each assessment, an information specialist and a statistician need to be part of the assessor/co-assessor organisations and part of each review. Table 2-3 illustrates the minimum requirements of these technical experts.

Table 2-3: Minimum criteria to satisfy the requirements for persons fulfilling the role of information specialist or statistician within an assessment team.

- Confirmation that the person proposed is working as an information specialist / statistician for the HTAb (as an employee or a freelancer) **AND** - has experience in developing search strategies and conducting searches for HTAs, systematic reviews and / or other evidence syntheses (information specialist) OR - has experience in statistical data analysis for clinical and epidemiological trials, meta-analyses and other evidence syntheses (statistician)

These requirements have to be checked by the secretariat. It is sufficient for the Secretariat to accept a declaration of compliance with these criteria by the employing HTAb.

A person acting as an assessor or co-assessor should not hold multiple roles at the same time, for example, project manager and assessor or co-assessor.

2.2 Exceptional circumstances

In accordance with the HTAR, if the health technology has been the subject of a JSC, the assessor and co-assessor shall be different from those appointed for the preparation of the JSC outcome document (Art. 8(4)) (criterion 6). Notwithstanding, 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 (Art. 8(5)). Such an appointment shall be justified and subject to approval by the CEB (Coordination Group in the future) and shall be documented in the JCA report.

In accordance with the Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA 21 Confidentiality Agreement (ECA) forms, under exceptional circumstances (e.g. lack of available experts without a Conflict of Interest (COI) for a rare/ultra-rare disease), EUnetHTA 21 may still seek the expert opinion from an individual with an existing COI if this expert has unique skills and no other expert (with at least the same level of competency and without COI) can be identified, despite having contacted multiple experts. This exception refers to individual(s) participating as external experts and not to the assessor and co-assessor.

The CEB is the committee responsible for approval of any exception to the above-mentioned criteria.

3 RULES OF THE COLLABORATION

3.1 Status of Outputs

It is important to mention that this activity is carried out within the framework of the EUnetHTA 21 consortium service contract and may not fully cover the needs detailed in the HTAR. For example, the HTAR implies that the same criteria will be applicable for JCAs and JSCs. However, the present document refers only to selection criteria for the JCA/CA assessor and co-assessor and further adaptation will be necessary in order to fully align criteria for JCAs/CAs and JSCs. In accordance with the HTAR, criterion 6 of this guidance document indicates that the assessor and co-assessor (referring to the institutions) shall be different from those who held these positions during the JSC for the same product. However, the members of the EUnetHTA 21 CSCQ consider that such a stipulation may in practice reduce considerably the pool of assessment agencies who can undertake assessments, thereby creating a backlog of assessments. It is suggested by the CSCQ and CEB that this criterion should be revisited in the future and is proposed its application at individual level to avoid the situation becoming a barrier to producing collaborative outputs in the form of JCAs and JSCs. In addition, the document does not cover the procedural steps for selection of assessors and co-assessors and who is

in charge of selecting them. The role of the observer within the assessment team – which existed in JA3 – is not subject of the current document, nevertheless, it could be relevant as a capacity-building measure in the framework for implementation of the HTAR. All of the aforementioned topics could be considered as recommendations for the future. In general, this Guidance Document should be revised in the future, as it is possible that further adaptation will be needed in order to comply with the HTAR.

4 RELATED DOCUMENTS

Document	Link with practical guideline
European Network for Health Technology Assessment, Joint Action 3: EUnetHTA Recommendations for production process of Relative Effectiveness Assessments after Joint Action 3. May 2021	*This document briefly discusses JA3 experience in the formation of assessment teams, and describes the difficulties encountered and future expectations.*
D5.3 Procedural Guidelines for Appointing Assessors and Co-Assessors – Project Plan	*The dedicated Project Plan was used as a basis for the development of this Guidance Document.*
Regulation of the European Parliament and of the Council on Health Technology Assessment and amending Directive 2011/21/EU, 15 December 2021	*This recently adopted document provides the basis for permanent EU-level cooperation on HTA. Details regarding the appointment of assessors and co-assessors were taken into account.*
European Network for Health Technology Assessment, EUnetHTA 21: Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA 21 Confidentiality Agreement (ECA) forms. Version 1.0, Date 22 November 2021.	*The objective of this guidance is to explain the procedure put in place to avoid conflicts of interest in JCA/CA and JSC production during EUnetHTA 21. Having no conflicts of interest is one of the criteria for assessors and co-assessors.*
European Network for Health Technology Assessment, EUnetHTA 21: D7.2.1 *"Guidance for the interaction with patient representatives, health care professionals (HCP) and other experts"*	*This guidance document is under development.*