GMDS Workshop 09.12.2022
“Health Technology Assessments: Wie wird die Europäische Nutzenbewertung aussehen? Wie entwickeln sich methodologische Aspekte für die Nutzenbewertung weiter?”

Presenter: Dr. Siw Waffenschmidt, IQWiG
EUnetHTA21: Guideline for appointing assessors and co-assessors

Historie JA3
“Call for Collaboration and Formation of Assessment Team”
- mandatory requirement that an information specialist and statistical skills have to be involved in each team.
- question is still open as to whether the involvement of a statistician should be a mandatory requirement

D5.3 Objectives
- “Procedural guidelines for appointing assessors and co-assessors”
- SOP recruitment of technical experts into a formal network and minimum requirements for technical experts
- designing a proposal for sustaining and resourcing of technical experts

D5.3.1 – Procedural guidance for appointment of assessors and co-assessors for JCA/CA
Hands-on Group:
- Agencia Española de Medicamentos y Productos Sanitarios [AEMPS], Spain
- Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen [IQWiG], Germany
- National Centre for Pharmacoeconomics [NCPE], Ireland
- National Institute of Pharmacy and Nutrition [NIPN], Hungary

Criteria for the appointment of an assessor and a co-assessor
The terms “assessor” and “co-assessor” refer to national or regional authorities

<table>
<thead>
<tr>
<th>Criteria for the appointment of assessors and co-assessors</th>
<th>Essential level</th>
<th>Desirable level</th>
<th>Additional level</th>
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<tbody>
<tr>
<td>1. Availability during suggested timelines.</td>
<td>X</td>
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<tr>
<td>2. No Conflict of Interest (COI) for participating persons identified as a result of evaluation by the COI Committee (following the Procedure Guidelines for COI and EUnetHTA in Confidentiality Agreement [CA] forms).</td>
<td>X</td>
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<tr>
<td>3. The assessment team shall be of members from different member states and be members of the EUnetHTA JCA subgroup in the future [ECA].</td>
<td>X</td>
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<td>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)</td>
<td>X</td>
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<td>5. One member of the assessment team has scientific expertise in information retrieval and one member is statistical analyses (see Table 2.3).</td>
<td>X</td>
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<tr>
<td>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).</td>
<td>X</td>
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</table>

In-depth specialised (internal or external) expertise should include:
- clinical experts in the therapeutic area concerned,
- patients affected by the disease,
- other relevant experts on, for example, the type of health technology concerned or issues related to clinical study design.

Criterion 4: Requirements related with scientific expertise
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

The terms “assessor” and “co-assessor” refer to national or regional authorities.
Criterion 5: Requirement for each assessment: an information specialist and a statistician

Exceptional circumstances
1. Criterion 6: assessor and co-assessor shall be different from those appointed for the preparation of the JSC
   - where, in exceptional circumstances, the expertise is otherwise not available, the same assessor or co-assessor, or both, involved in the JSC may be appointed to conduct the JSC

2. Involving experts without a Conflict of Interest
   - under exceptional circumstances, EUnetHTA 21 may still seek the expert opinion from an individual with an existing COI
   - exception refers to individual(s) participating as external experts and not to the assessor and co-assessor

D5.3.2 – Resourcing and maintaining HTAb technical expert working groups (sub deliverable of D5.3)

Hands-on Group:
- Agencia Española de Medicamentos y Produ ctos Sanitarios [AEMPS], Spain
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Why experts?
- JCAs: transparent, reproducible and consistently used methodology.
- necessary to involve both information specialists and statisticians.
- not sufficient to reduce these tasks to certain competencies
- these tasks cannot be provided by generalists.
- there might be assessments where they will be involved with lesser extend
- involvement is not possible at short notice

Why expert groups?
- To answer specific questions (ad-hoc or higher-level)
- making difficult decisions
- ensure consistently applied methodology
- Protect the assessor/co-assessor in case of difficult decisions
- Discuss and decide
- agreements within the HTAb on how to deal with certain methodological challenges
Suggested integration of the HTAb technical expert working groups within the HTAR governance

Structure and tasks of HTAb technical expert working groups

Comments from public consultation

Establishment of working groups is supported

Major comments from the public consultation

Next steps