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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA 21 - Guidance

D5.2 JCA REPORT TEMPLATE GUIDANCE

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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 is 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.

Associated HTAb & Stakeholders participating in public consultation

The draft deliverable was reviewed by associated HTAb and was open for public consultation between 01.08.2022 and 30.08.2022.

Associated HTA bodies who reviewed	Dachverband der Österreichischen Sozialversicherung, [DVSV], Austria Directorate for Pharmaceutical Affairs Ministry for Health [DPA], Malta Evaluation and Planning Unit – Directorate of the Canary Islands Health Service, [SESCS], Spain Finnish Medicines Agency [FIMEA], Finland The Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices [JAZMP], Slovenia Norwegian Institute of Public Health, [NIPH], Norway
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List of abbreviations

Abbreviation	Meaning
ATC	Anatomical Therapeutic Chemical (code)
ATMP	Advanced Therapy Medicinal Products
CE	Conformité Européenne
CEB	Consortium Executive Board
CHMP	Committee for Medicinal Products for Human Use
CSR	Clinical Study Report
CTD	Common Technical Document
DSM	Diagnostic and Statistical Manual of Mental Disorders
EMA	European Medicines Agency
EU	European Union
HTA	Health Technology Assessment
HTD	Health Technology Developer
ICD	International Statistical Classification of Diseases and Related Health Problems
IVD	In vitro Diagnostic
JCA	Joint Clinical Assessment
MA	Market Authorisation
MD	Medical Device
MDR	Medical Device Regulation
MS	Member State
PICO	Population – Intervention – Comparator - Outcome
PRIME	Priority Medicines
RCT	Randomised controlled trial
ROB	Risk of bias
UDI-DI	Unique Device Identification-Device Identifier (according to Regulation (EU) 2017/745

I Introduction

According to Regulation (EU) 2021/2282 a joint clinical assessment (JCA) report should be prepared reflecting the outcome of the assessment as required by the regulation. This assessment report is published and made available to Member States (MS) for them to give due consideration to the report and accompanying information from the assessment in their national Health Technology Assessment (HTA) procedures.

This guidance indicates an appropriate format for the information and data to be included in the assessment report. The guidance only provides a high-level structure. Within this structure, an outline is given for the presentation of information and data to facilitate understanding of the assessment.

This guidance is the first component of the overall framework of guidance on the assessment report. It describes the overall structure and the general requirements for the report. Further components will comprise a template for the assessment report and a set of table and figure templates further specifying technical requirements and supporting the implementation of methodological guidance.

In addition to the requirements laid down in this guidance, further guidance adopted by the Consortium Executive Board (CEB) has to be taken into consideration when preparing a JCA report (e.g. methodological guidance).

II General requirements for the assessment report

According to Regulation (EU) 2021/2282 (Art. 9.1) the JCA shall result in a JCA report that shall be accompanied by a summary report. According to the regulation, the JCA report shall meet the following requirements:

- it shall not contain any value judgement or conclusions on the overall clinical added value of the assessed health technology and shall be limited to a description of the scientific analysis of:
  - the relative effects of the health technology as assessed on the health outcomes against the chosen parameters which are based on the assessment scope
  - the degree of certainty of the relative effects, taking into account the strengths and limitations of the available evidence

The assessment report should be prepared on the basis of the dossier submitted by the Health Technology Developer (HTD). The dossier should contain complete and up-to-date information, data, analyses and other evidence submitted by the HTD to assess the parameters included in the assessment scope. Where the assessors consider that further specifications or clarifications or additional information, data, analyses or other evidence are necessary to carry out the assessment, the HTD should be requested to provide such additional details.

A summary of the involvement of external experts (patients, clinical experts and other relevant experts) will be provided as part of the assessment report.

If required, the report shall specify the need for an update when additional evidence for further assessments becomes available.

To finalise the JCA, the report shall be endorsed by the CEB by consensus. Where a consensus cannot be reached, divergent scientific opinions, including the scientific grounds on which those opinions are based, shall be incorporated in the report and the report shall be deemed endorsed.

III Structure and content of the assessment report

1 General information on the joint clinical assessment

At the beginning of the report general information on the JCA should be provided. This includes information on assessors and co-assessors, an overview of procedural steps and their dates as well as information on the involvement of patients, clinical experts and other relevant experts. Information on previous Joint Scientific Consultations should be provided.

2 Background

2.1 Overview of the healthcondition

Here a brief summary of the health condition should be given, including its prevalence or incidence. In addition, this should include a brief description of the target population and its characteristics. Specific characteristics that differentiate between (sub)populations reflected in the assessment scope are to be described.

2.1.1 Characterisation of the health technology Characteristics of the health technology

The characteristics of the intervention should be described in a tabular listing, including, if applicable, the following information: proprietary name; active substance(s); pharmaceutical formulation(s); indication; marketing authorisation holder; mechanism of action; Anatomical Therapeutic Chemical (ATC) code.

For medical devices (MDs), including IVDs, the product type according to the MD regulation code or the IVD regulation code, the function of the device, the intended use, the contraindications, and a product description, including its composition and its mode of action, can be summarised.

2.1.2 Requirements/instructions for use

The application/administration of the health technology should be described. For pharmaceuticals, this will include, at the very least, the method of administration, dosage and duration of treatment. For MDs, the text should describe, at the very least, the conditions of application and conditions for safe use.

2.1.3 Regulatory status of the health technology

For pharmaceuticals, the regulatory status of marketing authorisation (MA) should be provided, such as orphan status, conditional MA, exceptional circumstances, Advanced Therapy Medicinal Product (ATMP), or a Priority Medicine (PRIME).

For MDs (including IVDs), the regulatory status of the health technology should be clarified, such as MD risk class according to the MD Regulation (MDR); identification number [Unique Device Identification-Device Identifier (according to Regulation (EU) 2017/745) (UDI-DI)]; name, identification number and country of the Notified Body; date of initial Conformité

Européenne (CE) marking and expiry date of current certificate, and date and reference of the expert panel opinion.

3 Research question and scope

The JCA should be performed according to the assessment scope identified by the MSs and agreed upon by the CEB. The assessment scope including the PICO question(s) should be presented.

4 Results

The results section should provide the findings of the systematic information retrieval, characterise the included studies and present the results on relative effectiveness and safety of the health technology under assessment versus the comparators defined in the PICO question(s) as well as the degree of certainty of relative effects.

Within the results section the strengths and limitations of the available evidence will be depicted. Furthermore, the results sections will provide an assessment of the methods used by the HTD in the submission dossier, as appropriate. The assessment will be done in conformity with the existing methodological guidelines in force at the time of assessment.

4.1 Information retrieval

The description of the information retrieval review should include, as a minimum, the appropriateness of sources and search strategies and whether all relevant studies were identified and included by the HTD.

Resulting list of included studies: overall and by PICO question

An overview of all included studies and the associated references for these studies overall and per PICO question should be provided.

4.2 Characteristics of included studies

Study design and study populations

Information on the study design (e.g. on randomisation, blinding, or parallel observation; and inclusion and exclusion criteria) and on enrolled study populations (e.g. diagnosis, general severity of health condition, and line of therapy) should be provided. The study interventions should be characterised and information on the course of the study (e.g. planned and actual follow-up times per outcome) should be presented.

Risk of Bias at the study level

The ROB at the study level should be assessed and described.

4.3 Study results on relative effectiveness and relative safety

The results on relative effectiveness and relative safety should be presented by PICO question. All PICO question(s) relevant for a specific patient population should be clustered in one chapter. The relative effects versus each relevant comparator should then be assessed sequentially.

4.3.1 Results for patient population < x>

At the beginning of the section for a given patient population a table with references to the included studies enrolling this population should be provided.

4.3.1.1 Patient characteristics

The baseline demographics (e.g. age and sex) and disease characteristics (e.g. duration and severity) of the patients enrolled in the included studies should be presented in tables.

The comparability of patient characteristics between treatment groups in the included studies and between studies should be reported.

4.3.1.2 Outcomes for PICO <x-1>

An overview of the availability of evidence for the PICO question(s) by, for example, listing the included studies relevant for PICO <x-1>, should be provided. This section should present the results on the relative effectiveness and relative safety for a given PICO question. The approach to the comparison [e.g., direct comparison within randomised controlled trials (RCT), indirect comparison of RCTs, etc.] should be described. A list of all relevant outcomes for PICO <x-1> available in the included studies should be provided.

Data for the individual outcomes should be presented and described briefly. The relative effects of the health technology versus the comparator should be described. The description should address any issues affecting the degree of certainty of the relative effects, including ROB, at the outcome level.

The text will also describe cases for which insufficient evidence exists or is provided by the HTD.

4.3.1.3 Outcomes for PICO <x-2>

These should be detailed in the same way as for the preceding PICO.

4.3.2 Results for patient population < y>

These should be detailed in the same way as for the preceding patient population.

4.3.2.1 Patient characteristics

These should be detailed in the same way as for the preceding patient population.

4.3.2.2 Outcomes for PICO <y-1>

These should be detailed in the same way as for the preceding PICO.

4.3.2.3 Outcomes for PICO <y-2>

These should be detailed in the same way as for the preceding PICO.

5 Summary report

The summary report should present an independently readable overview of the assessment. It should include:

- Background information with, as a minimum, a description of the intervention and the health condition to be treated;
- Objective and scope (PICOs);
- Summary tables of the most important findings, including results on the included studies, and both outcomes and uncertainties on relative effectiveness and safety;
- Involvement of patients and healthcare professionals.