EUnetHTA 21

Template

D7.3 – TEMPLATE FOR CLINICAL EXPERT FOR JSC AND JCA

Part of D7.3 – Templates for inputs from patient representatives, HCP and other experts

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DOCUMENT HISTORY AND CONTRIBUTORS

Version	Date	Description
V0.1	20/02/2022	First draft
V0.2	20/06/2022	CSCQ input incorporated
V0.3	01/08/2022	Draft for public consultation
V0.4	28/09/2022	Final draft for validation by CSCQ
V0.5	24/10/2022	Final draft for endorsement by CEB
V1.0	04/04/2023	Publication of final version after incorporation of EC comments

Disclaimer

Participants

Hands-on Group	Austrian Institute for Health Technology Assessment [AIHTA], Austria Gemeinsamer Bundesausschuss [G-BA], Germany Belgian Health Care Knowledge Centre [KCE], Belgium National Centre for Pharmacoeconomics [NCPE], Ireland Haute Autorité de Santé [HAS], France Zorginstituut Nederland [ZIN], The Netherlands
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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 before validation. The Consortium Executive Board (CEB) endorsed the final deliverable before 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 Norwegian Institute of Public Health, [NIPH], Norway Evaluation and Planning Unit – Directorate of the Canary Islands Health Service, [SESCS], Spain Regione Emilia-Romagna, [RER], Italy Directorate for Pharmaceutical Affairs Ministry for Health [DPA], Malta Swedish Agency for Health Technology Assessment and Assessment of Social Services [SBU], Sweden Health Information and Quality Authority [HIQA], Ireland The Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices [JAZMP], Slovenia Finnish Medicines Agency [FIMEA], Finland
Stakeholders who reviewed during public consultation	Alira Health, Spain AstraZeneca, Europe Global Bayer AG & Bayer Vital GmbH, Germany BEUC, Belgium Childhood Cancer International – Europe (CCI Europe, or CCI-E), Austria Cancer Patients Europe (CPE), Belgium European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium European Hematology Association (EHA), Netherlands European Patients' Forum (EPF), Belgium European Society for Medical Oncology (ESMO), Switzerland EUCOPE, Belgium European Organisation for Rare Diseases (Eurordis), France European Society of Cardiology (ESC), France European Union of General Practitioners/Family Physicians –(UEMO), Belgium F. Hoffmann-La Roche Ltd (Roche), Switzerland HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG), International interest group Institut GmbH and HealthEcon AG" "IGES LifeScience", Germany ISPOR Headquarters is based in the USA, but nearly 20% (1 in 5) of our membership lies within the European Union. Lumanity, Lumanity is a global company with several European entities, including in Ireland and the Netherlands. Lymphoma Coalition, Lymphoma Coalition Europe (LCE), France Medtronic, Switzerland Myeloma Patients Europe (MPE), Belgium Osteogenesis Imperfecta Federation Europe (OIFE), Belgium Patient Focused Medicines Development (PFMD), Belgium Pancreatic Cancer Europe (PCE), Belgium (PDF FORMAT) The European Society for Paediatric Oncology (SIOP Europe, or SIOPE), Belgium SKC Beratungsgesellschaft mbH (SKC), Germany

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Clinical Expert Input Template for Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs)

Joint Clinical Assessment or Joint Scientific Consultation on <health technology> for <condition>; Project ID:

Introduction

In order to ensure that joint work is of the highest scientific quality, external experts with relevant in-depth specialised expertise should provide input on Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs). Patients, clinical experts and other relevant 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. As described in D7.2, such experts should be without/devoid of conflicts of interest. .

This template is intended to be completed by healthcare professionals (HCPs) when giving input as clinical experts either during the scoping process for a JCA or during a JSC. Clinical experts should be practising in EU/EEA countries.

Clinical experts will also be given the opportunity to provide further input by responding to ad hoc questions asked by (Co)-Assessors during the JCA or JSC processes. While this template is primarily designed to be used at the European level, it can be used by Health Technology Assessment (HTA) bodies to support engagement with clinical experts at a national level.

This is a generic template and please note that the questions in the template are optional and can be modified by the (Co)-Assessor as necessary. Although the template might have a focus on medicinal products, it can also be used to obtain input relating to medical devices. Questions can therefore be adapted by the (Co)-Assessor where needed.

How to complete this template

This template can be used by the (Co)-Assessor as a discussion guide for your interview or you can complete it as a written statement. If used as a discussion guide, your interview will be summarised by the (Co)-Assessor and you will have the opportunity to review and validate the summary before your input will be used. If you complete the template as a written statement, please provide details of references or sources for your input where necessary (e.g., when referencing specific guidelines or studies).

If you require an explanation on HTA-related terms, please refer to the HTA glossary (http://www.htaglossary.net/homepage). For information on joint HTA work, please refer to the EUnetHTA JCA frequently asked questions (https://www.eunethta.eu/jca/) or JSC page (https://www.eunethta.eu/jsc/).

The questions in this template follow the PICO framework (Population, Intervention, Comparator and Outcomes). The PICO framework provides a standard format for the definition of a research question, for example, for a comparative assessment of the effectiveness and safety of various treatment options. For further information on the PICO framework, please refer to https://www.eunethta.eu/pico/. You are not asked to define a PICO, but rather to answer questions related to the parameters of a PICO framework.

Your input may support the development of the final PICO(s) during the JCA scoping process or the written recommendations arising from a JSC. Your input may also be shared with national HTA bodies.

Questions in this template are optional and you also have an opportunity to present your views on any topic not covered by the questions asked. **When you are aware that there are differences between European and national practices, please highlight these in your response.**

If you have any further questions when completing this form, please contact <Name and e-mail of project manager>.

Please note that prior completion of a declaration of interest form and confidentiality agreement is required. For involvement in EUnetHTA 21: The expert can complete the template after clearance by the EUnetHTA Conflict of Interest Committee.

Declaration

□ **I complete this template as an individual expert and present my own knowledge. In the case that I am part of a healthcare professional organisation, I am not responding on their behalf. Their views may be different to mine.**

<For JCAs

□ **I understand and agree that (all or parts of) my responses can be stated in the JCA report which will be available (in EUnetHTA 21: on the EUnetHTA 21 website; under the HTAR: on the IT platform)>**

Please tick the appropriate box

□ **I agree to be named individually in the JCA report along with details of any affiliations I may have and my country of practice.**

OR

□ **I do not wish to be named individually in the JCA report but I understand that my area of practice will be described along with details of any affiliations I may have and my country of practice>**

<For JSCs

□ When providing input as part of a JSC, I understand and agree that (all or parts of) my responses can be included in the JSC Final Written Recommendations (if relevant).

□ I understand that my participation in a JSC procedure is completely confidential and that I may not share any information about the JSC with anyone.

Please tick the appropriate box

□ I agree to be named individually in the JSC Final Written Recommendations along with details of any affiliations I may have and my country of practice.

OR

□ I do not wish to be named individually in the JSC Final Written Recommendations but I understand that my area of practice will be described along with details of any affiliations I may have and my country of practice>

Background information

Question 1	Response
Your name and contact information Country of practice	

Question 2	Response
Please provide a brief summary of your clinical experience relevant to this JCA or JSC.	

Question 3	Response
Are you a member of a HCP organisation/ clinical society?	□ Yes □ No

Only if response to question 3 was "yes"

Question 3a	Response
Please name the HCP organisation/clinical society	

Only if response to question 3 was "yes"

Question 3b	Response (choose one option)
What role do you have in the HCP organisation/clinical society	o President/Vice President/Board Member o Member with mandate to speak on behalf of the organisation o Member (without any function or mandate) o Office staff o Other: please specify

Only if response to question 3 was "yes"

Question 3c	Response
Please state the health condition(s) represented by the HCP organisation/clinical society	Free text

For JSC: <(Co)-Assessor should insert indication according to consultation request> **For JCA scoping process: <(Co)-Assessor should insert indication under review>**
Please fill in the following form according to the PICO framework *(please justify your comments).*
1. P – Population
For JSC only: <How would you define the population to be included in a clinical trial to measure the efficacy of the intervention in the required indication? Would you expect differences between the clinical trial population and the population generally targeted by the intervention? If so, what is the potential impact of this difference on treatment effectiveness?

Are patients diagnosed or treated differently in the study compared to usual clinical care? If yes, please elaborate.>
Please state relevant patient sociodemographic (e.g., age, ethnicity, socioeconomic status) and clinical baseline characteristics (e.g., severity of condition, comorbidities) which may contribute to differences in treatment outcomes or treatment preferences. What are the relevant eligibility criteria for treatment decisions made by HCPs?
2. I – Intervention
Are there contextual factors, (e.g., prior, concurrent or subsequent treatments, training on administration, etc.) which may affect the safety and/or effectiveness of the intervention? Does the specific (professional) experience of the treating HCP or medical staff play a relevant role in the decision to use the intervention? Would the decision to use the intervention in clinical practice be affected by its route and/or frequency of administration? What would be relevant criteria for treatment discontinuation? Is there a specific time point at which you check the therapeutic effect? Where does the intervention fit in the current treatment landscape?
3. C – Comparator(s)
What is the standard of care in your country? Are you aware of the standard of care most commonly used in Europe? Are there different treatment options for different patient groups depending on severity, previous treatment, biomarker levels, etc.? What are the goals of current treatments? Are there contextual factors (e.g., prior, concurrent or subsequent treatments) which may affect the safety and/or effectiveness of the comparators? Would the decision to use comparators in clinical practice be affected by their route and/or frequency of administration?
4. O – Outcome
Please define relevant safety, efficacy and patient-centred outcomes (e.g., quality of life) which should be assessed.

What safety and efficacy outcomes are used in clinical practice to inform clinical decisions regarding treatment and how are they measured? If surrogate outcomes (e.g., laboratory parameters) are relevant to the indication given, do you consider them to be clinically meaningful?
Any other specific questions: ***Questions can be added or deleted by the (Co)-Assessor as appropriate***
Examples for JSC <What minimum study duration would be appropriate for this indication and what follow-up periods are important for patients? Please consider both long- and short-term outcomes. Please justify your statement>.
If you have any further comments or remarks please add them here.