EUnetHTA 21

Template

D7.3 – TEMPLATE FOR HCP STAKEHOLDERS FOR JCA

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

Version 1.0, 04.04.2023

Template version 1.0, October 2021

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
Project Management	Zorginstituut Nederland [ZIN], The Netherlands
CSCQ	Agencia Española de Medicamentos y Productos Sanitarios [AEMPS], Spain
CEB	Austrian Institute for Health Technology Assessment [AIHTA], Austria Belgian Health Care Knowledge Centre [KCE], Belgium Gemeinsamer Bundesausschuss [G-BA], Germany Haute Autorité de Santé [HAS], France Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen [IQWIG], Germany Italian Medicines Agency [AIFA], Italy National Authority of Medicines and Health Products [INFARMED], Portugal National Centre for Pharmacoeconomics [NCPE], Ireland National Institute of Pharmacy and Nutrition [NIPN], Hungary Norwegian Medicines Agency [NOMA], Norway The Dental and Pharmaceutical Benefits Agency [TLV], Sweden Zorginstituut Nederland [ZIN], The Netherlands

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

Copyright

EUnetHTA 21 recommendation for stakeholder input in Joint Clinical Assessments (JCA)

While the HTAR only defines the involvement of external experts, EUnetHTA 21 recommends a process for the involvement of stakeholders (i.e. patient organisations, HCP organisations) is also established. This recommendation is based on experiences from EUnetHTA Joint Action 3 and EUnetHTA 21, national HTA procedures as well as expectations and feedback received in public consultations. Therefore, EUnetHTA 21 developed a template for patient stakeholder input in JCA

The recommended process can be read in D7.2 – Guidance on Patient & Healthcare Professional Involvement.

Healthcare Professional Stakeholder Input Template for Joint Clinical Assessments (JCAs)

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

Introduction

In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should engage and consult widely with stakeholder organisations with an interest in European Union cooperation on Health Technology Assessment (HTA), including patient organisations, healthcare professional (HCP) organisations, clinical and learned societies, health technology developer associations, consumer organisations and other relevant nongovernmental organisations in the field of health.

This template is intended to be completed by HCPs when giving input on behalf of stakeholder organisations (e.g., HCP organisations, clinical and learned societies) during the scoping process for a Joint Clinical Assessment (JCA). The organisation should represent HCPs practising in EU/EEA countries.

While this template is primarily designed to be used at the European level, it can be used by HTA bodies to support engagement with HCPs at a national level.

This is a generic template and please note 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

You should complete this 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). Please note that we only accept one consolidated template per organisation. Your responses should reflect the position of your organisation and not your own individual/personal views, although these may be the same.

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/).

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. 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>.

For EUnetHTA 21: Information on EUnetHTAs privacy policy can be found at Privacy Policy - EUnetHTA

Declaration

☐ **I am completing this template on behalf of a stakeholder organisation (e.g., HCP organisation, clinical or learned society) and represent its views.**

☐ **When providing input as part of a JCA, I understand and agree that details of my stakeholder organisation and (all or parts of) my responses can be included in the JCA report (if relevant) or on the (for EUnetHTA 21, the EUnetHTA 21 website and under the HTAR on the IT platform).**

☐**I agree that my contact details are stored by the Secretariat.**

Background information

Question 1	Response
Please state the country where the HCP organisation/clinical society that you are representing is based:	Drop-down menu with a list of EU/EEA countries and “other”

Please note that organisations contributing via this HCP input template should ideally be situated in EU/EEA countries.	

Question 2	**Response**
Please name the HCP organisation/clinical society you are representing:	Free text

Question 3	**Response**
What role do you have in the organisation?	□□President/Vice President/Board Member □□Member with mandate to speak on behalf of the organisation □ Member (without any function or mandate) □□Office staff □□Other, please specify

Question 4	**Response**
Please state the health condition(s) represented by your organisation:	Free text

Question 5	**Response**
How many members does the organisation have?	Free text

Question 6	**Response**
How is the organisation funded? Please provide details of any funding from medical industry, during the last 3 years.	• Year • Name of company • Funding amount in Euro

	• % of overall funding in year received For each year, please add extra lines as needed

Question 7	**Response**
Please state the geographical spread of the organisation's membership:	□ European □ National □ Regional (particular region of a country) □ Local □ Other: please specify

Question 8	**Response**
Please provide the contact details for the person who completed this template:	Contact person in organisation: Email (organisation): Phone (organisation): Website of the organisation

For JCA scoping process: <(Co)-Assessor or Project Manager should insert indication under review>
Please fill in the following form according to the PICO framework *(please justify your comments).*
1. P – Population
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 these measured? If surrogate outcomes (e.g., laboratory parameters, etc.) 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
If you have any further comments or remarks please add them here.