EUnetHTA 21

Template

D7.3 – TEMPLATE FOR PATIENT STAKEHOLDERS FOR JCA

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

Version 1.0, 04.04.2023
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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

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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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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.

Template for Stakeholder Patient Input for JCAs

Health Technology Assessment (HTA) on <health technology> for <condition>; Project ID:

Introduction

EUnetHTA recognises that patients and those who support them have unique knowledge about what it is like to live with a specific disease or medical condition. Furthermore, EUnetHTA believes that patient organisations can help in understanding the unique perspectives of patients by collecting and presenting patients' views and experiences via engagement with a wide range of patients. Experience may relate to the entire lifecycle of the patient, including phases of the disease/conditions and/or outcomes the patient is no longer experiencing now and/or treatments patients have received in the past. These organisations can describe the advantages and disadvantages of health technologies on the basis of patients' experiences and what patients value for a new technology.

This generic template is for patient organisations to provide an input to a Joint Clinical Assessment (JCA). It forms the basis for question and if needed, questions can be modified and/or/added by EUnetHTA (Co)-Assessors. Organisations contributing via this patient input template[1] should ideally be situated in EU/EEA countries. Please note that EUnetHTA only accepts one consolidated template per organisation. *Input from stakeholders obtained during the JCA scoping process may also be shared with national Health Technology Assessment bodies.*

How to complete this template

What type of information is most helpful?

- Each question has a series of prompts. Please address any of the prompts that you feel are important and describe any other relevant issues that are not captured in the list of prompts. You are not expected to consider or go into depth with every single prompt.
- Describe experiences at different stages of the condition/disease (and if applicable differences in the severity of the disease), with a particular focus on symptoms in terms of their impact and how well they are currently managed with existing treatments.

[1] The template is based on the "HTAi Patient Group Submission Template for HTA of Health Interventions" (https://htai.org/interest-groups/pcig/resources/) and was revised by EUnetHTA 21 to ensure suitability for JCAs and JSCs.

- Where possible, please provide clear facts, information and summaries of experiences that give a concise, accurate and balanced overview of a range of patients' perspectives.
- Where possible, for any of the sections in the template for which there are groups that should have special consideration, please indicate the specific needs/issues of that group (e.g., children, women/men, ethnic groups, those living in a particular location, those with other disabilities, disease subtypes).
- State the source(s) of your information (e.g., web survey, helpline analysis, social networking, focus groups, patients' records, one-to-one conversations with those who have experience with a technology, patient stories, research studies, etc.) and provide clear references where they are available.

Help in completing the template

- If you require help in understanding HTA-related terms, please refer to the HTA glossary (http://www.htaglossary.net/homepage), the EUnetHTA JCA frequently asked questions (https://www.eunethta.eu/jca/) or the Joint Scientific Consultation (JSC) page https://www.eunethta.eu/jsc/
- The EUnetHTA 21 "*Guidance on Patient & Healthcare Professional Involvement*", which outlines the involvement processes and how the input is reported, can be found here (link to be added later).
- The template compiles possible aspects/options to consider in your response; all of the points listed are optional and do not have to be asked or answered.
- If you have any further questions when completing this form, please contact <Name and e-mail of project manager>.
- Information about EUnetHTA´s privacy policy can be found here: https://www.eunethta.eu/privacy-policy/

Declaration

☐ I am completing this template **on behalf of a patient organisation** (i.e., as a stakeholder) and represent its views.

☐ By submitting this template, I understand and agree that (parts of) my responses can be stated in the JCA report with the patient organisation/affiliation and country being mentioned. The JCA report will be publicly available on (In EUnetHTA 21: the EUnetHTA 21 website; 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 patient organisation that you are representing is based: Please note that organisations contributing via this patient input template should ideally be situated in EU/EEA countries.	Drop-down menu with a list of EU/EEA countries and "other" and "if other, please state name of country"

Question 2	Response
Please name the patient organisation:	Free text

Question 3	Response (choose one option)
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 the organisation and/or the remit of the 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 (choose all that apply)
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 the template:	Contact person in organisation: Email (organisation): Phone (organisation): Website of the organisation:

Question 9	Response
Where have you sourced information on patients' experiences? If relevant, how did you gather information about the experiences of patients? Options to consider in your response: • Own individual experience. • Individual patient stories, review of patient group helpline queries, surveys, social media, one-to-one discussions with patients, focus groups, interviews, documentation of clinic visits, published or unpublished research. • If applicable, how many patients were involved and what data collection methods were used for each source.	Free text

• If applicable, how representative are your findings compared with the views of the many patients that might potentially use this health technology? Did you approach or do you have information from patients who are seldom heard?	

Impact of the condition – patients with <condition>

Question 10	Response
• How does <condition> affect a patient's daily life? • Aspects to consider in your response: • Aspects of the condition that are most challenging (e.g., symptoms, loss of ability to work, loss of confidence in going out, inability to drive, social exclusion). • Emotional and psychological impacts such as fear, anxiety, uncertainty, stigma, embarrassment, loneliness/isolation. • Activities that patients find difficult or are unable to do. • Aspects of the condition that are the most important to control (e.g., symptoms that limit social interaction or ability to work such as difficulty breathing, pain, fatigue, incontinence, anxiety). • Support required for daily living (physical or emotional). • Types of patients who are most affected by the condition (e.g., men/women, children, ethnic groups). • Challenges in managing this condition when patients also have other medical conditions.	Free text

Question 11	Response
How does <condition> affect carers? • Aspects to consider in your response: • Challenges faced by family and friends who support a patient in managing the condition. • Impact of the condition on family/social life. • Pressures on carers' daily life (e.g., emotional/psychological effects, fatigue, stress, depression, physical challenges).	Free text

Experience with currently available therapies/health technologies

Question 12	Response

How well are patients managing <condition> with currently available therapies/health technologies? Currently available therapies/health technologies may include any form of medical intervention such as medicines, medical devices, rehabilitation, counselling, hospital interventions, etc. If no specific therapy is available, that should be stated. Aspects to consider in your response: • The main therapies/health technologies currently used by patients for this condition and how they are applied (tablet, injection, physiotherapy, hospital check-ups, etc.; at home or in hospital; dose and frequency; ease of access). • Extent to which current therapies/health technologies control or reduce the most challenging aspects of the condition (e.g., symptoms; ability to dress, work, go to school, socialise; improve breathing, swallowing, walking). • The most important benefits of current therapies/health technologies. • The burden that current therapies/health technologies impose on daily life (e.g., impact at different disease stages, interruption to work, stigma, clinic visits to receive infused medicines, need for weekly blood tests or describe a typical episode of therapy over a week or period of treatment; difficulty in using the technologies, challenges in recovering after treatment, need for rehabilitation, special clinic visits for treatments and examinations). • Side effects of the current therapies/health technologies that are difficult to tolerate. • Concerns about long-term use of the current therapies/health technologies. • If the current therapy is a medicine, what are the challenges in taking it as prescribed, or how is dosing modified according to prescription (e.g., dividing doses to avoid side effects or missing doses due to schedule). • If the current therapy is a medical device used by the patient, are there any issues with the social acceptability of using it (e.g., in a public place)?	Free text

Expectations for the new therapy/health technology being assessed (<name of new therapy/health technology>)

Question 13	Response
For those *without* experience using <name of new therapy/health technology>, what are the expectations for new therapies/health technologies *in general*? Aspects to consider in your response: Please list the **benefits** that people living with the health condition, and those caring for them, **expect** to gain from using this treatment. Consider: • The course or outcome of the condition • Physical symptoms • Pain • Level of disability • Mental health • Quality of life (such as lifestyle or work) • Positive effect on other people (e.g., family, friends and employers) • Ease of use (e.g., tablets rather than injection) • Where the treatment has to be used (e.g., at home or in hospital) • Any other issues not listed above. Please list any **concerns** people living with the health condition, and those caring for them, have about this treatment. Consider: • Aspects of the condition that this treatment cannot help with, or might make worse • Any difficulties in taking or using this treatment (e.g., injection rather than tablets, any training needed to use medical devices, or risk from using it incorrectly). • Any side effects (e.g., type or number of problems, how often they occur, how long they last, how severe they are). Please describe which side effects people living with the condition might be willing to accept or tolerate and which would be difficult to accept or tolerate and why. • Any concerns about where this treatment has to be used (e.g., in hospital rather than at home). • Any negative effect on others (e.g., family, friends and employers). • Any financial impact on people living with the condition or their family (e.g., the cost of travel to hospital or paying a carer). • Any other issues not listed above.	Free text

If applicable: Experience with the new health technology being assessed (<name of health technology>)

This information can help assessors in understanding the context of the condition, the experience of patients living with the condition, the remaining unmet needs of patients despite current treatment management options and its impact on their life. The input is used as complementary information for the JCA.

Question 14	Response
For those *with* experience using <name of new therapy/health technology> what difference does/did it make to their lives? Aspects to consider in your response: • Positive and negative impacts	Free text

Additional information

Question 15	Response
Please include any additional information you believe would be helpful to the EUnetHTA JCA Team (e.g., ethical or social issues).	Free text

Summary and key messages

Question 16	Response
In no more than ten statements, please try to summarise your submission by listing the most important points. However, please note that all information you provide in the template will be considered by the EUnetHTA (Co)-Assessors.	Free text For example: • The biggest challenges of living with <condition> are… • Current therapies/health technologies are inadequate because… The main expectations patients have regarding a new therapy/health technology are…