EUnetHTA 21

Template

D7.3 – TEMPLATE FOR PATIENT ACTING AS EXTERNAL 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

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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 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
CEB	

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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Individual Patients Acting as External Experts Input Template for Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs)

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

Introduction

This template is intended to enable individual patients/patient representatives to present their range of views and experiences with the disease/condition for which the health technology is being assessed.[1] 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. 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. In cases in which patients themselves are less able to express themselves (e.g., children, conditions inducing cognitive impairment), patients can be represented by proxies (e.g., parents, informal caregivers), ideally with collective knowledge. Individuals contributing via this generic patient input template should ideally be living in EU/EEA countries. It forms the basis for questions and if needed, questions can be modified and/or/added by EUnetHTA (Co)-Assessors. *Input from individual patients acting as external experts obtained during the Joint Clinical Assessment (JCA) scoping process may also be shared with national Health Technology Assessment (HTA) bodies.*

Please note that completion of a declaration of interest (DOI) form and an EUnetHTA confidentiality agreement form is required. The template can be completed after clearance by the EUnetHTA Conflict of Interest Committee.

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.
- 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).
- If applicable, 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.

[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.

Help with 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>.

Declaration

☐ **For JSC only**: I understand that my participation in an EUnetHTA 21 JSC procedure is completely confidential and that I may not share any information about the JSC with anyone.

☐ By submitting this template, I understand and agree that (parts of) my responses can be stated in the JCA report/JSC final recommendations with a general description of myself being mentioned**.**
You will be able to confirm the description before publication. Your individual name will not be stated. The JCA report will be publicly available on the EUnetHTA 21 website.

Background information

Question 1	**Response (choose one option)**
Please select in what capacity you are completing the template:	☐ I am completing this template **as an individual patient** and present my own knowledge and experiences. I may also include experiences from other individual patients that I am aware of. If I belong to a patient organisation, I am not responding on their behalf; their views may differ from mine. ☐ I am a **caregiver** and am completing this template on behalf of a patient**.** ☐ I am a **parent/legal guardian** and am completing this template on behalf of a patient. ☐ Other (please note that stakeholders/ individuals representing patient organisations should complete a different patient input template): please state_____

Question 2	**Response**
Please state the country where you live (main place of residence):	Drop-down menu with a list of EU/EEA countries and "other" and "if other, please state name of country"

Please note that persons contributing via this patient input template should ideally be living in EU/EEA countries.	

Question 3	**Response (choose one option)**
Are you a member of a patient organisation?	☐ Yes ☐ No

Only if response to question 3 was "yes"

Question 3a	**Response**
Please name the patient organisation:	Free text

Only if response to question 3 was "yes"

Question 3b	**Response (choose one option)**
What role do you have in the patient 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

Only if response to question 3 was "yes"

Question 3c	**Response**
Please state the health condition(s) represented by the organisation	Free text

Question 4	**Response**
To interpret and process your answers correctly, we would like to ask you to provide some personal information about your disease/condition (e.g., disease stage/severity, disease history) and/or the disease/condition of the patient(s) you represent. Please include any additional information you think would be helpful for the Assessor/Co-Assessor Please note this information will be treated according to General Data Protection Regulation (GDPR) rules. Only the respective EUnetHTA 21 Secretariat and the HTA bodies involved in the procedure will have access to this information. If the information is presented in the report, the information will be anonymised. The questions are open ended. Should you not wish to provide a response, you can include that as your answer. ☐ Please tick this box if you agree that your personal information can be stored by the EUnetHTA 21 Secretariat. If you do **not** agree that your personal information can be stored, please do **not** answer the questions in the right-hand column.	**1)** Disease stage/severity: **2)** Disease history a. How long have you been living with the disease/condition? b. Please describe your treatment history: **3)** Any additional information you think would be helpful for the assessor/co-assessor:

For JCA only: Question 5	Response
If applicable, 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 were the methods for data collection for each source • 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 that are seldom heard?	Free text

Impact of the condition – patients with <condition>

Question 6	Response
How does <condition> affect your (a patients') 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 to go 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).	Free text

• Challenges in managing this condition when patients also have other medical conditions.	

Question 7	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 8	Response
How well are you (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: • 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, exercise). • The most important benefits of current therapies/health technologies. • The burden imposed by current therapies/health technologies 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 technology, challenges in recovering after treatment, need for rehabilitation, special clinic visits for treatments and examinations).	Free text

• Side effects of the current therapies/health technologies that are difficult to tolerate. • Concerns about long-term use of 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 social acceptability in using it (e.g., in a in a public place)?	

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

Question 9	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 a new 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 a new 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,	Free text

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.	

For JCA only, 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.

For JCA only: Question 10	Response
For those *with* experience using <name of new therapy/health technology>, what impact does/did it have on your life (their lives)? Aspects to consider in your response: • Positive and negative impacts	Free text

For JSC only, if applicable - Clinical development plan

For JSC only: Question 11	Response
Based on information shared about the clinical development plan for the new medicine, what are the expectations/limitations for the current clinical trials proposed? Issues to consider in your response: • What is the current standard of care for patients who are included in relevant trials? • Does the comparator correspond to the current standard of care? The impact of	Free text

disease stage/activity and treatment history on treatment choice. • Specific groups of patients to be considered in the analyses of drug efficacy. • Whether the clinical studies include outcomes that are important to patients, whether the patient-reported outcomes considered (e.g., EQ-5D, SF-36 or any disease-specific PRO questionnaires) are relevant and easy to complete. Any recommendation on specific side-effect data to be collected. • Feedback on the time schedule for patient-reported outcome measures (questionnaires to be filled in by the patient; e.g., EQ-5D, SF-36). • Does the proposed length of the study cover all the questions you might have on the safety and efficacy of the product? From a patient's perspective, what would the criteria for re-treatment be?	

For JSC only: Question 12	**Response**
Based on the information shared about the clinical development plan for the new therapy/health technology, would you participate in the current clinical trials proposed?	☐ Yes (please elaborate): ☐ No (please elaborate): ☐ Unsure (please elaborate):

Additional information

Question 13	**Response**
Please include any additional information you believe would be helpful to the EUnetHTA JCA/JSC Team (e.g., ethical or social issues).	Free text

Summary and key messages

Question 14	**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…