

Patient, Consumer and Health Care Provider Involvement in EUnetHTA JA3

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Content

- Reminder of EUnetHTA activities
- Patient & Consumer contribution
 - Principles on patient engagement
 - Patients contribution
 - Work Package 4 (WP4)
 - Work Package 5 (WP5)
- Health Care Provider contribution
 - Feedback on WP4 experiences
- Common challenges

Reminder of EUnetHTA activities

Joint Action 3 Objectives

Sustainable model for joint HTA work

Increase use, quality and efficiency of HTA

Increase
collaboration

Increase
production

Increase
usage

Sharing
knowledge

Alignment of
processes

Implementation

Organisational and governance structure

DG Santé and CHAFEA



Work package 1 Coordination – Secretariat Dutch Health Care Institute

EUnethTA Assembly

Executive Board

WP 2
Dissemination

Lead:
ISCIII



WP 3
Evaluation

Lead:
TLV



WP 4 Joint
Assessment

Lead:
NIPHNO
Co-lead:
LBI
ZIN



WP 5 Evidence

Lead:
HAS
Co-lead:
GBA



WP 6 Quality
management

Lead:
IQWiG
Co-lead:
KCE



WP 7
Implementation

Lead:
NICE
Co-lead:
Agenas



WP4&5 – Principles on patient engagement

- **Patient perspective essential for WP4 and WP5:**
 - At the time forming the advice
 - When setting the scope for a Joint Assessment
 - Respect Conflict of Interest and Confidentiality rules

- Providing experiential knowledge of living with the condition and (available) treatment
 - Consider quality of life

- Advising on the signs and symptoms that have the greatest impact on their functional and psychological aspects of living

WP4: Patient engagement

Production Process: Stakeholder involvement

Topic selection and Team building

Identification of external experts
(health care providers) and patients

Contacting patient organisations, medical societies

Development of Project Plan

Review of project plan by external experts,
optional involvement of patients,
fact check by manufacturers

JA: scoping meeting with manufacturers

Completion of Submission File

Manufacturers provide evidence

Draft assessment

Manufacturers have opportunity for factual accuracy check and currently external experts review the assessment report.

3 possible approaches for patient engagement

Approach	Method	Patient contribution deliverables	Patient's time investment	Conflict of Interest and Confidentiality issues
Open call	<ul style="list-style-type: none"> ✓ Call published on EUnetHTA webpage ✓ HTAi questionnaire template ✓ Proactively propose relevant association to contribute 	<ul style="list-style-type: none"> - Feedback on scope of the assessment to be taken into account for PICO - HTAi questionnaire results to be published (appendix of the assessment report) - Mention in the final report reference to patient contribution 	~ 1 day of work	Low
Interview	<ul style="list-style-type: none"> ✓ HTAi questionnaire template ✓ Interview via phone ✓ Interview recorded and transcribed 	<ul style="list-style-type: none"> - Feedback on scope of the assessment to be taken into account for PICO - Summary of the interview to be part of appendix of the report - Mention in the final report reference to patient contribution 	~ 1 day of work	High
Focus group	<ul style="list-style-type: none"> ✓ Guided by moderator ✓ Based on HTAi questionnaire template ✓ Discussion recorded and transcribed ✓ Only for specific topics 	<ul style="list-style-type: none"> - Minutes of the focus group meeting to be part of appendix of the report - Feedback on scope of the assessment to be taken into account for PICO - Mention in the final report reference to patient contribution 	~ 2 days of work	High

Patient engagement in published (pharma) Joint Assessments



in primary and secondary prevention of sudden cardiac arrest in patients at risk

Pharmaceutical technologies

PTJA03



Alecensa as monotherapy is indicated for the first-line treatment of adult patients with ALK+ advanced NSCLC

23.01.2018

TLV

HVB, AAZ

NICE, Regione Veneto, AETSA, NIPN
Observer: MOH MALTA

20.10.2018

PTJA02

Regorafenib (Stivarga®) indicated as monotherapy for the treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib treatment

25.10.2017

HAS

INFARMED

AAZ, SNHTA, FIMEA, LBI-HTA, NIPN, AETSA
Observer: EOF, EKAPTY

10.07.2018

PTJA01



Midostaurin for the indication of Acute Myeloid Leukaemia

08.11.2017

FIMEA

NOMA

TLV, ZIN, HAS, NICE, AEMPS
Information retrieval: IQWIG
Observer: SUKL, SU, EOPPY, SESCO

20.06.2018

Bold means the assessment is ongoing. What does this icon mean? Patients have been involved in this assessment.

Get abbreviations: OT-other technologies, PT-pharmaceutical technologies, CA-collaborative assessment, JA-joint assessment

Semi-structured interview

- Interview as method of engagement in
 - PTJA01 – Midostaurin for AML
 - Interview prior to scoping F2F meeting
 - Results informed the scoping F2F meeting
 - PTJA03 – Alecensa for NSCLC
 - Interview at late stage in assessment phase
- Ability to go in-depth by probing
- Allow for involvement of patients outside assessment team
 - European perspective
- Possible language barrier
- Individual perspective

WP5

Patient engagement in Early Dialogues (ED)

ED status since beginning of JA3

28 Letters of Intent

- 12 Oncology
- 5 Neurology
- 3 Immuno-inflammation
- 1 Ophthalmology
- 1 Vaccine
- 2 Metabolic disorder
- 1 infectious disease
- 3 Hematology

4x withdrawn
by the
company

12x Individual Parallel
Consultation
(~1-3 HTABs)

12 EUnetHTA ED
multi-HTA EDs +
Consolidated Parallel
Consultation

- 5 oncology
- 2 neurology
- 3 Hematology
- 1 infectious disease
- 1 immuno-inflammation

5 Completed

Testing 3 possible approaches

Approach	Patient contribution deliverables	Patient investment	Conflict of Interest and Confidentiality issues
<p>Interview Individual Patients (living with the condition) in local language collecting general feedback on the disease + answer to specific questions related to the dossier (Min: 2 countries)</p>	<ul style="list-style-type: none"> - Minutes of the interview - Mention of patient contribution in final EUnetHTA recommendations - Feedback questionnaire 	~2 days of work	Low
<p>Interview national Patient representative (living with the condition/carer) in local language collecting general feedback on the disease + patient representative position on applicant dossier</p>	<ul style="list-style-type: none"> - Minutes of the interview - Mention of patient contribution in final EUnetHTA recommendations - Feedback questionnaire 	~5 days of work	High
<p>Participation of EU patient representative (living with the condition/carer) to the overall ED process including interview with coordinator, F2F meeting, review final recommendation</p>	<ul style="list-style-type: none"> - Minutes of the interview - Review final EUnetHTA recommendations - Feedback questionnaire 	~7 days of work	High

Experience so far...

10/12 EunetHTA ED with patient contribution following the 3 approaches:

- 5 EDs with **interview individual patients** (France, UK, Spain)
- 7 EDs with **interview of a national patient representative** (German patients representative involved in any ED that G-BA participates)
- 3 EDs with **an EU patient representative participating to overall ED process**

Health Care provider involvement in EUnetHTA

WP4 experiences

Clinical expert involvement – *To be discussed in Task Group*

- Review of draft project plan
 - Provide clinical expertise on scope of the assessment
 - Input before scoping meeting with company
- Review of 3rd draft assessment report
 - Same time as factual accuracy check by company
- All comments will be answered by (co-) authors and published as an appendix to final documents

Issues with expert involvement

- Conflict of Interest (COI) of experts
 - Due to specific experience, risk of COI
 - COI an issue due to current tasks?
- Review of draft assessment is too late in the process
- Review of draft assessment is burdensome for clinical experts

Options for Health Care Provider engagement discussed in task group

- COI of experts
 - Open call for organisations
 - Only specific question on PICO table
 - Possible to receive organisational perspective?
- Review of draft assessment is too late in the process
 - Consider continuous Q&A (involvement in e-meetings etc.)

Remaining challenges

Remaining Challenges

- EUnetHTA is not a legal entity
 - Currently follow rules WP lead partner
 - Developing EUnetHTA ‘guidance’ on
 - Confidentiality
 - Conflict of Interest
 - Compensation
- Restricted resources for EDs &JA
- Patient engagement
 - Develop procedure for interview and focus group
 - Availability of different tools in local languages (adaptation of HTAi questionnaire).

Questions?