EUnetHTA Update on current and future stakeholder involvement

EUnetHTA JA3 Secretariat, Zorginstituut Nederland
Update on current and future stakeholder involvement

**EUnetHTA Forum**
- 11th April 2019, Amsterdam
- Open call for topic suggestions

**Schedule of regular meetings with stakeholders**
- Proposed dates
- Check availability & send invitations

**Cross-WP TG on stakeholder involvement**
- Develop strategy on stakeholder involvement - to be also used post-2020
- Strategy available for open consultation

**Conflict of interest**
- Agreed criteria on conflict of interest
- Next step: implementation of the agreed criteria
# Schedule of regular meetings with stakeholders

<table>
<thead>
<tr>
<th>Proposed meeting dates</th>
<th>Proposed meeting dates</th>
<th>Type of meeting</th>
<th>Location</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.02.2019</td>
<td>14.02.2019</td>
<td>E-meeting</td>
<td>SABA</td>
<td>EUnetHTA - Payers</td>
</tr>
<tr>
<td>21.03.2019</td>
<td>21.03.2019</td>
<td>Meeting</td>
<td>TBC</td>
<td>EUnetHTA - Health Care Providers</td>
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<tr>
<td>11.04.2019</td>
<td>11.04.2019</td>
<td>Meeting</td>
<td>Amsterdam</td>
<td>EUnetHTA Forum 2019</td>
</tr>
<tr>
<td>28.05.2019</td>
<td>28.05.2019</td>
<td>Meeting</td>
<td>TBC</td>
<td>2nd Workshop for Coordinated Activities on HTA and Medical Device Authorities</td>
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<tr>
<td>06.06.2019</td>
<td>06.06.2019</td>
<td>E-meeting</td>
<td>SABA</td>
<td>EUnetHTA - Patient &amp; Consumer Organisations</td>
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<tr>
<td>14.11.2019</td>
<td>14.11.2019</td>
<td>E-meeting</td>
<td>SABA</td>
<td>EUnetHTA - Patient &amp; Consumer Organisations</td>
</tr>
<tr>
<td>03.12.2019</td>
<td>03.12.2019</td>
<td>Meeting</td>
<td>Amsterdam</td>
<td>EUnetHTA 2019 Technical Meeting with Pharma industry</td>
</tr>
<tr>
<td>13.02.2020</td>
<td>13.02.2020</td>
<td>E-meeting</td>
<td>SABA</td>
<td>EUnetHTA - Payers</td>
</tr>
<tr>
<td>26.03.2020</td>
<td>26.03.2020</td>
<td>E-meeting</td>
<td>SABA</td>
<td>EUnetHTA - Health Care Providers</td>
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<tr>
<td>02.04.2020</td>
<td>02.04.2020</td>
<td>Meeting</td>
<td>Amsterdam</td>
<td>EUnetHTA Forum 2020</td>
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<tr>
<td>07.05.2020</td>
<td>07.05.2020</td>
<td>E-meeting</td>
<td>SABA</td>
<td>EUnetHTA - Patient &amp; Consumer Organisations</td>
</tr>
</tbody>
</table>
Task Group for Patient and Consumer (P&C) and Healthcare Provider (HCP) engagement

- Task Group (TG) established in September 2017
  - By EUnetHTA Secretariat

- Objective:
  - To support the development of a Patient, Consumer and Healthcare provider involvement process within WP4 and WP5.
  - Recommendations for patient engagement within EUnetHTA products
Stakeholder engagement

Early Dialogues and Assessments
WP4 – Joint Production

Pharmaceutical Technologies (PT)
&
Other Technologies (OT)
Stakeholders in assessment production (excerpt)?

**Identification**
- Contacting manufacturers
- Contacting patient organisations, medical societies

**Scoping**
- Scoping: involvement of patients, JA: scoping meeting with manufacturer(s); Review of PP by external experts & factual accuracy check by manufacturers

**Assessment**
- Manufacturer(s) provide evidence via submission file
- Review by external experts (currently)
- Option for factual accuracy check by manufacturer
<table>
<thead>
<tr>
<th>Method</th>
<th>Other Technologies</th>
<th>Pharmaceuticals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview</td>
<td>OTCA10 Stool DNA testing/colorectal cancer</td>
<td>PTJA01 Midostaurin for AML</td>
</tr>
<tr>
<td></td>
<td>OTCA12 C-reactive protein point of care testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OTCA15 Irreversible electroporation liver, pancreatic cancer</td>
<td>PTJA03 Alecensa for NSCLC</td>
</tr>
<tr>
<td>Focus group</td>
<td>OTCA01 WCD</td>
<td></td>
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<tr>
<td></td>
<td>OTJA08 glucose monitoring</td>
<td></td>
</tr>
<tr>
<td>Patient input template</td>
<td>OTJA08 glucose monitoring</td>
<td>PTJA04 Sotagliflozin Diabetes</td>
</tr>
<tr>
<td></td>
<td>OTCA07 cataract surgery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OTCA18 regional hyperthermia</td>
<td>PTJA05 Enasidenib AML</td>
</tr>
<tr>
<td></td>
<td>OTCA19 screening osteoporosis</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>OTCA04 MammaPrint (scoping meeting)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OTCA03 NIPT (input PP)</td>
<td></td>
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<tr>
<td></td>
<td>OTCA15 irreversible electroporation (review PICO)</td>
<td></td>
</tr>
</tbody>
</table>
Summary: current patient involvement

**Statistics**

Patients involved in 9/18 in OT and 3/5 in PT assessments

**Visibility**

- Description in methods section
- Summary in results section
- On EUnetHTA website
### 3 possible approaches for patient engagement

<table>
<thead>
<tr>
<th>Approach</th>
<th>Method</th>
<th>Patient contribution deliverables</th>
<th>Patient's time investment</th>
<th>Conflict of Interest and Confidentiality issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call for patient input</td>
<td>✓ Call published on EUnetHTA webpage ✓ HTAi questionnaire template ✓ Proactively propose relevant association to contribute</td>
<td>- 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</td>
<td>~ 1 day of work</td>
<td>Low</td>
</tr>
<tr>
<td>Interview</td>
<td>✓ HTAi questionnaire template ✓ Interview via phone</td>
<td>- 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</td>
<td>~ 1 day of work</td>
<td>High</td>
</tr>
<tr>
<td>Focus group</td>
<td>✓ Guided by moderator ✓ Based on HTAi questionnaire template ✓ Only for specific topics</td>
<td>- 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</td>
<td>~ 2 days of work</td>
<td>High</td>
</tr>
</tbody>
</table>
Obstacles – patient involvement

- Identification of patients is burdensome and time consuming
- No response by patient organisations or no willingness to participate
- Representation of specific patient group
- Completion of DOICU form; industry funding of patient organisations not always accessible
- Tight timelines of assessments
Healthcare Provider involvement

- **Current involvement:**
  - 2 experts to review draft Project Plan & Draft Assessment Report
    - In almost all assessments, experts were involved

- **Identification of experts is challenging**
  - Conflict of interest
  - Burden of tasks
  - Tight timelines (pharma assessments)

- **Focus on ‘fit-for-purpose’ engagement by EUnetHTA P&C/HCP TG**
  - Discussion of different approaches
    - e.g. flexible involvement, pre-defined questions etc.

- **Planned experts database**
Outlook for stakeholder engagement

- Patient engagement
  - Discussions ongoing to have open call for patient input as a standardized approach for all assessments
    - If needed, to be completed with other preferred methods
    - EUnetHTA patient input template to be created
      - Based on HTAi template
    - Evaluation of patient involvement (questionnaire to patients and patient organisations)
- SOP on identification of stakeholder
- Revised methods for external expert involvement (currently being discussed)
- Working on ‘plain language summary’ for Assessment reports
WP5 – Scientific Advice

Maggie Galbraith, Project Manager WP5A, HAS
Stephanie Said, Project Manager WP5A, G-BA
Current stakeholder involvement – general input, product unspecific

June-July 2018: Public consultation on the procedure and briefing book template for Early Dialogues on Medical Devices

- Comments received from +10 organizations including several EUnetHTA partners and 6 stakeholder organizations (patients and professional organizations)
- Feedback received primarily related to transparency regarding the process, inclusion criteria for external stakeholders, how stakeholders are recruited and the iteration of advice.
- Official launch set for January 2019
Current stakeholder involvement – general input, product unspecific

November-December 2018: Consultation on Registry Quality Standards tool and Vision paper

- Feedback received from 12 HTAb partners, 7 external partners: EMA, 5 professional associations (EAHP, EFPC, EUPHA, ESC, ICON), and industry (COCIR). Additional feedback expected from EURORDIS…

- Many interesting comments that should support next version of the tool:
  - further guidance and requirement related to endpoint,
  - stage and frequency of registry assessment,
  - Sharing of confidential information from the registry for the assessment…

- Update REQueST and Vision paper using stakeholder comments then out to wide public consultation in early 2019.
Further Consultations to come…

<table>
<thead>
<tr>
<th>Strand A: Early Dialogues</th>
<th>Q3 2019 Multi stakeholders consultation</th>
</tr>
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<tbody>
<tr>
<td>Updated ED Procedures for pharma</td>
<td></td>
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<tr>
<td>Updated ED Briefing Book Template</td>
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<tr>
<td>Guidances for patients and HCP contribution for ED</td>
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</table>

<table>
<thead>
<tr>
<th>Strand B: Post-Launch Evidence Generation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Update REQuesST</td>
<td>1Q 2019 Multi-stakeholders</td>
</tr>
</tbody>
</table>
# Current stakeholder involvement – Early Dialogues (Pharma & MD)

Graduated approach to expert contribution

<table>
<thead>
<tr>
<th>Approach</th>
<th>Patient contribution deliverables</th>
<th>Health Care Professional (HCP) contribution deliverables</th>
</tr>
</thead>
</table>
| Approach 1: Individual patient/HCP - interviewed regarding the disease    | • Minutes of the interview  
• Patient contribution visible in final EUnetHTA recommendations  
• Feedback questionnaire                                                | • Minutes of the interview  
• Feedback questionnaire                                                 |
| and their experience                                                     |                                                                                                      |                                                          |
| Approach 2: Approach 1 + discussion with local HTAB regarding submission  | • Minutes of the interview  
• Patient contribution visible in final EUnetHTA recommendations  
• Feedback questionnaire                                                | • Minutes of the interview  
• Feedback questionnaire                                                 |
| file (without applicant)                                                 |                                                                                                      |                                                          |
| Approach 3: Expert; Approach 1 + discussion with all participating         | • Minutes of the interview  
• Share final EUnetHTA recommendations  
• Feedback questionnaire                                                | • Minutes of the interview  
• Feedback questionnaire                                                 |
| HTABs regarding the submission file and participation in the F2F meeting |                                                                                                      |                                                          |
| with the applicant                                                       |                                                                                                      |                                                          |
Current stakeholder involvement – Early Dialogues (Pharma & MD)

Timeline
~ 4,5 months
- D -60 Letter of Intent
- D -30 Draft Briefing Document
- D 0 Final Briefing Document
- D +30 E-Meeting HTAs
- D +60 F2F meeting
- D ~ +75 EUnetHTA final recommendations

- Call for involvement to partners
- Interview & Sharing input
- Possibility of participation
- Feedback questionnaire
Current patient involvement – Early Dialogues

Experiences - systematic approach

13/17 EUnetHTA EDs with patient contribution (~ 75%):

- 7x approach 1: interviews with patients (France, UK, Spain)
- 8x approach 2: interviews with national patient representatives (German patients’ representative involved in any ED in which G-BA participates)
- 4x approach 3: involvement of patient representatives from European patient organizations to overall process
Paradigm Workshop on patient EDs contribution

Workshop last fall with other HTAB and representatives from Paradigm and HTAi PCIG to discuss patients contribution in Eds.

5 members of the EUnetHTA EDWP participated; exchanges demonstrated alignment of the 3 EUnetHTA approached with those of other HTAb

From this workshop, 4 priorities outlined

1. Patient recruitment process
2. Guidance on Patient Interviews
3. Minimum standards framework
4. Rationale for patient involvement in early dialogues
Current stakeholder involvement – Early Dialogues (Medical devices)

Only 1 Early Dialogue performed for Medical Devices so far:

• 4 of 8 participating HTAB included a **clinical expert**; 1 clinical expert participated in the closed HTAb meeting the morning of the F2F
  • 2 did not share the briefing book with the expert (corresponds to approach 1)
  • 2 shared the briefing book with the expert (corresponds to approach 2)
• Expert advice collected from each HTAb shared with other participating HTAb
• Expert contribution not included in the final recommendations
Future stakeholder involvement – Early Dialogues

Patients in Early Dialogues:
Dedicated group of HTABs to refine approach for patient involvement (procedure and tools) and produce guidance document

HCP in Early Dialogues:
Establish systematic approach

WP5 Lead and Co-Lead participation in EUnetHTA internal Patient & Consumer / Health Care Professionals Task Group:
Alignment on general principles on external stakeholder engagement, management of conflict of interest and payment
Thank you

Any questions?
Pharmaceutical EDs July 2017 through Nov 2018

45 Letters of Intent

<table>
<thead>
<tr>
<th>Requests</th>
<th>Therapeutic field (from letter of intent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Auto-immune disease/dysfunction</td>
</tr>
<tr>
<td>17</td>
<td>Cancer</td>
</tr>
<tr>
<td>3</td>
<td>Neurodegenerative disorder</td>
</tr>
<tr>
<td>3</td>
<td>Viral disease</td>
</tr>
<tr>
<td>17</td>
<td>Other</td>
</tr>
</tbody>
</table>

22 Individual Parallel Consultations
Including 1 vaccine
16 Completed
6 On-going

2 SME applicants
3 Orphan drugs
0 ATMP

17 EUnetHTA EDs
(3 Multi-HTA + 14 Consolidated Parallel Consultations (PCC))

6 Cancer
2 Neurodegenerative disorder
1 Viral disease
8 Other

4 withdrawn (by the Applicant, 1 resubmitted and accepted as PCI)
2 declined (procedure not followed; did not meet eligibility criteria for multi-HTA)

6 SME applicants
9 Orphan designations
4 ATMP

14 Completed (as of Nov 2018)