Meeting called by: EUnetHTA-EFPIA
Type of meeting: Face-to-face
Facilitator: EUnetHTA
Chairs: Niklas Hedberg, EUnetHTA (TLV)
Ansgar Hebborn, EFPIA

Attendees

Adam Heathfield | Pfizer  
Adam Parnaby | Celgene  
Adrian Griffin | J&J  
Ali Hussain | ZIN  
Ansgar Hebborn | Roche  
Beate Wieseler | IQWiG  
Chaienna Schreuder | ZIN  
Chantal Bélorgey | HAS  
Chantal Guilhaume | HAS  
Charlie Nicholls | Sanofi  
Douglas Gregory | Amgen  
Edith Frénoy | EFPIA  
Gabriele Kapfer | Bayer  
Gesa Pellier | Novartis  
Ingvil Sæterdal | NIPH  
Irena Guzina | HAS  
Jake Lebiecki | Pfizer  
James Ryan | AstraZeneca  
John Borrill | BMS  
Kalitsa Filioussi | Novartis  
Louise Timlin | Lilly  
Maggie Galbraith | HAS  
Marcus Guardian | ZIN  
Marie Charlotte le Goff | AbbVie  
Mihai Rotaru | EFPIA  
Milena Richter | Sanofi  
Patrice Chalon | KCE  
Patrick Hopkinson | BMS  
Philip Spearpoint | Vifor Pharma  
Pilar Martin Vivaldi | NOMA  
Stephanie Lane | MSD  
Pierre Le Gal | Sanofi  
Zoe Garrett | NICE

Minutes

Agenda item #1 Welcome, introductions, and adoption of the agenda  
Presenter: Niklas Hedberg, EUnetHTA  
Ansgar Hebborn, EFPIA

Summary

a) Introduction of meeting co-chairs
b) Tour de table

Agenda item #2 Update on governance changes in EUnetHTA  
Presenter: Niklas Hedberg, EUnetHTA

Summary

The Chair of the EUnetHTA Executive Board presented an overview of governance changes within EUnetHTA. This primarily revolved around the addition of subgroups – groups that specifically work on cross-work package issues and prepare recommendations for the Executive Board – into the project’s governance structure. For more information, please see the accompanying slide deck.
Agenda item #3  Refined Joint Assessment Production Process  Presenter: Various

Summary
a)  Refined Joint Assessment Production Process:
   - Update on outcome-feedback workshop | Chaienna Schreuder, EUnetHTA
     - ZIN (WP4) provide a brief update on the outcome-feedback workshop held recently.
   - Interface with EMA - Experience and fine-tuning | Ansgar Hebborn, EFPIA
   - General Discussion | Michael Berntgen, EMA

b)  Submission requirements on citations and publication policy:
   - Outline of requirements | Chaienna Schreuder, EUnetHTA
   - Definition & examples of Academic Confidence and Commercially Sensitive Information | CH
     - There is some disagreement over the extent to which exceptions can be made in citing data.
     - Work in this area is noted as being of particular interest to smaller pharmaceutical companies.
   - General Discussion

c)  The 2019 EUnetHTA Prioritisation List:
   - Discussion of results | Pilar Martin, EUnetHTA
     - NOMA briefly recap results following the second rendition of the EUnetHTA Prioritisation List.
   - Feedback from industry | Adam Parnaby, EFPIA
     - Industry representatives suggest that when putting together an EPL, companies would be willing to comment
during the first review round as they may be able to indicate which compounds may not be relevant at a very
early stage (if a third rendition is pursued).
     - EUnetHTA informs EFPIA that although there may not be an EPL.3, methodology followed for the first two
   renditions will be very similar for potential future situations.
     - EFPIA notes that it would be useful to know why certain topics on the EPL are more important than others
   (and vice versa).
     - EFPIA would like to scope the possibility of having the particular set of minutes which describes the key ideas
   floated during the industry feedback meeting.
   - General Discussion

Action items
- EUnetHTA to explore potentially setting up a committee on
  evaluating potential exceptions to citing commercially and
  academically sensitive information. EFPIA representative
  express their willingness to work on this as a joint initiative.
- EFPIA to consider sharing real world examples as a follow-up
  to the slide on the topic of confidentiality considerations.
- EFPIA would like to scope the possibility of having the
  particular set of minutes which describe the key ideas
  floated during the industry feedback meeting, and ZIN WP4 will
  consider request.

Agenda item #4  Guidelines and SOPs (WP6)  Presenter: Various

Summary
a)  Update on SOPs and guidelines | Beate Wieseler, EUnetHTA
   IQWIG provide a brief update on the progress and status of SOP development within EUnetHTA.

b)  Methodological review of clinical HTA guidelines | Patrice Chalon, EUnetHTA
   Stakeholders are now informed in advance of forthcoming public consultations. A structured feedback form for published
guidelines is available on the EUnetHTA website.

c)  General Discussion | Adam Parnaby/ James Ryan, EFPIA

Action items
- EFPIA to indicate high priority reflections following their

<table>
<thead>
<tr>
<th>Agenda item #3</th>
<th>Refined Joint Assessment Production Process</th>
<th>Presenter: Various</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Summary</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a)  Refined Joint Assessment Production Process:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Update on outcome-feedback workshop</td>
<td>Chaienna Schreuder, EUnetHTA</td>
<td></td>
</tr>
<tr>
<td>- Interface with EMA - Experience and fine-tuning</td>
<td>Ansgar Hebborn, EFPIA</td>
<td></td>
</tr>
<tr>
<td>- General Discussion</td>
<td>Michael Berntgen, EMA</td>
<td></td>
</tr>
<tr>
<td>b)  Submission requirements on citations and publication policy:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Outline of requirements</td>
<td>Chaienna Schreuder, EUnetHTA</td>
<td></td>
</tr>
<tr>
<td>- Definition &amp; examples of Academic Confidence and Commercially Sensitive Information</td>
<td>CH</td>
<td></td>
</tr>
<tr>
<td>- There is some disagreement over the extent to which exceptions can be made in citing data.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Work in this area is noted as being of particular interest to smaller pharmaceutical companies.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- General Discussion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c)  The 2019 EUnetHTA Prioritisation List:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Discussion of results</td>
<td>Pilar Martin, EUnetHTA</td>
<td></td>
</tr>
<tr>
<td>- Feedback from industry</td>
<td>Adam Parnaby, EFPIA</td>
<td></td>
</tr>
</tbody>
</table>
|   - Industry representatives suggest that when putting together an EPL, companies would be willing to comment
during the first review round as they may be able to indicate which compounds may not be relevant at a very
early stage (if a third rendition is pursued). | | | |
|   - EUnetHTA informs EFPIA that although there may not be an EPL.3, methodology followed for the first two
   renditions will be very similar for potential future situations. | | | |
|   - EFPIA notes that it would be useful to know why certain topics on the EPL are more important than others
   (and vice versa). | | | |
|   - EFPIA would like to scope the possibility of having the particular set of minutes which describes the key ideas
   floated during the industry feedback meeting. | | | |
|   - General Discussion | | | |
| **Action items** | | | |
| ✓ EUnetHTA to explore potentially setting up a committee on
  evaluating potential exceptions to citing commercially and
  academically sensitive information. EFPIA representative
  express their willingness to work on this as a joint initiative. | EUnetHTA Secretariat | Q1, 2020 |
| ✓ EFPIA to consider sharing real world examples as a follow-up
  to the slide on the topic of confidentiality considerations. | EFPIA | Q1, 2020 |
| ✓ EFPIA would like to scope the possibility of having the
  particular set of minutes which describe the key ideas
  floated during the industry feedback meeting, and ZIN WP4 will
  consider request. | ZIN (WP4) | Q1, 2020 |

<table>
<thead>
<tr>
<th>Agenda item #4</th>
<th>Guidelines and SOPs (WP6)</th>
<th>Presenter: Various</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Summary</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a)  Update on SOPs and guidelines</td>
<td>Beate Wieseler, EUnetHTA</td>
<td></td>
</tr>
<tr>
<td>IQWIG provide a brief update on the progress and status of SOP development within EUnetHTA.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b)  Methodological review of clinical HTA guidelines</td>
<td>Patrice Chalon, EUnetHTA</td>
<td></td>
</tr>
</tbody>
</table>
|   Stakeholders are now informed in advance of forthcoming public consultations. A structured feedback form for published
guidelines is available on the EUnetHTA website. | | | |
| c)  General Discussion | Adam Parnaby/ James Ryan, EFPIA | | |
| **Action items** |                           |                    |
| ✓ EFPIA to indicate high priority reflections following their | EFPIA | Q1, 2020 |
Action items

- Presentation on clinical HTA guidelines.
- EUnetHTA to explore whether a specific meeting on the reflections presented on methodological guidelines would be appropriate.

<table>
<thead>
<tr>
<th>Agenda item</th>
<th>Action</th>
<th>Responsible</th>
<th>Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>#5</td>
<td>Evidence Generation (WP5)</td>
<td>Presenter: Margaret Galbraith, HAS Irena Guzina, HAS</td>
<td></td>
</tr>
</tbody>
</table>

Summary

a) Update on Early Dialogues and PLEG project

HAS provide an update on the number of Early Dialogue requests received and processed since the beginning of the Joint Action. The results of ongoing PLEG pilots are also briefly recapped, the presentation focuses on the evidence gaps table to be included in REA reports. Possibilities of EFPIA involvement on PLEG are discussed.

b) General Discussion

Action items


<table>
<thead>
<tr>
<th>Agenda item</th>
<th>Action</th>
<th>Responsible</th>
<th>Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>#6</td>
<td>Update from DG SANTE, European Commission</td>
<td>Presenter: Flora Giorgio, DG SANTE</td>
<td></td>
</tr>
</tbody>
</table>

Summary

The European Commission shares a short update that includes the topics of high scientific quality and transparency, the main areas of joint work, and an update on the timeline of progress.

Agenda item #7

Update on EMA-EUnetHTA collaboration

| Presenter: | Michael Berntgen |

Summary

EUnetHTA can cite CHMP final AR and draft SmPC following new confidentiality arrangement with EMA.

Agenda item #8

Summary of decisions, actions, and closing remarks

| Presenter: | Niklas Hedberg, EUnetHTA Ansgar Hebborn, EFPIA |

Summary

The chairs conclude the meeting.
Other Information

Apologies:

Adam Heathfield | Pfizer
Patrick Hopkinson | BMS