EUnetHTA- EFPIA Technical Meeting

SUMMARY AND OVERVIEW OF ACTION POINTS

2 December 2019
12:00- 18:15 CET
French National Authority for Health 5, Avenue du Stad
Cedex
France

Meeting called by: EUnetHTA-EFPIA

Type of meeting: Face-to-face

Facilitator: EUnetHTA

Chair/s: 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
Niklas Hedberg |EUnetHTA
Patrice Chalon |KCE
Patrick Hopkinson |BMS
Philip Spearpoint |Vifor Pharma
Pilar Martin Vivaldi |NOMA
Stephanie Lane |MSD
Sylvie Duclaux |Servier
Tuomas Oravilahti | Fimea
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, EFIPIA
  - 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	**Responsible**	**Deadline**
✓ 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

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	**Responsible**	**Deadline**
✓ EFPIA to indicate high priority reflections following their	EFPIA	Q1, 2020

Action items	Responsible	Deadline
presentation on clinical HTA guidelines. ✓ EUnetHTA to explore whether a specific meeting on the reflections presented on methodological guidelines would be appropriate.	EUnetHTA Secretariat	Q1, 2020

Agenda item #5 Evidence Generation (WP5) **Presenter:** Margaret Galbraith, HAS
Irena Guzina , HAS

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	Responsible	Deadline
✓ EUnetHTA to provide an update on the Early Dialogue Financing Mechanism in January 2020.	EUnetHTA (HAS)	Q1, 2020

Agenda item #6 Update from DG SANTE, European Commission **Presenter:** Flora Giorgio, DG SANTE

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