EUnetHTA-EFPIA Technical Meeting

A summary of the meeting

01-12-2020 | 13:00-15:00 CET
Microsoft Teams

Meeting called by: EUnetHTA-EFPIA

Type of meeting: Microsoft Teams e-meeting

Facilitator: EUnetHTA Secretariat (ZIN)

Chair: Niklas Hedberg, TLV
Ansgar Hebborn, EFPIA (Roche)

Participating EUnetHTA Members
Agnese Cangini, AIFA | Italy
Ali Hussain, ZIN | The Netherlands
Alric Ruether, IQWiG | Germany
Anna Zaremba, AOTMiT | Poland
Anne Willemsen, ZIN | The Netherlands
Annette Abraham, GBA | Germany
Beate Wieseler, IQWIG| Germany
Bjørn Oddvar Strøm, NOMA | Norway
Catharina Helmink, ZIN | The Netherlands
Cecilia Tollin, TLV | Sweden
Chaienna Schreuder, ZIN | The Netherlands
Chantal Guilhaume, HAS | France
Claudia Wild, AIHTA | Austria
Lauren Law, ZIN | The Netherlands
Maggie Galbraith, HAS | France
Marcus Guardian, ZIN | The Netherlands
Nick Crabb, NICE | United Kingdom
Niklas Hedberg, TLV | Sweden
Pilar Martin Vivaldi, NOMA | Norway
Sari Susanna Ormstad, NIPHNO | Norway
Veronika Deák, GBA | Germany
Zoe Garrett, NICE | United Kingdom

Participating Industry Members
Adam Parnaby, BMS
Agnes Kisser, Pfizer
Andras Borsi, Johnson & Johnson
Ansgar Hebborn, Roche
Edith Frenoy, EFPIA
Gesa Pellier, Novartis
Jake Liebiecki, Pfizer
James Ryan, AstraZeneca
Kalitsa Filioussi, Novartis
Mihai Rotaru, EFPIA
Pieter Drost, AbbVie
Stephanie Lane, MSD
Sylvie Duclaux, Servier
Tina Taube, VFA

Participating European Commision Members
Flora Giorgio, DG SANTE
Ioana Siska, DG SANTE
Martina Ciccarello, DG SANTE

Participating EMA Members
Michael Berntgen, EMA

Summary

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

The Chairs welcomes EUnetHTA and EFPIA members to the meeting.

Agenda item #2 An update from EUnetHTA **Presenter:** Various

a) 2020: A year of achievements and challenges | Niklas Hedberg, EUnetHTA

The Chair of the EUnetHTA Board shares an update on the past year in EUnetHTA. EUnetHTA was planned to be a four-year project, running from June 2016 to May 2020. However before coming to an end, EUnetHTA applied for and was granted a one-year prolongation and the project will hence run until May 31, 2021.

Given the current situation, the Executive Board has in its May meeting ensured there are the necessary financial funds to continue through the prolongation year and decided that the prolongation activities shall focus on four main categories:

1. Coordination of vital functions of the cooperation.
2. Deliverables stated in the Grant Agreement that are not yet due (such as the final evaluation report and preparing a Future Model of Cooperation on HTA).
3. The main output deliverables in the Grant Agreement – Joint Assessments and Early Dialogues.
4. Activities related to COVID-19.

On a proposal of the European Commission the Executive Board in its May meeting supported the suggestion to prioritise COVID-19 related activities during the remaining 12 months of EUnetHTA JA3.

That decision allowed EUnetHTA:

- To support the fact that the concept of rolling collaborative reviews could be used.
- To work in activity clusters when applicable.
- To adopt a common reporting structure and monthly updates for COVID-19-related activities to make thorough follow up possible.

b) Collaboration with EMA | Michael Berntgen, EMA

EMA and EUnetHTA have jointly identified several areas as the focus of their European regulatory-HTA collaboration during 2017-2021. The work plan is complementary to actions foreseen in EUnetHTA Joint Action 3, which runs until 2021 and the EMA/EUnetHTA bilateral meetings are the platform for oversight of the delivery of the work plan.

The joint EMA/EUnetHTA work plan guides the collaboration towards tangible outcomes. Apart from product-specific engagement there are several items that allow sharing methodologies and practices.

A technical report about the delivery of the current work plan 2017-2021 will be prepared in 2021.

Agenda item #3 An update from DG SANTE **Presenter:** Flora Giorgio, DG SANTE (European Commission)

An update from the European Commission is provided. The main topics include:

- EC Proposal - state of play
- HTA-related Commission initiatives
- EU cooperation on HTA beyond May 2021

Agenda item #4 Session 1: Work on combatting COVID-19 **Presenter:** Claudia Wild, AIHTA
Anne Willemsen, ZIN

<u>EUnetHTA: Our joint response to COVID-19</u>

- Rolling Collaborative Reviews | Claudia Wild, AIHTA

An update is provided by AIHTA on Rolling Collaborative Reviews:

- The purpose of RCRs are to inform health policy at the national, regional, and European levels at an early stage in the lifecycle of therapies, of which interventions are currently undergoing clinical trials.
- To monitor permanently – in the format of a living document – potential therapies against COVID-19.
- To support preparations for an evidence-based purchasing of regional/national health politicians, if necessary.

The scope of the RCR is of a descriptive nature.

These EUnetHTA RCRs are not meant to substitute a joint REA adhering to the agreed procedures, aiming at critical appraisal of the clinical evidence submitted for approval.

- Rapid Collaborative Reviews | Anne Willemsen, ZIN

ZIN shares an update on Rapid Collaborative Reviews. Two important lessons learned are recapped. These include:

1. Fast reactions need flexibility in methods and reporting.
2. Realistic estimation of coordination resources to avoid international redundancies.

Some brief questions and answers are exchanged on the uptake and implementation of Rapid and Rolling Collaborative Reviews. EFPIA asks EUnetHTA how it sees the role of RWE in the ongoing pandemic? How can organisations speed up learning from RWE and how is EUnetHTA reacting to it?

EUnetHTA responds. There are a number of voices in the EU who are pragmatically seeking evidence generation. However this is not consistent and Member States are designating different levels of importance to it. Further discussion needs to take place on an EU level to try and centralise and coordinate RWE needs across Member States.

Both sides agree on the importance of RWE.

On the subject of what has been learnt during the COVID-19 pandemic that could be applied to a non-COVID-19 scenario:

- EUnetHTA notes that flexibility is key and is one of the most important lessons of the pandemic. This is as well as the need to be more pragmatic and deliver both speedy and high-quality products.
- EUnetHTA also notes that conducting a review without manufacturer involvement also led to a lot of internal learnings that are still being reflected upon.
- EFPIA note that the pandemic has reiterated the need to be flexible and collaborative. The need for accelerated processes is something EFPIA has also encountered.

Agenda item #5 Session 2: Joint Production (WP4) **Presenter:** Anne Willemsen, ZIN
Ansgar Hebborn, EFPIA

A discussion on academic confidence and commercially sensitive information ensues.

<u>EUnetHTA: Status update and reflections on the Industry Feedback Meeting</u>

ZIN shares an update on the future of Joint Assessments. The current numbers are as follow:

- Published: 13 PTJA
- 2 Rapid Collaborative Review on COVID-19
- Ongoing: 3 PTJA, 15 Rolling Collaborative Reviews → monthly basis.

A short reflection on the industry feedback meeting is also provided.

<u>EFPIA: Industry experience from recent Joint Action 3 assessments and recommendations</u>

EFPIA shares recommendations for the uptake of the joint assessments at a national level.

Agenda item #6	Session 3: Evidence Generation (WP5)	**Presenter:**	Maggie Galbraith, HAS Chantal Guilhaume, HAS Gesa Pellier, Novartis

EFPIA again reiterates the need to enhance Early Dialogue capacity where possible.

EUnetHTA notes that while it recognises industry needs, and agrees that capacity in general is indeed an issue, industry partners must understand that capacity within HTA organisations is limited and is stretched more so because of COVID-19. However, this should not hinder collaboration on methodology to enhance the common processes which benefit both sides.

EUnetHTA: Modifications to the Early Dialogues procedure and PLEG

Early Dialogues
HAS discusses the modifications to the Early Dialogue Request process and procedure, noting a revised Early Dialogue procedure, making it simplified and shorter. They also share an overview of patient involvement in EUnetHTA Early Dialogues along with an overview of Early Dialogues since 2017. Finally, a qualitative Analysis of the first 21 EUnetHTA Early Dialogues is shared.

PLEG Pilots
An update on PLEG activities is shared. This includes a registry Evaluation and Quality Standards Tool (REQueST), examples of REQueST use on an EU level and the ongoing EUnetHTA PLEG pilots arising from HTA.

EFPIA: Industry need for Early Dialogue capacity enhancement

EFPIA shares information on Early Dialogues. An essential advice to manufacturers on optimising evidence generation plans to satisfy the needs of both HTA bodies and regulators. It is also noted that feedback from the major HTA bodies during the ED procedures will be essential in light of the forthcoming EU HTA regulation.

Agenda item #7	Session 4: Methodological guidelines	**Presenter:**	Adam Parnaby, BMS James Ryan, AstraZeneca

EFPIA: Methodological review of clinical HTA guidelines and experience from recent assessments

EFPIA goes through different viewpoints from HTA guidelines and experiences.

Agenda item #8	Session 5: Future Model of Collaboration on HTA	**Presenter:**	Zoe Garrett, NICE

NICE shares an update on the FMC-HTA White Paper. This final stage of the work has been taken into the Executive Board and the original task group has been stood down. The White Paper will be based on the roadmap and also incorporates findings from existing or in progress documents produced by EUnetHTA. The aim is to compile the outputs of EUnetHTA JA3 into a single document that, using a framework, describes the way we worked, what we have achieved, what we have learnt and what we recommend for the future.

Signposting for those taking HTA cooperation forward:

- The most relevant documents and tools from JA3.
- The areas of alignment and agreement.
- The areas of disagreement and reasons why.
- The areas requiring further work.

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Action items	**Responsible**	**Deadline**
✓ EUnetHTA Secretariat to ensure EFPIA and its partners are included in the consultation on the FMC-HTA White Paper.	ZIN (WP1)	Q2 2021
✓ EFPIA to share the most up-to-date company feedback report	EFPIA	Q1 2021

Action items	Responsible	Deadline
and recommendations with the EUnetHTA Secretariat (who will then disseminate it amongst partners).		

Agenda item #9 An outlook to what's next **Presenter:** Marcus Guardian, ZIN

ZIN shares a brief update on what is to come in the next year and thanks all participants for participating in all of the past EUnetHTA-EFPIA technical meetings.

Agenda item #10 Any other business **Presenter:** Niklas Hedberg, TLV
Ansgar Hebborn, EFPIA

No any other business is raised.

Agenda item #11 Summary of decisions, actions and closing remarks **Presenter:** Niklas Hedberg, TLV
Ansgar Hebborn, EFPIA

With no further points to discuss, the Chair ends the meeting.