



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA-EMA Bilateral

28-04-2021 | 10:00-12:00 CET

Meeting called by: EUnetHTA Executive Board

Type of meeting: Microsoft Teams e-meeting

Facilitator: EUnetHTA Secretariat (ZIN)

Chair: Niklas Hedberg, TLV
Michael Berntgen, EMA

Attendees: EUnetHTA Members

Alex Correia, INFARMED
Anna Zaremba, AOTMIT
Anne Willemsen, ZIN
Annette Abraham, GBA
Beate Wieseler, IQWIG
Catharina Helmink, ZIN
Chantal Belorgey, HAS
Chantal Guilhaume, HAS
Daniel Ritter, GBA
Iñaki Imaz Iglesia, ISCIII
Krystyna Hviding, NOMA
Lauren Law, ZIN
Luciana Ballini, RER
Marcus Guardian, ZIN
Niklas Hedberg, TLV
Regina Skavron, GBA

EMA Members

Ana Hidalgo-Simon, EMA
Bruno Sepodes, EMA
Dominik Karres, EMA
Francesco Pignatti, EMA
Gunter Egger, EMA
Jordi Llinares Garcia, EMA
Kristina Larsson, EMA
Laurent Brassart, EMA
Lise Flaunoe, EMA
Maria Mavris, EMA
Michael Berntgen, EMA
Silvy Da Rocha Dias, EMA
Thorsten Olski, EMA
Xavier Kurz, EMA

European Commission Members

Flora Giorgio, DG SANTE
Martina Ciccarello, DG SANTE

Minutes

Agenda item #1 Introduction to the day and adoption of the draft agenda **Presenter:** Niklas Hedberg and Michael Berntgen

Discussion:

The meeting is opened by a welcome by co-chairs, Niklas Hedberg and Michael Berntgen. Both praised the very open and fruitful collaboration, as both partners have been able to exchange perspectives and collaborate on a number of topics of mutual interest. This meeting will be the concluding EMA-EUnetHTA bilateral under the current framework, since the collaboration originally started in 2010. These meetings have built up mutual trust and understanding in each other's work, which will lay foundation for future work.

The draft agenda was adapted for timings, so those who are presenters can join.

Agenda item #2 Conclusion of the EMA/EUnetHTA work plan 2017–2021 **Presenter:** Various

Discussion:

For each of the following topics, please refer to the EMA-EUnetHTA Technical Reporting of the joint Work Plan 2017-2021.

- a) Early Dialogue / Scientific Advice | Thorsten Olski
- b) Late dialogues/ peri-licensing advice | Thorsten Olski, Xavier Kurz
- c) Information exchange between regulators and HTA bodies | Michael Berntgen
- d) Methodologies to identify the treatment eligible population | Laurent Brassart, Dominik Karres
- e) Significant benefit vs. added therapeutic value for orphan medicines | Kristina Larsson
- f) Patient and clinical engagement | Maria Mavris
- g) Shared understanding of methodological approaches for design, analysis and interpretation of clinical trials and observational studies | Beate Wieseler
- h) Population-specific or Intervention-specific areas | Gunter Egger, Beate Wieseler, Ana Hidalgo Simon
- i) Unmet medical need (UMN) and therapeutic innovation for priority setting | Jordi Llinares Garcia, Michael Berntgen

Agenda item #3 Update from DG SANTE on activities related to the EMA/EUnetHTA collaboration **Presenter:** Flora Giorgio

Discussion:

The European Commission provided an update on the proposal for the HTA regulation that is being discussed in trilogues with the co-legislators since end of April 2021. The Commission also mentioned that the EMA-EUnetHTA work plan and collaboration were essential to provide information and the technical basis for the future HTA regulation. The work plan has provided input to the new framework of EU cooperation on HTA. Co-legislators are currently agreeing on provisions related to the implementing powers of the Commission, allowing it to adopt an implementing act to set up procedural rules for the exchange of information between EMA and the future Coordination Group of HTA. The future regulation will provide the legal basis for a sustainable cooperation between regulators and HTAs at European level.

Agenda item #4 Next steps – technical reporting **Presenter:** Michael Berntgen, Anne Willemsen

Discussion:

To conclude the EMA-EUnetHTA collaboration as laid-out in the joint work plan 2017-2021, a Technical Report is being developed. The updates as given in this meeting will be reflected in the Technical Report and will be shared with EMA and EUnetHTA for final review

Action:

- Finalize the Technical Report of the 2017-2021 EMA-EUnetHTA work plan.

Agenda item #5 Concluding activities of EUnetHTA JA3 **Presenter:** Marcus Guardian

Discussion:

The EUnetHTA Secretariat echoed the appreciation and thanks for the fruitful collaboration between EUnetHTA and EMA over the last decade.

EUnetHTA JA3 will conclude by end of May 2021, and all its deliverables will have been achieved. The EUnetHTA HTA White Paper being one of the key deliverables. EUnetHTA now tries to envision the work of the HTA collaboration in the interims

period between the end of Joint Action 3 and the entry into force and application of the EU HTA Regulation. This transition period will potentially come with some uncertainties in relation to continued HTA collaboration. The members of EUnetHTA JA are envisioning to continue collaborating and are currently looking into creating a framework that compensates for the loss of the legal and financial foundation the Joint Actions have provided.

We try to bring the network together in new form, and are defining goals and objectives for this collaboration for the next few years especially considering the upcoming regulation and all the activities that will be regulated via that.

The EUnetHTA Heads of Agencies has been created in JA3 and the group has decided to continue its function and body. It is now creating its own independent framework with the aim to prepare its members the future EU HTA system envisioned in the HTA Regulation.

There is clear commitment from all sides to seek continuing the extremely successful collaboration on joint scientific consultations (JSC). With entry into force of the Regulation the relevant framework for collaboration on joint clinical assessments (JCA) will be provided, in the interim period all sides agree to equally ensure that collaboration on JCA will be mutually supported.

Agenda item #6	"A toast to 11 years of collaboration"	Presenter:	Niklas Hedberg and Michael Berntgen
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Discussion:

The chairs conclude the meeting with "A toast to 11 years of collaboration".

The work as presented under the Work Plan has paved the way also for future cooperation, it is conclusion of a period of collaboration under a certain framework, namely Joint Action, and we look forward to the next phase of cooperation/collaboration.

The review of the achievements also identified items for future collaborative work, such as methodologies and scientific work, and a list of priority areas for future collaboration between regulator and HTA would be beneficial. Such plan would need to be flexible, so that work can move into the official legislative framework, once adopted.

EUnetHTA will keep connected as a network, which is very important also for EMA to be able to reach out and invite people for for example webinars or workshops.

There is a joint commitment to move forward and work together, and on these short intermit timeframes and communication.

Action:

- EUnetHTA and EMA to establish priority areas for future collaboration between regulators and HTAs at European level.

Other Information

Apologies:

N/A

Special notes:

N/A

Key:

Not applicable.