



11 July 2014
EMA/299386/2014

Final Minutes of EMA/EUnetHTA meeting

15 May 2014 – chaired by Hans-Georg Eichler and Finn Børlum Kristensen

Role	Name
Chairs	Hans-Georg Eichler and Finn Børlum Kristensen
Present:	<p><u>EMA</u>: Michael Berntgen, Katerina Fameli, Xavier Kurz, Jordi Llinares, Jane Moseley, Francesco Pignatti, Tomas Salmonson, Almath Spooner, Spiros Vamvakas</p> <p><u>EUnetHTA</u>: Luciana Ballini, Lidia Becla, Ana Brzezinska, Agnese Cangini, Julia Chamova, Elisabeth George, Wim Goettsch, Tom Jefferson, Marianne Klemp, Christoph Künzli, François Meyer, Alric Rütter, Beate Wieseler, Eva Zebedin-Brandl</p> <p><u>European Commission</u>: Flora Giorgio</p>

Item	Preliminary draft agenda	Name
1.	Welcome by the co-chairs	Hans-Georg Eichler (EMA) Finn Børlum Kristensen (EUnetHTA)
2.	Adoption of draft agenda, review of minutes from last meeting and update on action points	All
3.	EC update on the development of HTAN	Flora Giorgio (EC)
4.	Discussion theme: The roles of regulation and HTA in the life-cycle of a drug from innovation to healthcare practice / obsolescence (including request from EUnetHTA regarding REA pilots)	Hans-Georg Eichler, Spiros Vamvakas, Michael Berntgen (EMA) and Finn Børlum Kristensen, François Meyer, Wim Goettsch, Luciana Ballini (EUnetHTA)
5.	"Effects tables" - First feedback from the joint recent exchange	Tomas Salmonson, Francesco Pignatti (EMA), and Wim Goettsch, Beate Wieseler (EUnetHTA)
6.	Feedback on the reflection paper re the indication wording of antidiabetic medicines	Wim Goettsch (EUnetHTA)
7.	Initial experience with patient interactions (eliciting patient values, preferences)	Francesco Pignatti (EMA)
8.	IMI topics of interest	Hans-Georg Eichler (EMA)
9.	Three-year Work Plan implementation update	All



Item	Preliminary draft agenda	Name
10.	Any other Business: - EUnetHTA Conference Update	EUnetHTA
11.	Closing remarks	Hans-Georg Eichler (EMA) Finn Børllum Kristensen (EUnetHTA)

1. Welcome by the co-chairs

This was the eighth meeting between the European Medicines Agency (EMA) and representatives from the European Network for Health Technology Assessment (EUnetHTA).

2. Adoption of draft agenda & update on action points from the last meeting

The draft agenda was adopted without changes. The action points from the last meeting were reviewed in the context of the subsequent discussion items including the 3-year work programme.

3. EC update on the development of HTAN

The EC provided an update on the development of the HTA network. The outcome of the second meeting (7th April) was the agreement on chapter 1 and 2 of the strategy paper (including discussions with stakeholders). Also preliminary discussions were held on chapter 3. Key messages of the strategy paper include recognition of a new phase of cooperation (through pilots), broad scope including a full range of technologies, uptake of joint work in national activities, life cycle approach with exploring more synergies with regulators and payers, as well as the development of a sustainable cooperation.

The next working group meeting on 12th June will further develop chapter 3, with the aim of coming to a network consultation for July/August, and EUnetHTA recommendations on next steps. Agreement on the paper is aimed for the meeting on 29th October. Also planned are discussions and agreement on priorities for Joint Action 3 as well as preliminary discussion on conditions to facilitate take up and reuse of joint work and assessment results at national level.

Action point: none

4. Discussion theme: The roles of regulation and HTA in the life-cycle of a drug

EUnetHTA proposed to map the activities of HTA and regulatory along the timelines of the life-cycle to identify areas of commonality/interaction. With such overview it is expected to identify areas for strengthened corporation and collaboration.

In terms of scientific advice / early dialogue, the EMA presented as an example the qualification advice and options on novel clinical endpoints to explore interest on a case by case basis to collaborate on the development of scales to define disease activity in specific therapeutic areas. In the discussion EUnetHTA representatives voiced support for such collaboration in principle even though it needs to be seen how this can be translated into concrete advice and also how to see whether to agree. There is a high need of measurement scales to ascertain the impact on the clinical outcome. In the context of multiple scales (e.g. for MS) it would be beneficial to identify which of these are considered workable for both regulators and HTAs. Early involvement in such activities seems reasonable. Such involvement

can also address concerns from some HTA organisations that this might lead to new surrogate endpoints that are of no use for HTA and only drive faster developments. It was also noted that patients and clinicians will be asked to be involved and that HTA organisations and regulators will likely work with the same pool of external experts / stakeholders. The experience from parallel advice for regulatory and HTA aspects could be used as framework to address the need to get a view whether something can be of use for both regulators and HTAs. In this context EUnetHTA noted that what is coming out from parallel scientific advice is solely reflecting the view of HTA organisations that are participating, i.e. there is not a common view available in the HTA community. It was stressed to ensure that the opinions are being published.

Around the licensing phase, EUnetHTA approached EMA to receive the CHMP assessment report before publication of the EPAR. This is because experience so far showed that even if companies are willing to provide the report, they were sometimes only provided with four weeks delay. As highlighted in previous discussions, EMA stated the challenges around providing these reports. Alternatives including consent from the company or release of an already prepared EPAR before Commission Decision could be explored. EMA would certainly be willing to inform companies of ongoing MAA procedures about the REA pilots and the possibility for participation. Finally with regard to upcoming CHMP opinions, reference was made to the publication of agendas and minutes. EMA and EUnetHTA, in collaboration with the EC, will continue exploring the options with the aim to facilitate information exchange.

In terms of additional data collection, the new framework for post-authorisation efficacy studies was outlined as well as the upcoming work on a scientific guideline. It was confirmed that this framework is meant to be used exceptionally and should not lead to premature licensing. Yet one might wish to explore how in such context the study programme can be designed to also meet data needs in the context of HTA. There is an opportunity for open dialogue on the imposed studies but also on other studies listed in the RMPs, collaboration at an early stage can be of help. The topics will be discussed further at the next meeting, also taking into consideration the ENCePP experience.

Action points:

- Continue sharing information and seek advice mutually on specific activities in early dialogues/scientific advice (EMA/EUnetHTA), specific opportunities for cooperation on the surrogate endpoints subject to be explored, EUnetHTA to be invited to attend EMA scientific advices involving HTA bodies as observer.
- EMA to explore a framework for providing EPARs to EUnetHTA before Commission Decision and for informing companies on opportunity to participate in the REA pilots performed by EUnetHTA
- Additional data collection to be on the next meeting agenda (December 2014)

5. Effects tables feedback

Following from the discussions at the last meeting, an update was provided on the working meeting in March with representatives from EMA/CHMP and EUnetHTA. This exchange allowed for a reflection on use of the effects tables by various organisations followed by a general discussion on the data display. The outcome from this meeting is currently being considered by the EMA/CHMP as part of the ongoing pilot on the use of effect tables in the context of Marketing Authorisation application procedures. EUnetHTA representatives confirmed that the challenges are the same including the communication of the outcome using this tool and the link to the overall discussion throughout the assessment process. A list of tables currently produced in the EMA pilot has been provided to EUnetHTA. Follow-up discussions based on the experience with the pilots are needed.

Action point:

- Update on the experience with the pilots at the next meeting (December 2014)

6. Reflection paper feedback

The EMA/CHMP provided an update on the ongoing public consultation concerning the wording of the indication for medicinal products for treatment of type 2 diabetes, for which comments from EUnetHTA organisations are invited. The current wording in section 4.1 of the Summary of Product Characteristics for recently approved centrally authorised medicinal products intended for the treatment of patients with type 2 diabetes contains 2 sections addressing mono- and combination therapy. With the reflection paper the CHMP outlines considerations based on which a more general, simplified wording for these products could be considered as a more relevant way of reflecting the intended use. All available data would be reflected in the SmPC and based on this information it would be up to the prescriber to use the product in line with treatment algorithms. However, it is recognized that a fully simplified and harmonized indication wording may have drawbacks and may lead to misunderstandings and therefore several questions have been put for a public consultation.

The different HTA organisations concurred that it would be very important to provide comments reflecting the individual perspective. A EUnetHTA position cannot be obtained at this point. Questions were raised whether this would lead to lower evidence requirements, gaps in study programmes, and difficulties to have a defined patient population. EMA/CHMP clarified that it would be very important to get the different viewpoints into the discussion. The EUnetHTA secretariat will therefore encourage its member organisations to provide comments on the reflection paper. Furthermore, SmPC/labelling aspects should be a discussion item for future meetings.

Action point:

- EUnetHTA Secretariat to encourage EUnetHTA partners to provide feedback to the public consultation

7. Initial experience with patient interactions

The EMA presented a recent case study with PCWP representatives on decision making where a patient jury was successful in building two multi-criteria decision analysis models in a short time with minimal methodological guidance. This experience included very informative discussions about weights, and a patient feedback saying that whilst this was a difficult exercise it was very interesting and allows for better engagement.

Different views were expressed, including the importance to hear about the patient, the usefulness of expert panels as a general advising group on patient's views (experience versus expertise), the best stage of engagement (assessment versus appraisal), and the need for further research in this field.

Action point: none

8. IMI topics of interest

A preliminary exchange was held with regard to engagement of EMA and EUnetHTA in IMI projects, based on concrete proposals as well as first experiences. Clinical trial data sharing is a particular topic of common interest including how to anonymise patient data, set standards and rules for CT data sharing within the scientific community, IT/ legal/governance/IP aspects as well as IPD data storage, handling and sharing. This topic will be followed up by EUnetHTA. Other topics, such as patient

involvement in informing clinical trial design or in decision making, have also been found of potential mutual interest and will be explored further.

Action point:

- EUnetHTA to review the list of potential topics for projects and indicate where it might consider engagement

9. Three-year Work Plan implementation update

The activities related to the 3-year work plan have been reviewed. It was noted that the first disease-specific guideline developed under WP 7 will be for osteoarthritis; exact timelines are to be confirmed. For the next meeting a discussion on the development of orphan drugs should occur in view of current developments of MOCA.

Action point:

- Follow-up on the potential EMA contribution to the development of the first disease-specific guideline
- Orphan drugs (MOCA developments) to be put on the agenda of the next meeting (December 2014)

10. EUnetHTA conference update

The 2-day HTA2.0 Teaming up for Value conference will be held on 30-31 October in Rome (www.eunetha2014.it/). There will be EMA contribution to specific sessions, which are under development.

Action point:

- EUnetHTA to provide EMA with details of the programme to identify EMA speakers

11. Closing remarks

The next meeting will be hosted by the Dutch ZIN in Diemen, likely in December 2014 (date TBD)¹.

¹ By the time of finalization of the minutes, December 9 has been agreed as the date of the next EMA/EUnetHTA meeting