EMA-EUnetHTA meeting

November 20, 2012
Copenhagen

10h30-17h30

***Local host**:* Danish Health and Medicines Authority, *DHMA*
Address of the meeting venue:
Islands Brygge 67, meeting room 501
2300 Copenhagen S

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Summary report

Agenda

Coffee – light refreshment	10.0 – 10.30
1.Welcome to Danish Health and Medicines Authority (DHMA): *Director General and Chief Medical Officer Else Smith* Introduction to the EMA-EUnetHTA meeting: *Finn Børlum Kristensen*	10.30 –10.50
2. EPAR improvement project – reporting of first experiences, additional proposals from EUnetHTA in light of the reviews of recent EPARS (HAS, EMA)	10:50 – 11:30
3. Databases for post-licensing studies (HAS) Update on the new EU PhV Legislation and opportunities for bridging to HTA (EMA) The FP7 IMI Protect Project (DHMA)	11:30 – 12:30
Lunch break	12.30 - 13.30
4. Rapid model for REA, pilot and future developments; i.e. possibilities to streamline the timelines of rapid pilots with EMA assessments (CVZ)	13:30 – 14:15
5. Early scientific advice; EMA-HTA scientific advice, and multi-HTA scientific advice (NICE, HAS, EMA)	14:15 – 15:15
Coffee	15.15 – 15.45
6. EUnetHTA Methodological guidelines for REA (HAS)	15.45 – 16.30
7. Significant benefit for orphan medicinal products: concept and experience (EMA)	16:30 – 17:00
8. Conclusion of EMA-EUnetHTA meeting and next steps: *Hans-Georg Eichler, Finn Børlum Kristensen*	17.00 - 17.30

1. Opening remarks and welcome

Ms Else Smith, the Director General and Chief Medical Officer at the Danish Health and Medicines Authority (DHMA), welcomed the participants to the meeting and to the DHMA. She expressed DHMA's continuous commitment to EUnetHTA coordination since 2005 and wished the participants a fruitful meeting underlining the importance of the corporation between EUnetHTA and EMA.

Finn Børlum Kristensen, EUnetHTA Secretariat, chaired the meeting and also welcomed everybody. He introduced EUnetHTA and stressed the importance of the Directive 2011/24 EU on Cross-border healthcare and the work of reaching a sustainable and permanent HTA network in Europe. As a follow up on previous meeting between EUnetHTA and EMA he emphasised the importance of the continuity in the collaboration between the Agency and the Network.

2. EPAR improvement project – reporting of first experiences, additional proposals from EUnetHTA in light of the reviews of recent EPARS (EMA, HAS)

Michael Berntgen (EMA) presented the progress of the EPAR Project (*Presentation no. 2*). Since the last meeting between EMA and EUnetHTA, all agreed items for implementation and monitoring had been delivered. Currently work is going on in the areas of: Implementation of new Pharmacovigilance Legislation, Pilots for an Executive Summary, Guidance regarding data in geriatric patients, further strengthening of internal review and a continuous reflection on the best approach for templates.

Anne Gourvil (HAS) presented EUnetHTA's observations after review of 10 EPARs (*Presentation no. 3*) and the key discussion points on the content of EPAR and post-authorisation measures were summarized as follows:

- Results of the progress and current development in the collaboration between EUnetHTA and EMA should be presented to the CHMP and in parallel a manuscript should be developed to be published in a relevant journal should be made. Action point: EMA and HAS to follow up.

- In general EMA expressed the continuous improvement initiatives hence a readiness to take in suggestions from outside. Regarding the recent EPAR revisions (e.g. executive summary) EMA welcomed comments from EUnetHTA. Also on new and future templates (e.g. template for extensions of indications; new RMP summary document) EUnetHTA comments are welcome Action point: EUnetHTA will follow up.

- On the issue of EMA's draft quality review of Summary of Product Characteristics (SmPC) – Anne Bucsics (HVB) should send a letter of request and EMA will reply accordingly. Action point: Anne Bucsics to send a letter and EMA to reply.

3. Databases for post-licensing studies (HAS); Update on the new EU PhV Legislation and opportunities for bridging to HTA (EMA) and The FP7 IMI Protect Project (DHMA)

Irena Guzina (HAS) presented the EVIDENT database which was launched in November 2012 (*Presentation no. 4*). The goal of the EVIDENT database on new technologies is to promote generation of further evidence and facilitate European collaboration in conducting requested additional data collection. The scope of the database is studies requested by European HTA bodies after HTA that are in initial stage of development and is addressing all health technologies (i.e. drugs, devices, procedures). The content of the database is information on additional studies or any kind of additional collection (ADC) and information on related health technology (i.e. assessment status, evidence gaps, research questions, required additional studies, coverage decision status).

Ana Hidalgo-Simon (EMA) updated the meeting participants on the implementation of the new Pharmacovigilance Legislation and the newly created ENCePP working group on HTA (*Presentation no. 5*). The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP®) is a collaborative scientific network coordinated by the European Medicines Agency and developed in collaboration with European experts in the fields of pharmacoepidemiology and pharmacovigilance. The ENCePP Database of Research Resources and the E-Register of Studies for the registration of pharmacoepidemiological and pharmacovigilance studies are both publicly available.

Steffen Thirstrup (DHMA) presented the EU FP7 IMI funded project 'Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium (PROTECT)'. The goal of the project is to strengthen the monitoring of benefit-risk of medicines in Europe by developing innovative methods to enhance early detection and assessment of adverse drug reactions from different data sources and to enable the integration and presentation of date on benefits and risks. Both methods will be tested in real-life situations (*Presentation no. 6*).

The key discussion points on the three presentations were summarized as follows:

- The EVIDENT database has just been launched. There is a need to clarify how parts of the EVIDENT database can be made publicly available without compromising the confidentiality of some of the information. Action point: EUnetHTA to follow up.

- The ENCePP working group on Health Technology Assessment can help in exploring methodologies and initiatives to link ENCePP and EUnetHTA. The key element could be for EUnetHTA and EMA to develop and agree on a methodology for observational studies to identify and collect information to fill knowledge gaps in the post licensing phase. Francois Meyer (HAS) participated in the ENCePP's working group on HTA's first meeting, and has been named EUnetHTA liaison with the working group. EMA is happy to consider additional EUnetHTA members and stronger presence of EUnetHTA on the working group. Action point: EMA and EUnetHTA Secretariat will follow up on this.

- In relation to post-authorisation safety and efficacy studies (PASS/PAES) Anders Tysse encouraged EUnetHTA to send concrete suggestions to his Unit, Risk Assessment, Head: Tapani Piha, in DG Sanco (i.e. to Jerome Boehm). Action point: EUnetHTA to follow up.

4. Rapid model for REA, pilot and future developments; i.e. possibilities to streamline the timelines of rapid pilots with EMA assessments (CVZ)

Wim Goettsch (CVZ) presented the model for Rapid REA of Pharmaceuticals and shared the planned work on pilot REAs in EUnetHTA Joint Action 2 (*Presentation no. 7*). Potential collaboration with EMA and the possibilities to streamline the timelines of rapid pilots with EMA assessments was discussed and the key discussion points were summarized as follows:

- It is possible for HTA bodies to get CHMP assessment reports soon after a positive opinion of CHMP from the applicant; it is difficult to get an indication on a possible decision before the final CHMP discussion and this depends on the applicants to provide the information; Information from the CHMP assessment report should not be included in a REA document for public consultation before Commission Decision; the time between the CHMP opinion and the final availability of the EPAR for specific products is about 80-90 days (around 70 days are for the Commission's Decision Making Process). As a way forward EUnetHTA should explore and encourage the companies to share the assessment information – EUnetHTA could ask EFPIA to facilitate this. EMA cannot share this information with EUnetHTA at any stage. Action point: EUnetHTA to follow up.

5. Early scientific advice; EMA-HTA scientific advice, and multi-HTA scientific advice (NICE, HAS, EMA)

Spiros Vamvakas (EMA) provided a presentation on HTA-EMA Scientific Advice and shared EMAs experience and examples of HTA discussions. Scientific advice is an important activity for EMA and advice is given by the CHMP on recommendations of the Scientific Advice working Party (*Presentation no. 8).*

Carol Longson (NICE) gave a short presentation NICE's early scientific advice service and provided insight into NICE's experiences with scientific Advice Projects in collaboration with EMA (*Presentation no. 9*). Work is in progress to develop an efficient and acceptable procedure for the provision of 'parallel' written advise and there is a need to explore how best to involve both regulatory and HTA experts in the advice meetings.

Mira Pavlovic (HAS) presented the EUnetHTA initiative on early dialogues - multi-HTA scientific advice and the first experience gained (*Presentation no. 10*). Several EUnetHTA partners have participated and the experiences have been rather successful. However, cooperation between EMA and EUnetHTA should be considered for a better process and result.

The key discussion points on the three presentations were summarised as follows:

- The Commission hopes this exploratory phase of early scientific advice will lead to a new framework and a new basis, and there is a push from the Commission on two areas: 1. is it possible to have shared ground in terms of Early Scientific Advice and to some extend aligning practices? 2. Could EUnetHTA involve smaller HTA organizations as participants in early scientific advice pilots? Action point: EUnetHTA to follow up.

- EUnetHTA should keep EMA informed and there will be a formal invitation to participate as observer at the meeting on the 18th of December in Paris and all dates for meetings in 2013. Spiro Vamvakas from EMA has green light for participating as observer but cannot give EMA advice in evaluation process but give personal comments and inputs. Action point: EUnetHTA to send invitation and EMA to follow up.

- Every agency that participates will be required to share the basis for their advice in writing. There should be time for reflection on the procedure and process after each EUnetHTA pilot. Action point: EUnetHTA.

- The expert involvement in the EMA early scientific advice and the EUnetHTA early scientific advice pilots should be a topic for discussion in the coming EMA-EUnetHTA meetings. Action point: EMA and EUnetHTA.

6. EUnetHTA Methodological guidelines for REA (EMA, HAS)

Michael Berntgen (EMA) and Mira Pavlovic (HAS) both presented an overview and current status of the mutual commenting on Guidelines (*Presentation no. 12 and 13*) and the processes for the exchange was discussed. The key discussion points were summarized as follows:

- There is a need to elaborate on the processes of how EUnetHTA will be commenting on EMA draft guidelines and concept papers – not many members have contributed with comments so far. EMA welcomes and encourages EUnetHTA to continuously in the future comment on both draft guidelines and concept papers and specifically disease specific guidelines in the framework of early dialogue. Information should be sent to the Secretariat for posting (current procedure), but the task of deciding who should comment will be handled by the Lead Partners in WP5 - CVZ (Wim) and HAS (Francois). Next year, this process should be evaluated. Action point: EUnetHTA.

- The EMA disease specific guidelines will be a starting point for EUnetHTA's JA2 work on disease specific guidelines for HTA. Action point: EUnetHTA.

7. Significant benefit of orphan medicinal products: concept and experience (EMA)

Jordi Llinares (EMA) presented EMA's experience with significant benefit of orphan medicinal products (*Presentation no.13*). The concept of orphan medicinal products and their marketing authorisation were discussed. The key discussion points for the way forward were summarized as follows:

- As the topic is very complicated it should be discussed further during next meetings. Action point: EUnetHTA and EMA.
- The possibility to develop a confidentially agreement or memorandum of understanding to facilitate information exchange between EMA and EUnetHTA similar to the agreement that was made between EMA and FDA, has legal implications and it should be explored with the European Commission. Action point: EUnetHTA (and EMA).

8. Conclusion of EMA-EUnetHTA meeting and next steps

Finn Børlum Kristensen (EUnetHTA Secretariat, DHMA) and Hans-Georg Eichler (EMA) thanked the participants for a good meeting. The key discussion points for way forward were summarized as follows:

- Should a memorandum of understanding be drafted between EMA and EUnetHTA in order to be able to share confidential information?
- The development of a 3-year work plan was suggested. Action point: EUnetHTA to come up with a draft.
- The communication and cooperation between EMA and the EUnetHTA should be made public at a relevant stage. Action point: EUnetHTA Secretariat, EMA.
- The next meeting will be around April 2013 in EMA. Action point: EMA to follow up.

The meeting was adjourned at 17.30.

Participants List

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