



27 August 2010
EMA/364003/2010

Minutes of the Second Workshop on High Level Pharmaceutical Forum Recommendations on EPARS' contribution to Relative Effectiveness Assessment

3 June 2010 – chaired by Hans-Georg Eichler

Role	Name
Chair/Vice-chair	Hans-Georg Eichler (EMA)
Present:	Patrick Le Courtois (EMA), Xavier Luria (EMA), Francesco Pignatti(EMA), Michael Berntgen (EMA), Agnès Saint Raymond (EMA), Laurent Brassart (EMA), Antonio Cherchi (EMA), Spiros Vamvakas (EMA), Eric Abadie (CHMP), Harald Enzmann (CHMP), Patrick Salmon (CHMP/COMP).Kerstin Westermarck (COMP), Jerome Boehm (EC), Wim Goettsch (EUnetHTA), Finn Børlum Kristensen (EUnetHTA), Francois Meyer (EUnetHTA), Anna Bucsis (EUnetHTA), Sarah Kleijnen (EUnetHTA), Anne Dandon (EUnetHTA), Marianne Klemp (EUnetHTA), Carole Longson (EUnetHTA), Pietro Folino Gallo (EUnetHTA)

This was the second meeting between the European Medicines Agency (EMA) and representatives from the European network for Health Technology Assessment (EUnetHTA) in the context of a collaboration with the objective to explore how the European Public Assessment Report (EPAR) can make better contribution to the assessment of relative effectiveness of pharmaceuticals by health technology assessment (HTA) bodies in the EU Member States.

1. Introduction and Updates

The Chair introduced the objectives of the meeting. The agenda as well as the minutes of the previous meeting were adopted without changes.

Brief updates on topics of interest for the participants were provided by the European Commission, EUnetHTA as well as the EMA. It was noted that EUnetHTA is currently developing guidance documents on comparators/comparisons, outcomes and level of evidence, respectively; these topics could become areas for future exchange. From the EMA update the initiatives about publication of reports on the



maintenance of orphan criteria at time of marketing authorisation as well as the review of conflict of interest rules were identified for discussion at future meetings.

2. Discussion on EPAR Improvements

The following documents circulated prior to the meeting:

- Preliminary Analysis of EPAR Improvements in view of Contribution to Health Technology Assessments



Analysis - EPAR
contribution t...

- EUnetHTA response to the preliminary analysis



Response
netHTA on EMA draf

- Action Plan for EPAR Improvements – Draft 1



Action Plan for
EPAR Improve...

The discussion was based on the draft action plan. Agreed items for implementation with the next template update (section 1) as well as items for monitoring as part of current templates (section 3) were briefly summarised. Regarding the presentation of data in tabular format (section 5) the comments were discussed and additional input will be received by EUnetHTA by the end of the month, after which EMA will produce an updated version. The main discussion was held on the items for further reflection (section 2); here the outcome of the discussion was either implementation with the next template update (Structural characteristics for biologicals; inclusion of references), follow-up discussion at the next meeting (Conflict of interest) or internal review by EMA (Dedicated section related to "Product Information"; Enhanced QC review procedures; Version control of printed labelling documents; Fulfilment of commitments). With regard to the additional items raised by EUnetHTA (section 4), these were discussed and no actions other than the ones already agreed need to be taken.

An updated action plan (draft 2) as a result from these discussions will be produced and distributed to participants.

3. Next Steps

EUnetHTA will provide additional comments on the presentation of data in tabular format by **end of June**. Based on this input EMA will produce a revised template table together with an updated action list by **mid July**. Any additional comments on these documents should be provided by **10 September** given that documents would need to be finalised and circulated for formal adoption by the CHMP in **October**. It is planned to issue a dedicated press release once these changes to the template are finally adopted and about to be implemented.

Regarding the implementation of the template, it was agreed that this should occur with Opinions on initial marketing authorisations after adoption in October 2010 acknowledging that EPARs will only be published after adoption of the Commission Decision, i.e. the first EPARs with this information could be expected in 1Q10. Both EMA and EUnetHTA intend to monitor the implementation of the improvement. A joint meeting to exchange the first experience is planned after around 10 EPARs have been published, which would be envisaged by July 2011.

Brief minutes of the meeting will be prepared by EMA for review by EUnetHTA.

4. Next meeting

The next meeting will be held end of 2010 / beginning of 2011. The following topics are envisaged for this meeting:

- Assessment of potential Conflict of Interest by EMA;
- Experience exchange on reports about the maintenance of orphan criteria at time of marketing authorisation;
- Information on EUnetHTA guidelines (Work Package 5) regarding comparators/comparisons, outcomes and level of evidence, respectively.