



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

11 February 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 Berntngen (EMA), Agnès Saint Raymond (EMA), Jordi Llinares (EMA), Laurent Brassart (EMA), Antonio Cherchi (EMA), Frida Rivère (EMA), Spiros Vamvakas (EMA), Eric Abadie (CHMP), Harald Enzmann (CHMP), Anders Lamark Tysse (EC), Wim Goettsch (EUnetHTA), Finn Børlum Kristensen (EUnetHTA), Francois Meyer (EUnetHTA), Anna Bucsis (EUnetHTA), Sarah Kleijnen (EUnetHTA), Anne Dandon (EUnetHTA)
Teleconference:	Alar Irs (CHMP), Patrick Salmon (CHMP/COMP), Kerstin Westermark (COMP)

The European Medicines Agency (EMA) and representatives from the European network for Health Technology Assessment (EUnetHTA) Joint Action initiated a new collaboration, in which the EMA and EUnetHTA will be considering how the European Public Assessment Report (EPAR) could make a better contribution to the assessment of relative effectiveness of pharmaceuticals by health technology assessment bodies in the EU Member States.

1. Introduction

The Chair introduced the meeting summarising the background of this initiative. The collaboration between the EMA and EUnetHTA was initiated to address one of the recommendations made by the High Level Pharmaceutical Forum to improve the availability and best use of data relevant to relative effectiveness assessment. It was agreed that this new collaboration should be explored in a step-wise approach starting from the politically agreed mandate to consider how EPARS can further contribute to the relative effectiveness assessment of pharmaceuticals. Any further topics will be jointly reflected upon by the EMA and EUnetHTA. The primary objective of this meeting was therefore to allow for an



initial discussion about the role of EPARs in activities of HTA bodies and to agree on next steps to explore future topics.

Introductory presentations were given on the following topics:

- European network for Health Technology Assessment - Finn Børlum Kristensen
- European Medicines Agency - Patrick Le Courtois
- Joint Action Work Packages 5 and 7 - Wim Goettsch, Francois Meyer

The presentations are provided for reference.

2. Discussion on EPARs

Focus of the collaboration will be the EPARs, which reflect the scientific conclusions reached by the EMA's Committee for Medicinal Products for Human Use (CHMP) at the end of the evaluation process, after deletion of commercially confidential information. An overview of the EPAR structure and workflow was provided by Francesco Pignatti. A broader initiative at the EMA was noted aimed at facilitating access to EPAR information by stakeholders; recent revisions were introduced in the assessment report templates and the CHMP continues to look at new ways to improve the transparency of the scientific assessment.

In 2009, MEDEV provided comments on the usefulness of the EPARs and Summary of Product Characteristics (SmPCs) in the context of relative effectiveness assessment of pharmaceuticals. The domains quality, structure and content were covered by these comments. A summary of these comments together with some examples was provided by Anna Bucsis.

It was agreed that the EMA should draft guidance for improved data presentation that would address the usability for HTA bodies. The MEDEV comments should be the starting point for this exercise. This draft guidance would then be subject to a wider consultation within the EUnetHTA network as part of the Work Package 5.

3. Next Steps

EMA will draft guidance for improved data presentation in the EPAR based on the MEDEV comments by **25 March 2010**. EUnetHTA will perform a consultation on this draft and provide comments by **7 May 2010**. Contacts for this exercise are Francesco Pignatti (EMA) and Wim Goettsch (EUnetHTA).

A meeting to discuss these comments will be arranged in **June 2010**. The aim is to have a joint document agreed by **July / August 2010** to allow for implementation with the next revision of CHMP assessment report templates scheduled for **October 2010**.

Separate from this initiative, a road map to explore other areas of possible collaboration or exchange of information in future will be developed. Contacts for this exercise are Hans-Georg Eichler (EMA) and Finn Børlum Kristensen (EUnetHTA).

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

A joint press release of the two organisations will be published. A draft will be prepared by EMA for review by EUnetHTA

Next meeting:

The next meeting will be held in June 2010 (date/time tbd).