

# Third EUnetHTA - EMA meeting

March 7, 2011, CVZ, Diemen

10.30-17.00



Role	Name
Chair	Wim Goettsch (EUnetHTA)
Present:	Ad Schuurman (CVZ/MEDEV), Finn Børlum Kristensen (EUnetHTA), Francois Meyer (EUnetHTA), Mira Pavlovic (EUnetHTA), Anna Bucsis (EUnetHTA), Sarah Kleijnen (EUnetHTA), Elisabeth George (EUnetHTA), Marianne Klemp (EUnetHTA), Beate Wieseler (EUnetHTA), Alric Ruther (EUnetHTA), Anders Lamark Tysse (EC DG Sanco), Hans-Georg Eichler (EMA), Patrick Le Courtois (EMA), Michael Berntgen (EMA), Peter Arlett (EMA), Alar Irs (CHMP), Harald Enzmann (CHMP) Sandra Kruger (CBG)

## Background

In 2010 The European Medicines Agency (EMA) and representatives from the European network for Health Technology Assessment (EUnetHTA) Joint Action initiated a collaboration, in which the EMA and EUnetHTA are 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. The current meeting was planned to discuss the follow-up of the changes that have been implemented and other shared topics.

## Introduction

The meeting was opened by Bert Boer, member of the Board of the Dutch Health Care Insurance Board (CVZ) with a description of the tasks of CVZ

## Follow-up on EPAR

Michael Berntgen presented an update on the implementation (process) of the new EPAR template. From November 2010 onwards the updated assessment report templates have been implemented for CHMP opinion meetings. In addition a questionnaire is currently being developed with specific focus on the changed items in the EPAR. This questionnaire will be used to evaluate the implementation of the changes by EMA.

It was discussed that there also is a need to evaluate the implementation by HTA agencies functioning as external customers. This evaluation should preferably be one joint response through EUnetHTA including also comments from MEDEV. The HTA agencies will discuss the approach of the evaluation in the coming period. It was indicated that during the summer 5-10 EPAR with the implemented changes will be available which will be a decent number for an evaluation. For this review it was considered beneficial if this EMA questionnaire was not only used by EMA but also by the EUnetHTA partners as a part of their evaluation.

## Short update on WP5 and WP7 of EUnetHTA

Finn Kristensen briefly provided an update on the EUnetHTA network. A proposal is being drafted for a Joint Action 2 which should start in 2012 and will focus on the production of assessment reports.

Presentations were provided by Wim Goettsch (WP5) and Mira Pavlovic (WP7) on the progress of the projects. The presentations are provided for reference.

For WP5 a public consultation will soon start on a background review. In addition EMA will be consulted in the near future for the selection of a specific topic (pharmaceutical) for a pilot assessment based on the model that is under development within this work package.

WP7 focuses on new technologies. Opportunities for collaboration will be discussed during the agenda item on 'Cooperation in post marketing data collection'.

### **Guidelines**

Mira Pavlovic provided a presentation on the guidelines that are under development by WP5 on methodological issues. The presentation is provided for reference.

A consultation of EMA is planned in April 2011 for all these draft guidelines. It was indicated by EMA that the consultation period of 1 month will be a challenge for them. WP5 will reconsider the consultation period and moment of consultation. HAS will send EMA a list with the subjects of the guidelines and dates for the consultation.

*Post-meeting note:* EUnetHTA indicated to EMA after the meeting that the consultation on draft guidelines was re-scheduled for later in 2011 or 2012.

### **EMA Reflection paper on 'Active Controls'**

The content of the reflection paper was presented by Hans-Georg Eichler. The paper proposes that there are 2 situations in which 3-armed studies should be a requirement. The paper is currently open for public consultation with a deadline for 31 March 2011. The HTA agencies will either provide a joint response if this can be arranged in time, otherwise agencies will respond individually. It was indicated by EMA that a week delay in response would be possible but should preferably be indicated in time. MEDEV will respond but maybe a week late.

### **Cooperation in post marketing data collection**

A presentation was provided by Peter Arlett on the changes to the post authorisation data collection and the ENCePP database. The presentation is provided for reference.

It was discussed that it would be helpful to identify a minimum dataset that would be useful for postmarketing studies as well as studies for additional evidence generation (EIFFEL database). In addition it might be explored if information on studies on pharmaceuticals that are collected in the EIFFEL database should maybe be transferred to the ENCePP database. The lead of WP7 will join the ENCePP meeting in June and a discussion will be started on possible collaboration.

### **Scientific Advice**

Mira Pavlovic provided a presentation on the experience of scientific advice in the Tapestry network. The presentation is provided for reference.

EMA indicated that a joint or parallel advice of regulators/ reimbursement agencies should be pursued. The HTA agencies indicated that the agencies first need to sort out how they can combine input for several reimbursement agencies before further collaboration with EMA. On scientific advice EUnetHTA can facilitate with knowledge, but not be an official partner as the official partners are the reimbursement agencies.

### **Next meeting:**

The next meeting will be held in the second half of 2011 (date/time tbd) in Paris.