



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Organisational matters

CHMP meeting 18-21 November 2013

The CHMP noted that Aldona Paluchowska was appointed as the new CHMP Alternate from Poland, replacing Kinga Borowicz in this role.

The main organisational topics addressed during the November 2013 CHMP meeting related to:

- The appointment of Maryam Mehmandoust as new core member of the Quality Working Party.
- The appointment of Kari S. Lankinen as observer to the Vaccine Working Party.
- The appointment of Sigrid Klaar and Sinan Bardakei as observers to the Oncology Working Party.
- The appointment of Peter Szitanyi as a standing observer on the Gastroenterology Drafting Group.
- A new pharmacovigilance training resource available for CHMP members and their assessors.
- The set-up of a new EMA/FDA cluster to discuss specific pharmacovigilance topics.
- Discussion on RMP assessment in the pre-authorisation phase based on evidence that the current approach may not be the most efficient way of cooperation between the PRAC and the CHMP. Discussion took place on finding a more effective way based on the national resource at hand.
- Discussion regarding the feedback from the Infectious Disease Working Party following a CHMP request on the format of indications (section 4.1. of the SmPC) for direct acting antivirals against Hepatitis C virus infection, and related issues on the structure of the product information.

Of note, the European Medicines Agency intends to publish for the first time the meeting agenda of the CHMP for its next meeting taking place on 16-19 December 2013.

