



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 December 2015
EMA/38810/2015
Press Office

Organisational matters

CHMP meeting 14-17 December 2015

The main organisational topics addressed during the December meeting related to:

- The CHMP elected Dr Koenraad Norga as a CHMP Co-opted member with expertise in Pharmacology.
- The CHMP elected Dr Karolina Törneke as Chair of the Respiratory Drafting Group.
- The CHMP re-elected Dr Pierre Demolis as Vice-Chair of the Oncology Working Party.
- The CHMP elected Dr Kristina Dunder as Vice-Chair of the Cardiovascular Working Party.
- The CHMP appointed Dr Arantxa Sancho Lopez and Dr Kristina Dunder as new members to the Guideline Consistency Group.
- Nomination of Dr Anders Lindblom from Sweden as new member to the Blood Products Working Party, following the step down of Dr Bengt Ljungberg.
- Update on the pilot on patient involvement in CHMP. The CHMP noted the three cases of patients involvement and positive feedback received. Involvement of patients has been a learning curve and has improved with experience. However, in order to complete the pilot, at least 2-3 more cases are needed before being able to deliver a sufficient analysis.
- Information on analysis of the experience of the 1-year pilot phase on Publication of Risk Management Plan (RMP) summaries. During the pilot, RMPs have been prepared and published for all medicines (84 altogether) authorised since March 2014. Interest from different audience groups have been observed - each with different needs and expectations. In 2016, pilot phase will finish, a new template will be published and a transition from its current format for the RMP summaries to the new one will take place.
- Information on Workshop on Statistical Principles for Clinical Trials on Choosing Appropriate Estimands and Defining Sensitivity Analyses in Clinical Trials to be held in EMA 25-26 February 2016.

