



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 February 2014
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Press Office

Organisational matters

CHMP meeting 17-20 February 2014

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

- The election of Dr Robert Hemmings as co-opted CHMP member.
- The election of Dr Sol Ruiz as new chair of the Biologics Working Party. The Committee expressed its gratitude to Jean Hugues Trouvin (past chair of the BWP) for his contribution to the excellent work achieved by the Working Party.
- The nomination of Klaudia Hettinger from Austria as additional expert to the Safety Working Party.
- The appointment of Vitalis Briedis from Lithuania as new member of the Biologics Working Party.
- The nomination of Nele Bertheis from Belgium as observer to the Vaccines Working Party.
- The nomination of Olga Kholmanskikh from Belgium as observer to the Oncology Working Party.
- The resignation of Martin Rossor from the UK as member of the SAG Neurology.
- The resignation of Sue Benbow from the UK as member of the SAG Diabetes/Endocrinology.
- Discussion regarding the Medical Device Expert Group proposals for definitions of pharmacological-, immunological- and metabolic mode of action as well as medical diagnosis.
- Discussion on the procedure for coordinating GCP inspections requested by CHMP.
- Endorsement of the Sampling and Testing list programme for 2015.
- Discussion on activity report from the Modelling and Stimulation Working Group and proposal to transition to a Working Party. The work plan for 2014 was adopted.
- Discussion and report on 3-year activity for the SmPC advisory group. The CHMP adopted the SmPC Guideline Checklist.
- An update on the calculation of the voting quorum and majority vote leading to a majority at CHMP of 17 votes. The quorum remains at 22.
- The nomination of Martina Weise and Andrea Laslop to participate in the ICH Biosimilars Working Group.



- Discussion around a pilot study setting up multinational assessment teams in order to broaden European involvement. A pilot study started with split assessment responsibilities across countries from the Baltic sea for a few applications but further experience is needed before deciding to expand this process or not.
- Discussion on proposal for communicating on measures to prevent medication errors.
- Discussion regarding consultation process on proposed process improvements as part of 'Review and Reconnect' programme being currently carried out within the EMA.
- Additional information on the move of the EMA to Churchill Place in July 2014.