



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2016
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Press Office

Organisational matters

CHMP meeting 12-15 September 2016

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

- Election of Pierre Demolis as Chair to the Oncology Working party.
- Election of Karl Broich as Chair to the Central Nervous System Working Party.
- Election of Anders Lignell as Chair to the Infectious Diseases Working Party.
- Election of Anabel Cortés Blanco as Chair to the Radiopharmaceutical Drafting Group.
- Information about proposed topics and agenda for Joint CHMP-PDCO Strategic Review & Learning Meeting to be held in Brussels, 19-21 October 2016 under the Slovakian Presidency of the Council of the European Union.
- Information about the outcome of a review of experience with the Early Background Summaries. A survey amongst CAT/CHMP/PRAC assessors was conducted following the pilot starting at the end of 2014. The data collection and analysis was completed based on a total 121 responses for the 21 products in scope of the exercise.
- Update on data gathering project, which started in March 2014 in order to gather evidence needed by the European Commission in drafting future legislative proposal on fees. The goal was to assemble evidence about the time spent on procedures at EMA and national competent authorities.
- Information about the intention to start publication CHMP ORGAM meeting agendas and minutes from October 2016 onwards. In addition, the Annex to the CHMP meeting Plenary agenda and minutes will be made public. This would improve transparency of the CHMP meeting outcome. Furthermore the publication of 4 annexes under CHMP monthly highlights: "Opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures", "Opinions on safety variations", "Guidelines and concept papers adopted" and "Organisational matters" (current document) will be discontinued.
- Appointment of 2 additional experts to the Pharmacogenomics Working Party: Giuseppe Novelli and Ronald van Schaick.
- Appointment of new member Jasenka Mršić Pelčić to replace Blaženka Jurišić (HR) to the Safety Working Party.



- Appointment of Greg Markey as a member to the Guideline Consistency Group replacing Pierre Demolis.
- Nomination of Christian Schneider as observer to the Biosimilar Medicinal Product Working Party.
- Nomination of Uta Buckpesch-Heberer (DE) and Giancarlo Zito (IT) as observers to the Central Nervous System Working Party.
- Nomination of Yolanda Barbachano (UK) as observer to the Biostatistics Working Party.