



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 July 2014
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Press Office

Organisational matters

CHMP meeting 21-24 July 2014

The Committee welcomed Hrefna Gudmundsdottir new alternate member from Iceland. The Committee also noted that this was Jens Ersboll, Danish member, last meeting and thanked him thoroughly for his work and contributions to the system over the years.

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

- The election of Keith Pugh as Vice chair of the Quality Working Party.
- The election of Martina Weise as Vice chair of the Biosimilar Products Working Party.
- The election of Maria Fernandez-Cortizo as Vice chair of the Infectious Diseases Working Party.
- The election of Daniel Brasseur as Vice chair of the Vaccines Working Party.
- The appointment of Erika Szabo from Hungary as new BWP member.
- Follow-up discussion on the CHMP Work Plan for 2015.
- Follow-up action plan on the Quality of Opinions.
- Discussion on area of expertise of Co-opted CHMP members.
- Follow-up discussion on the preparation of PAES Scientific guidance.
- Information regarding the Revision of the Guideline on good pharmacovigilance practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products. The updated module will be published on the EMA website in the near future.
- An update on the bioterrorism database on the EMA website in relation to medicinal products potentially useful for post-exposure prophylaxis and/or treatment of infectious diseases in the context of biological warfare. The Committee agreed that additional experts' views should be gathered prior publication.
- An update from the SmPC Advisory Group regarding the Q&As which may affect a number of products. The update relates to reference to official recommendations in SmPC of vaccines; information on environmental risk assessment in section 5.3; statement for biosimilar product in section 5.1; dosage information in paediatric population; communication of new identified risk;



presentation of contraindicated combinations; benefits in the package leaflet; fixed combination medicinal products.

- Initial presentation regarding the draft program for the informal CHMP meeting to be held in Rome late October 2014.
- An update on answers to requests for scientific advice regarding the impact on public health and animal health of the use of antibiotics in animals. This was endorsed by CHMP and CVMP and will be released for public consultation shortly.
- The adoption of the core membership for the SAG Oncology.
- An update on the procedural Advice on CAT-CHMP-PRAC Rapporteur Appointments.
- An update regarding an Industry Forum on Pharmacovigilance to be scheduled on 16th September.
- A visit by the members to their new premises located 30 Churchill Place in Canary Wharf. The Committee will meet in the new building comes September.