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Press Office

Organisational matters

CHMP meeting 19-22 May 2014

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

- The adoption of revised composition for all temporary Working Parties and Radiopharmaceutical and Gastroenterology Drafting Groups.
- The appointment of Fabien Lavergne from France and Alessandra Tamburella from Italy as additional experts to the Safety Working Party.
- The appointment of Christian Mayer from Austria as new BWP alternate member.
- The appointment of Charlotte Gluk from the Netherlands as additional expert observer on the Infectious Disease Working Party.
- The appointment of Prof. Malcolm Macleod from the UK as core member on the SAG Neurology.
- The appointment of Barbara van Zwieten Boot as chair of the EMA Guidelines Consistency Group and the adoption of an updated mandate for this group.
- Discussion on the composition of an Inter Committee Oncology SAG that could be operating comes September 2014.
- Information on the revised EMA policy on the handling of declaration of interests for scientific committees' members and experts. The aim of the revision should enable a better balance at managing Declaration of Interests (DoIs) versus accessing the best expertise without dropping standards when assessing DoIs. The revised policy should also make involvement of experts more attractive. The revised policy and procedural guidance will be published in the coming weeks.
- Follow-up discussion on principles to revise the RMP assessment process. Discussions were initiated taking into account the basic principles agreed by the CHMP/ PRAC RMP Champions back in November 2013, as well as further experience obtained over the past 6 months with the current RMP assessment process. The revised process clarifies in greater details the roles and responsibilities of involved parties with specific time points for interaction during the initial marketing authorisation phase. The Committee was supportive of the revised principles and as a next step this will now be discussed by the EMA Management Board in June.
- The adoption of a revision of the guideline on the acceptability of names for human medicinal products processed through the centralised procedure – Revision 6 (EMA/219064/2014) which will

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be published shortly. The changes concerned the clarifications of the principles applied to address safety/public health, product specific concerns; simplifications of the criteria applied to address INN related issues and further clarifications of the requirements for submission of proposed invented names.

- The adoption of two ICH Questions & Answers documents:
  - ICH E2C(R2) Guideline: Periodic Benefit-Risk Evaluation Report Questions & Answers (CHMP/ICH/271908/2014)
  - ICH E14 Guideline: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs Questions & Answers (R2) (CHMP/ICH/310133/2008)
- Initial discussion regarding proposed changes for processing some type II variations. The Committee discussed the potential introduction of rolling timetables for "simple" type II variations and subsequent changes to the assessment report template. Further discussion on this topic was deemed necessary and will take place over the coming weeks.
- Initial discussion regarding the mandate, objectives and rules of procedures for establishing a new Inter-Committee ad hoc Ethics Advisory Group.
- Additional information on the move of the EMA to Churchill Place in July 2014.