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Press Office

Organisational matters

CHMP meeting 16-19 September 2013

The CHMP welcomed Daniel Brasseur as new Belgian CHMP member replacing Pieter Neels and Bart Van der Schueren replacing Walter Janssens as Belgian alternate.
The Committee also welcomed Pieter de Graeff as new Dutch CHMP member replacing Barbara van Zwieten-Boot and Hans Hillege as Dutch alternate.
Finally new UK member Greg Markey was also welcomed to the Committee as replacing Ian Hudson who was recently appointed Chief Executive of the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA).

The main organisational topics addressed during the September 2013 CHMP meeting related to:

- The call for nominations of a new CHMP Vice Chair following the departure of Ian Hudson. The election is foreseen at the October CHMP meeting.
- The election of a number of chairpersons for the EMA temporary working parties and drafting groups following the end of the previous 3-year term.
  - The CHMP elected Christian Schneider as chair of the Biosimilar Working Party.
  - The CHMP elected Michael Pfleiderer as chair of the Vaccine Working Party.
  - The CHMP elected Anneliese Hilger as chair of the Blood Working Party.
  - The CHMP elected Krishna Prasad as chair of the Pharmacogenomics Working Party.
  - The CHMP elected Pieter de Graeff as chair of the Cardiovascular Working Party.
  - The CHMP elected Karl Broich as chair of the Central Nervous System Working Party.
  - The CHMP elected Mair Powell as chair of the Infectious Disease Working Party.
  - The CHMP elected Bertil Jonsson as chair of the Oncology Working Party.
  - The CHMP elected Jan Welink as chair of the Pharmacokinetics Working Party.
  - The CHMP elected David Wright as chair of the Biostatistics Working Party.
  - The CHMP elected Jan Mueller-Berghaus as chair of the Rheumatology/Immununology Working Party.

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  - The CHMP elected Elmer Schabel as chair of the Gastroenterology Drafting Group.
  - The CHMP elected Patrick Salmon as chair of the Radiopharmaceuticals Drafting Group.
- The appointment of Louise Lauritsen as new Safety Working Party (SWP) member from Denmark replacing Tina Zinck who was also Vice Chair of the SWP. A call for nominations for a new SWP Vice Chair has been launched with the election foreseen at the October CHMP meeting.
- The nomination of Maria Grazia Evandri as a new expert (observer for Italy) for the SWP.
- The nomination of Jobst Limberg from Germany and Andrea Kranjc from Slovenia as new Quality Working Party (QWP) members.
- The nomination of two new alternate members Marek Surowiec replacing Piotr Fiedor from Poland and Niklas Ekman from Finland for the Biologics Working Party (BWP).
- The nomination of a new alternate member Daniela Philadelphy from Austria following the resignation of Gabriela Steiner for the Blood Products Working Party (BPWP).
- The resignation of the Chair Prof Jaap T van Dissel of the SAG Anti-infectives, a call for nominations has been made together with a call for nominations for 3 vacant positions for core members. In addition a new core member Kees van Nieuwkoop from Nederland has been appointed.
- The organisation of a workshop on Quality by Design to be held on 28-29 January 2014 for assessors working in national competent authorities.
- The organisation of a BWP/BMWP workshop on overarching guidelines on biosimilar medicinal products taking place on 31st October 2013. The workshop is aimed at discussing with stakeholders the three overarching guidelines on biosimilars currently under revision and address controversial issues identified through the comments received during the public consultation with a view for the BMWP and BWP to finalise the revision of three guidelines.
- An assessor's training on baseline covariates to be held on 4th November 2013 at the EMA.
- A follow up on practical implementation of the Variation Guideline. CHMP members were given concrete examples regarding the handling of some Post Authorisation Measures now classified as variations; variations having a PRAC lead when only the RMP is concerned or dealing with results of non-interventional PASS studies; it was also clarified that RMP updates should be finalized within the relevant procedure, rather than requesting RMP updates after conclusion of a procedure. An assessment on the impact on Quality variations was also made. Finally members were informed about the scope extension of the worksharing to include NAPs and the consequences on the Decision Making process at EC level.
- The organisation of an EMA workshop on best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem. This workshop will take place on 8 November 2013.

- **Notice to all Marketing Authorisations Holders of medicinal products which are part of a single assessment of periodic safety update reports (PSUR) of active substances contained in both centrally and nationally authorised medicinal products**

  This is to inform all Marketing Authorisation Holders that have submitted PSURs subject to a single assessment, pursuant to Article 28(5) of Regulation (EC) No 726/2004 and Article 107e-g of Directive 2001/83/EC, that the said PSURs will be jointly assessed by the lead Pharmacovigilance Risk Assessment Committee (PRAC) Rapporteur and the PRAC with a view to forming a single assessment report.
  In accordance with the procedural steps laid down in the aforementioned provisions, the preliminary single assessment report by the PRAC Rapporteur, the updated single assessment report by the PRAC Rapporteur, the PRAC recommendation and the single CHMP Opinion (if applicable) will be circulated amongst all the Marketing Authorisation Holders whose medicinal product(s) are part of the PSUR single assessment procedure. The data contained therein should be solely used for the purposes of the concerned procedure.