20 March 2014
EMA/CHMP/123343/2014
Press Office

Organisational matters

CHMP meeting 17-20 March 2014

The Committee welcomed Dr. Dimitrios Kouvelas new CHMP member from Greece and Dr. Panayiotis Triantafyllis new Cypriot member. The Committee also noted that this was the last meeting for Bengt Ljunberg alternate member from Sweden and thanked him for all his contributions to the work undertaken by the Committee.

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

- Discussion regarding the draft programme for the informal CHMP meeting to be held in Uppsala on 26th to 28th May2014.
- Follow-up discussion on proposals for amendments to the definitions of pharmacological, immunological and metabolic means as reported in the EC Medical guidance document MEDDEV 2001/3 Rev. 3. Discussion was also extended to address the definition of medical diagnosis at the request of the European Commission. It was agreed to set up a drafting group to progress this matter.
- Follow-up discussion on Q&A document regarding practical implementation of Article 20 Pharmacovigilance Procedure.
- Feedback from the PCWP and HCPWP joint meeting workshop held on 26 February on regulatory and methodological standards to improve benefit/risk evaluation of medicines.
- Discussion on pilot phase proposal to involve patients in some CHMP oral explanations in the future.
- Awareness on the change of procedure for disclosure of invented names of Orphan medicinal products prior to the adoption of CHMP Opinion
- Procedure for coordinating GCP inspections.
- Discussion to define exceptional circumstances under which combination packs could be considered and defining scientific criteria and procedure to manage such Applicant's requests within EMA.
- Update on the future EMA product team support for evaluation activities.
- Decision to cease activities of the Respiratory Drafting Group for the time being and set up a specific drafting group to finalise the revision of the Asthma guideline.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

- Discussion on international Standards on Identification of Medicinal Product (ISO IDMP) with an update on current status and next steps foreseen.
- Update of the geriatric section of assessment reports and guidance provided following initial experience. Documents updated are CHMP D210 assessment report template and guidance, Day 120 LoQ, Day 80 clinical assessment report and Day 80 assessment report overview templates and guidances.
- Additional information on the move of the EMA to Churchill Place in July 2014.
- Information regarding the timing of the April CHMP meeting. The meeting will start at 3pm on Tuesday 21st and finish on Friday 25th April.