



25 September 2014  
EMA/CHMP/129678/2014  
Press Office

## Organisational matters

### CHMP meeting 22-25 September 2014

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

- The appointment of Michael Lennon from Ireland as new QWP member.
- The appointment of Agnes Mambole-Dema from France as alternate BWP member.
- The election of Markus Paulmichl as Vice chair of the Pharmacogenomics Working Party.
- The election of Thomas Lang as Vice chair of Biostatistics Working Party.
- The election of Alfredo García-Arieta as Vice chair of the Pharmacokinetics Working Party.
- Discussion on the area of expertise of co-opted CHMP members in the Committee in light of Jan Mueller-Berghaus' mandate coming to an end in November. The CHMP agreed on the area of expertise of the 5<sup>th</sup> co-opted CHMP member position should remain as "Quality and safety of biological medicinal products, including biotechnology derived medicines, cell therapy and gene therapy".
- The adoption of updated procedural advice on CHMP/CAT Rapporteur/Co-Rapporteur appointment principles, objective criteria and methodology in accordance with Article 62 (1) of Regulation (EC) No 726/2004A status update on proposed process improvement for initial MAA.
- The extension of lifetime of Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (Replacement, Reduction, Refinement) by a further 2 years. This will be sent to The Management Board for endorsement in October.
- Discussion on revised Biostatistics Working Party Work Programme. The Committee adopted two modifications on Work Programme: postponement of reflection on revision of adaptive design guideline to 2015 and postponement of publication of draft multiplicity guideline from 3<sup>rd</sup> to 4<sup>th</sup> quarter 2014.
- Information from Biosimilar Medicinal Product Working Party regarding WHO INN Committee proposal for a Biological Qualifier (BQ). The EMA comments on the BQ scheme will be communicated to WHO, particularly that there is no need to implement the BQ scheme in EU, because biologicals have a well-established identification system in Europe.

