29 January 2016
EMA/67044/2016
Press Office

Organisational matters

CHMP meeting 25-28 January 2016

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

- Changes in the procedural documents planned to be implemented in February. From February 2016, the Agency plans to implement a number of changes in the procedural documents for centrally authorised medicines. The Marketing Authorisation Holders (MAH) and applicants are therefore informed that the information contained in the Opinion cover letters will be reduced, and part of the text will be moved to the Eudralink message, opinion, assessment report and/or translation timetable.
- Type II variations and PSURs: following the planned changes in procedural documents in February, the Marketing Authorisation Holders (MAHs) are informed that, for PSUR single assessment (PSUSA) and Type II variation procedures, the MAH cover letter, in word format, will be discontinued and communication to the MAH will be by Eudralink message only. Information previously included in the cover letter will be moved to the recommendation, opinion, assessment report or translation timetables documents. For any detailed questions on the procedure, the MAHs are advised to contact the procedure manager.
- A status update on changes to the initial MAA process.
- Discussion on experience of Article 83 compassionate use opinions at EMA. Since the introduction of Article 83 of Regulation EC No 726/2004 in 2005, the CHMP adopted 5 scientific opinions for Compassionate Use for two conditions (hepatitis C and influenza). CHMP was invited to share its views on this topic and identify questions for consideration by the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP).
- Information on Workshop on immunogenicity assessment of biotechnology-derived therapeutic proteins to be held on 9 March 2016. The workshop is held to discuss the draft CHMP/Biosimilar Medicinal Products Working Party (BMWP) guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins. Participants will include experts from the BMWP, the Biostatistics Working Party (BWP), other regulatory authorities and stakeholders who provided comments on the draft guideline as well as specifically invited interested parties.
- The CHMP elected Dominique Masset as Chair and Laivi Saaremäel as Vice-chair to Excipients Drafting Group.

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- Appointment of new core members Christian Gartner (AT) and Jörg Zinserling (DE) to Biostatistics Working Party.
- Appointment of David Lyons (IE), Janet Schriever (DE) and Hanneke van der Woude (NL) as new core members to Respiratory Drafting Group.
- Nomination of Petre Cojocaru from Romania as new alternate to Safety Working Party.
- Nomination of Bart van der Schueren from Belgium as new observer to Cardiovascular Working Party.